

# PRODUCT INFORMATION FILE\*

RegimA

Zone 30 Power Peel  
Natural Exfoliating Gel  
- Maintenance Masque

Prepared: May 2016  
(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 30 Power Peel Natural Exfoliating Gel - Maintenance Masque

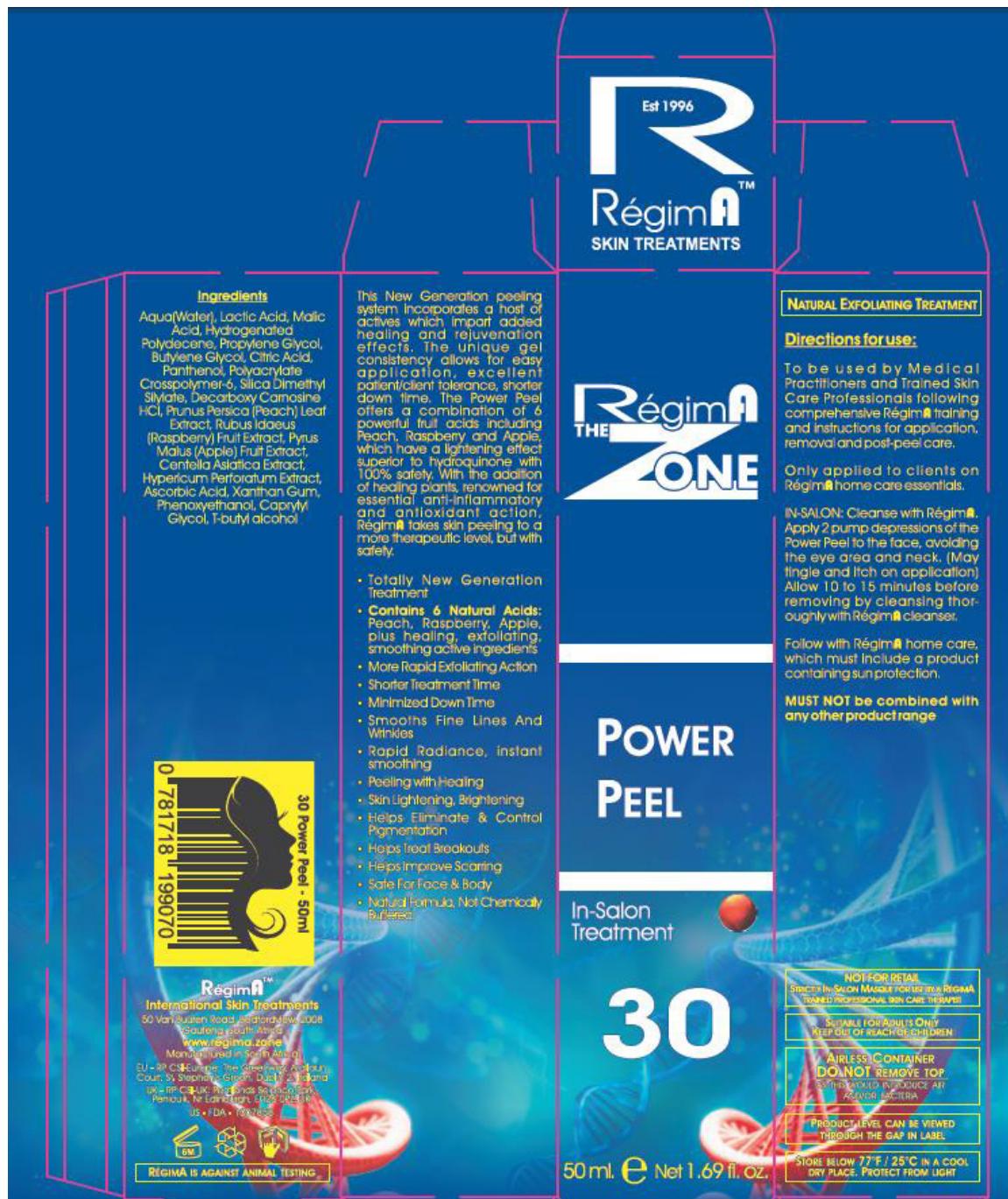
Product type	Exfoliating masque
Form	Lotion
Colour	Light brown
Pack size	50ml
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	30P 002
Normal use	In-salon use only. Apply 2 pump depressions to the face, avoiding the eye area and neck. Allow 10 to 15 minutes before removing by cleansing thoroughly with RegimA cleanser. This is an in-salon masque applied as part of a RegimA facial ideally every 4-6 weeks.

**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 visibly help improve the appearance of most skins and make the signs of aging less prominent.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Zone 30 Power Peel NE Gel- Maintenance Masque base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Lactic Acid	14.7	15	79-33-4 50-21-5	201-196-2 200-018-0	Skin conditioning	Purac	Lactic Acid 90%
	Aqua (Water)	0.3		7732-18-5	231-791-2			
2	Malic Acid	13.5	13.5	6915-15-7 97-67-6	230-022-8 202-601-5	Skin conditioning	Merck KGaA	Malic Acid BP
3	Hydrogenated Polydecene	10	10	68037-01-4	500-183-1	Emollient	IMCD	Dekanex 2006
4	Citric Acid	3	3	77-92-9	201-069-1	Buffering	Merck KGaA	Citric Acid BP
5	Aqua (Water)	2.4175	5	7732-18-5	231-791-2	Humectant/ Skin conditioning	Greentech (Natchem)	Rayolys D
	Propylene Glycol	2.4675		57-55-6	200-338-0			
	Prunus Persica (Peach) Leaf Extract	0.08		84012-34-0	281-678-7			
	Rubus Idaeus (Raspberry) Fruit Extract	0.01		84929-76-0	284-554-0			
	Pyrus Malus (Apple) Fruit Extract	0.01		85251-63-4	286-475-7			
	Ascorbic Acid	0.015		50-81-7	200-066-2			
6	Butylene Glycol	3	3	107-88-0	107-88-0	Humectant	Daicel Chemical Industries Ltd	Butylene Glycol
7	Aqua (Water)	0.97	2	7732-18-5	231-791-2	Solvent/ Antimicrobial/ Skin protecting/ Soothing	Greentech (Natchem)	St. John's Wort Hydroglycolic Extract (300837)
	Propylene Glycol	0.971		57-55-6	200-338-0			
	Hypericum Perforatum Extract	0.059		84082-80-4	282-026-4			
8	Decarboxy Carnosine HCl	0.2	2	57022-38-5	415-470-6	Skin conditioning	Exsymol	Alistin P5

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
9	Butylene Glycol	0.1636		107-88-0	203-529-7		(Akulu Marchon)	
	Aqua (Water)	1.6164		7732-18-5	231-791-2			
	Phenoxyethanol	0.02		122-99-6	204-589-7			
9	Aqua (Water)	0.926	2	7732-18-5	231-791-2	Humectant/ Skin conditioning	Greentech SA (Natchem)	Phytelene EG 356 Centella Asiatica
	Propylene Glycol	1.05		57-55-6	200-338-0			
	Centella Asiatica Extract	0.024		84696-21-9	283-640-5			
10	Panthenol	2	2	81-13-0	201-327-3	Skin conditioning	Zhejiang Xinfu Biochemical	D-Panthenol
11	Polyacrylate Crosspolymer-6	1.9	2	#	#	Emulsion stabilising	Seppic (CJP)	SepiMax ZEN
	T-butyl alcohol	0.1		75-65-0	200-889-7			
12	Phenoxyethanol	0.75	1.5	122-99-6	204-589-7	Emollient/ Preservative	Acti-Chem (Thor)	Microcare PHG
	Caprylyl Glycol	0.75		1117-86-8	214-254-7			
13	Silica Dimethyl Silylate	1	1	68611-44-9	271-893-4	Anticaking	Evonik Degussa (Protea Speciality Chemicals)	Aerosil R 972
14	Xanthan Gum	0.3	0.3	11138-66-2	234-394-2	Binding	Jungbunzlauer	Xanthan Gum
15	Aqua (Water)	37.7	37.7	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

# not assigned

Ingredient order for the label: Aqua (Water), Lactic Acid, Malic Acid, Hydrogenated Polydecene, Propylene Glycol, Butylene Glycol, Citric Acid, Panthenol, Polyacrylate Crosspolymer-6, Silica Dimethyl Silylate, **Phenoxyethanol, Caprylyl Glycol, Xanthan Gum, Decarboxy Carnosine HCl, T-butyl alcohol, Prunus Persica (Peach) Leaf Extract, Hypericum Perforatum Extract, Centella Asiatica Extract, Ascorbic Acid, Pyrus Malus (Apple) Fruit Extract, Rubus Idaeus (Raspberry) Fruit 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 30 Power Peel Natural Exfoliating Gel - Maintenance 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	Lotion
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Lotion
3 organoleptic properties (colour, odour, whenever relevant)	Light brown with a characteristic odour
4 pH (at 25°C)	1.62
5 viscosity (at 25°C)	28800 cPs
6 thermal stability (glass bottle)	Stable at room temperature for 12 weeks but with a pH increase from 1.62 to 1.87
7 Specific gravity	1.076 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 room temperature for 12 weeks although an increase in pH of around 23% was noted at 40°C 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 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 30 Power Peel NE Gel- Maintenance Masque is a product designed to visibly help improve the appearance of most skins and make the signs of aging less prominent. 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 training program. It is used once every 4-6 weeks **in the salon only** on the face, avoiding the eye area and neck.

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

Site of application	Face (avoiding eye area and neck)
Surface area of application (cm <sup>2</sup> )	565 cm <sup>2</sup>
Volume of product applied (ml)	0.5 ml (2 pump depressions)
Frequency of application	1 application/4 weeks (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)	0.5 ml exposure per 4 weeks Estimated exposure based on 60 kg adult= 8.34 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)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw)
Lactic Acid 79-33-4 50-21-5	14.7	8.34	1	1.2260
Malic Acid 6915-15-7 97-67-6	13.5	8.34	1	1.1259
Hydrogenated Polydecene 68037-01-4	10	8.34	1	0.8340
Propylene Glycol 57-55-6	4.4885	8.34	1	0.3743
Butylene Glycol 107-88-0	3.1636	8.34	1	0.2638
Citric Acid 77-92-9	3	8.34	1	0.2502
Panthenol 81-13-0	2	8.34	1	0.1668
Polyacrylate Crosspolymer-6 #	1.9	8.34	1	0.1585
Silica Dimethyl Silylate 68611-44-9	1	8.34	1	0.0834
Phenoxyethanol 122-99-6	0.77	8.34	1	0.0642
Caprylyl Glycol 1117-86-8	0.75	8.34	1	0.0626
Xanthan Gum 11138-66-2	0.3	8.34	1	0.0250
Decarboxy Carnosine HCl 57022-38-5	0.2	8.34	1	0.0167
T-butyl alcohol 75-65-0	0.1	8.34	1	0.0083
Prunus Persica (Peach) Leaf Extract 84012-34-0	0.08	8.34	1	0.0067
Hypericum Perforatum Extract 84082-80-4	0.059	8.34	1	0.0049
Centella Asiatica Extract 84696-21-9	0.024	8.34	1	0.0020
Ascorbic Acid 50-81-7	0.015	8.34	1	0.0013

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw)
Pyrus Malus (Apple) Fruit Extract 85251-63-4	0.01	8.34	1	0.0008
Rubus Idaeus (Raspberry) Fruit Extract 84929-76-0	0.01	8.34	1	0.0008

# 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
Lactic Acid 79-33-4 50-21-5	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 1; International Journal of Toxicology 17(S1): 1-242, 1998								
Malic Acid 6915-15-7 97-67-6	B									Safe use in this product is supported by human usage information (see section A.10 and B.1).
Hydrogenated Polydecene 68037-01-4	C	-	Non- irritant	Not a primary irritant/non- corrosive	Non- sensitizing	Non- irritant, non- genotoxic	1000- 6771 4620 for females in a 90- day study	0.209	22105	Safety assessment of polyene group as used in cosmetics, CIR, 2014
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								
Butylene Glycol 107-88-0	A	Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006								
Citric Acid 77-92-9	A	2014 CIR Compendium, safe for use up to 39%, IJT 33 (S2): 16-46, 2014								
Panthenol 81-13-0	A	Safe up to 25%, JAQCT 6(1): 139-62, 2006								
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).

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
										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
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								
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								
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								
Decarboxy Carnosine HCl 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 in vitro), tested in vivo volunteers well tolerated to 1.5% concentration.								
T-butyl alcohol	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>	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
75-65-0										
Prunus Persica (Peach) Leaf Extract 84012-34-0	##		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 in-salon use and historical safe use based on experience of this product.							
Hypericum Perforatum Extract 84082-80-4	A		Acute toxicity studies using rats, guinea pigs and mice indicate that the extract is relatively non-toxic, mixtures containing the extract and oil were not irritants or sensitizers in animals and produced minimal/no ocular irritation in rabbits and was not irritating in clinical studies. Also, hypericum perforatum extract is used in over 50 cosmetic foundations across a wide range of product types, International Journal of Toxicology 20(S2): 31-39, 2001. As there is no data available on the efficacy and safety of the extract in children and adolescents, use below the age of 18 is not recommended. The use of Hypericum has been documented for a long period and beside the risk of increased photosensitivity of the treated skin (the label will contain a suitable warning, see Section B.2 of this PIF) no concerns are known. The risk has been deemed an acceptable level for traditional herbal medicinal products, Assessment Report on Hypericum Perforatum L., Herba, Doc. Ref.: EMA/HMPC/101303/2008.							
Centella Asiatica Extract 84696-21-9	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
Ascorbic Acid 50-81-7	A		2014 CIR Compendium, safe when used up to 10%, International Journal of Toxicology 24(2): 51-111, 2005							
Pyrus Malus (Apple) Fruit Extract 85251-63-4	A		Safe (concentration of use not reported) CIR Compendium, 2014, Food item GRAS							
Rubus Idaeus (Raspberry) Fruit Extract 84929-76-0	##		Rubus Idaeus (Raspberry) <b>Seed Oil</b> - is safe up to 5%, 2014 CIR Compendium. In addition, raspberries are food items and raspberry leaf is a well-known herb that has been used orally for decades against various ailments according to handbooks and articles. Raspberry leaf preparations are generally recognized as safe. In mice an oral dose of extract equivalent to 10% of body weight of dried raspberry leaves was considered non-toxic. Neither the chemical composition nor the long-term widespread use in the European Union suggest that there is a high risk							

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
associated with the use of raspberry leaf preparations, Reference: EMA/HMPC/44209/2012.										

<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 related ingredient as presented

**Fragrances:**

Zone 30 Power Peel Natural Exfoliating Gel- Maintenance Masque does not contain a fragrance.

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

A letter describing in-salon use of this product and its immediate effects is included in Appendix 4 and described here.

‘On application of the Power Peel Masque there may be a tingling, itching sensation. The tingling is alleviated by the application of Laser Azu-Gel, which is massaged around the face. There is rarely erythema, unless the skin is dehydrated or there are extensive solar keratosis. Over the next few days following the in-Rooms application there may be slight flaking or peeling of the skin which subsides quickly and the patient applies Scar Forte Serum and day protection as desired. The patients tolerate these treatments extremely well, are very happy with the results and attend the Rooms regularly for these Power Peel Masques.

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

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

Zone 30 Power Peel NE Gel- Maintenance Masque was released in 2013. Over the period October 2014 to May 2016, 2489 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

Ingredients no. 1 (a mixture containing Lactic Acid), 2 (Malic Acid) and 4 (Citric Acid) and declare up to 14.7%, 13.5% and 3% alpha hydroxyl acid (AHA) content respectively, which would equate to a maximum of 31.2% content in the formulated product which has a pH of 1.03. 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.

In this product the concentration of AHA is greater than 10 percent and the pH is less than 3.5. Consequently the product is for strictly in-salon use by professional therapists who have been trained according to the RegimA training scheme. Additionally the product insert and labelling contain the advice to use daily protection from the sun.

When used according to the label and product insert directions, it is not expected that Zone 30 Power Peel Natural Exfoliating Gel - Maintenance Masque will cause lasting damage to human health. This is supported by a letter from Richard J Van Der Poel MB ChB FRCS (Edin.) Plastic and Reconstructive Surgeon who has supervised the use of this product in-salon in South Africa (see below).

It is therefore concluded that Zone 30 Power Peel Natural Exfoliating Gel- Maintenance Masque can be placed on the market in the EU as an exfoliating masque, under the condition **that it is only to be applied in-salon by a RegimA trained professional skin care therapist.**

#### 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, whose patients have tolerated the 30% AHA formulation without lasting adverse effects such as irritation being reported.

Richard J Van Der Poel reports ‘On application of the Power Peel Masque there may be a tingling, itching sensation. The tingling is alleviated by the application of Laser Azu-Gel, which is massaged around the face. There is rarely erythema, unless the skin is dehydrated or there are extensive solar keratosis. The Power Peel Gel is then thoroughly cleansed with RégimA Derma Zest Cleansing + Toning Gel ensuring all masque has been removed. Following cleansing Scar Forte Serum and a RégimA product containing sun protection is always applied.

Over the next few days following the in-Rooms application there may be slight flaking or peeling of the skin which subsides quickly and the patient applies Scar Forte Serum and day protection as desired.

The patients tolerate these treatments extremely well, are very happy with the results and attend the Rooms regularly for these Power Peel Masques.

I feel that these products and treatments offer safe, continuity of care at home and in-Rooms for my patients pre and post-op.’ The statement is included in Appendix 4.

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

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

Directions for use: In-salon: Cleanse with RegimA products. Apply 2 pump depressions to the face, avoiding the eye area and neck. Allow 10 to 15 minutes before removing by cleansing thoroughly with RegimA cleanser. This is an in-salon masque applied as part of a RegimA facial ideally every 4-6 weeks. Follow with RegimA home care products, which must include a product containing sun protection.

Label warnings:

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

‘All skin types- except sensitive’

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

‘Keep out of reach of children’.

‘Protect from temperatures above 25°C’.

'Suitable for adults only'.

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for its exfoliating properties. There are no reasons to anticipate tolerance problems with intermittent 4-6 week use. Supporting evidence has been given by Richard J Van Der Poel, plastic and reconstructive surgeon, who has used this product as an in-salon treatment. Clients have tolerated the 30% AHA formulation without lasting adverse irritating effects being reported.

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". It is written in a cursive style with a long horizontal flourish at the end of the "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**

#### 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 50 Power Peel  
Natural Exfoliating Gel  
- Advanced Masque

Prepared: May 2016  
(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 50 Power Peel Natural Exfoliating Gel - Advanced Masque

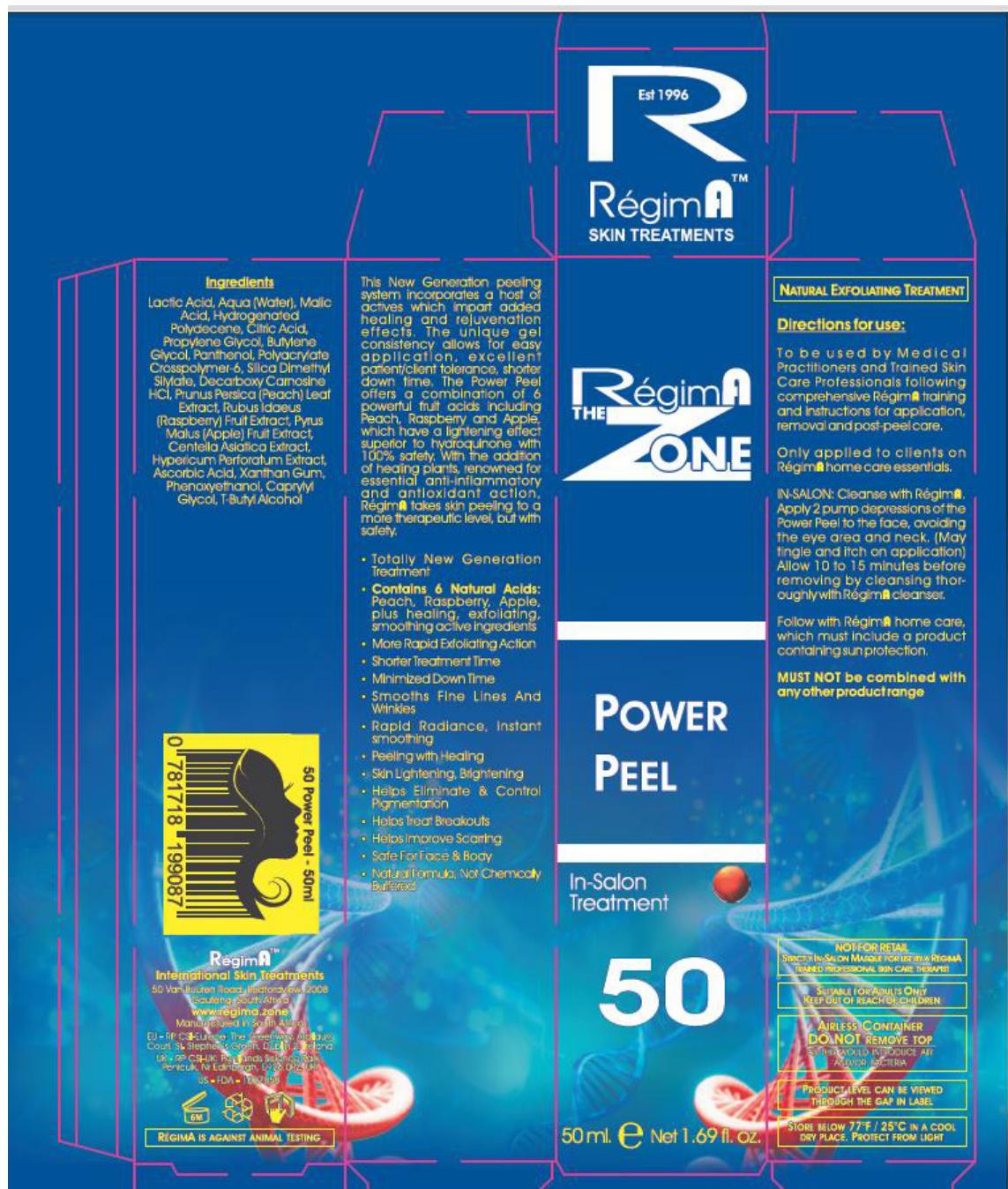
Product type	Exfoliating masque
Form	Gel
Colour	Brown
Pack size	50ml
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	50P 002
Normal use	<b>In-salon use only.</b> Apply 2 pump depressions to the face, avoiding the eye area and neck. Allow 10 to 15 minutes before removing by cleansing thoroughly with RegimA cleanser. This is an in-salon masque applied as part of a RegimA facial, ideally every 4-6 weeks.

**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 visibly help improve the appearance of most skins and make the signs of aging less prominent.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

**Zone 50 Power Peel NE Gel- Advanced Masque base formula**

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Lactic Acid	24.5	25	79-33-4 50-21-5	201-196-2 200-018-0	Skin conditioning	Purac	Lactic Acid 90%
	Aqua (Water)	0.5		7732-18-5	231-791-2			
2	Malic Acid	22.5	22.5	6915-15-7 97-67-6	230-022-8 202-601-5	Skin conditioning	Merck KGaA	Malic Acid BP
3	Hydrogenated Polydecene	10	10	68037-01-4	500-183-1	Emollient	IMCD	Dekanex 2006
4	Citric Acid	5	5	77-92-9	201-069-1	Buffering	Merck KGaA	Citric Acid BP
5	Aqua (Water)	2.4175	5	7732-18-5	231-791-2	Humectant/ Skin conditioning	Greentech (Natchem)	Rayolys D
	Propylene Glycol	2.4675		57-55-6	200-338-0			
	Prunus Persica (Peach) Leaf Extract	0.08		84012-34-0	281-678-7			
	Rubus Idaeus (Raspberry) Fruit Extract	0.01		84929-76-0	284-554-0			
	Pyrus Malus (Apple) Fruit Extract	0.01		85251-63-4	286-475-7			
	Ascorbic Acid	0.015		50-81-7	200-066-2			
6	Butylene Glycol	3	3	107-88-0	107-88-0	Humectant	Daicel Chemical Industries Ltd	Butylene Glycol
7	Aqua (Water)	0.97	2	7732-18-5	231-791-2	Solvent/ Antimicrobial/ Skin protecting/ Soothing	Greentech (Natchem)	St. John's Wort Hydroglycolic Extract (300837)
	Propylene Glycol	0.971		57-55-6	200-338-0			
	Hypericum Perforatum Extract	0.059		84082-80-4	282-026-4			
8	Decarboxy Carnosine HCl	0.2	2	57022-38-5	415-470-6	Skin conditioning	Exsymol	Alistin P5

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
9	Butylene Glycol	0.1636		107-88-0	203-529-7		(Akulu Marchon)	
	Water	1.6164		7732-18-5	231-791-2			
	Phenoxyethanol	0.02		122-99-6	204-589-7			
9	Aqua (Water)	0.926	2	7732-18-5	231-791-2	Humectant/ Skin conditioning	Greentech SA (Natchem)	Phytelene EG 356 Centella Asiatica
	Propylene Glycol	1.05		57-55-6	200-338-0			
	Centella Asiatica Extract	0.024		84696-21-9	283-640-5			
10	Panthenol	2	2	81-13-0	201-327-3	Skin conditioning	Zhejiang Xinfu Biochemical	D-Panthenol
11	Polyacrylate Crosspolymer-6	1.9	2	#	#	Emulsion stabilising	Seppic (CJP)	SepiMax ZEN
	T-butyl alcohol	0.1		75-65-0	200-889-7			
12	Phenoxyethanol	0.75	1.5	122-99-6	204-589-7	Emollient/ Preservative	Acti-Chem	Microcare PHG
	Caprylyl Glycol	0.75		1117-86-8	214-254-7			
13	Silica Dimethyl Silylate	1	1	68611-44-9	271-893-4	Anticaking	Evonik Degussa (Protea Speciality Chemicals)	Aerosil R 972
14	Xanthan Gum	0.3	0.3	11138-66-2	234-394-2	Binding	Jungbunzlauer	Xanthan Gum
15	Aqua (Water)	16.7	16.7	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

# not assigned

Ingredient order for the label: Lactic Acid, Aqua (Water), Malic Acid, Hydrogenated Polydecene, Citric Acid, Propylene Glycol, Butylene Glycol, Panthenol, Polyacrylate Crosspolymer-6, Silica Dimethyl Silylate, **Phenoxyethanol, Caprylyl Glycol, Xanthan Gum, Decarboxy Carnosine HCl, T-butyl alcohol, Prunus Persica (Peach) Leaf Extract, Hypericum Perforatum Extract, Centella Asiatica Extract, Ascorbic Acid, Pyrus Malus (Apple) Fruit Extract, Rubus Idaeus (Raspberry) Fruit 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 50 Power Peel Natural Exfoliating Gel- Advanced 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	Gel
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Gel
3 organoleptic properties (colour, odour, whenever relevant)	Brown with a characteristic odour
4 pH (at 25°C)	1.03
5 viscosity (at 25°C)	50000 cPs
6 thermal stability (glass bottle)	Stable at room temperature for 12 weeks but with a pH increase from 1.03 to 1.22
7 Specific gravity	1.137 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 room temperature for 12 weeks although an increase in pH of around 29% was noted at 40°C 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 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 50 Power Peel NE Gel- Advanced Masque is a product designed to visibly help improve the appearance of most skins and make the signs of aging less prominent. 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 training program (see Appendix 4). It is used once every 4-6 weeks **in the salon only** on the face, avoiding the eye area and neck.

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

Site of application	Face (avoiding eye area and neck)
Surface area of application (cm <sup>2</sup> )	565 cm <sup>2</sup>
Volume of product applied (ml)	0.5 ml (2 pump depressions)
Frequency of application	1 application/4 weeks (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)	0.5 ml exposure per 4 weeks Estimated exposure based on 60 kg adult= 8.34 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)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw)
Lactic Acid 79-33-4 50-21-5	24.5	8.34	1	2.0433
Malic Acid 6915-15-7 97-67-6	23.1299	8.34	1	1.9290
Hydrogenated Polydecene 68037-01-4	10	8.34	1	0.8340
Citric Acid 77-92-9	5	8.34	1	0.4170
Propylene Glycol 57-55-6	4.4885	8.34	1	0.3743
Butylene Glycol 107-88-0	3.1636	8.34	1	0.2638
Panthenol 81-13-0	2	8.34	1	0.1668
Polyacrylate Crosspolymer-6 #	1.9	8.34	1	0.1585
Silica Dimethyl Silylate 68611-44-9	1	8.34	1	0.0834
Phenoxyethanol 122-99-6	0.77	8.34	1	0.0642
Caprylyl Glycol 1117-86-8	0.75	8.34	1	0.0626
Xanthan Gum 11138-66-2	0.3	8.34	1	0.0250
Decarboxy Carnosine HCl 57022-38-5	0.2	8.34	1	0.0167
T-butyl alcohol 75-65-0	0.1	8.34	1	0.0083
Prunus Persica (Peach) Leaf Extract 84012-34-0	0.08	8.34	1	0.0067
Hypericum Perforatum Extract 84082-80-4	0.059	8.34	1	0.0049
Centella Asiatica Extract 84696-21-9	0.024	8.34	1	0.0020
Ascorbic Acid 50-81-7	0.015	8.34	1	0.0013

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw)
Pyrus Malus (Apple) Fruit Extract 85251-63-4	0.01	8.34	1	0.0008
Rubus Idaeus (Raspberry) Fruit Extract 84929-76-0	0.01	8.34	1	0.0008

# 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
Lactic Acid 79-33-4 50-21-5	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 1; International Journal of Toxicology 17(S1): 1-242, 1998								
Malic Acid 6915-15-7 97-67-6	B	Safe use in this product is supported by human usage information and strictly in-salon use by RegimA trained professionals (see section A.10 and B.1).								
Hydrogenated Polydecene 68037-01-4	C	-	Non- irritant	Not a primary irritant/non- corrosive	Non- sensitizing	Non- irritant, non- genotoxic	1000- 6771 4620 for females in a 90- day study	0.209	22105	Safety assessment of polyene group as used in cosmetics, CIR, 2014
Citric Acid 77-92-9	A	2014 CIR Compendium, safe for use up to 39%, IJT 33 (S2): 16-46, 2014								
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								
Butylene Glycol 107-88-0	A	Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006								
Panthenol 81-13-0	A	Safe up to 25%, JAQCT 6(1): 139-62, 2006								
Polyacrylate Crosspolymer-6 #	C	-	Slightly irritating	Non-irritant	Non- sensitizing	Non- sensitizing and non- irritating in humans	Not available	Not available	Not available	Not genotoxic (negative bacterial revere

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
						at ~5%				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
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								
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								
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								
Decarboxy Carnosine HCl 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 in vitro), tested in vivo volunteers well tolerated to 1.5% concentration.								

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
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)
Prunus Persica (Peach) Leaf Extract 84012-34-0	##									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 in-salon use and historical safe use based on experience of this product.
Hypericum Perforatum Extract 84082-80-4	A									Acute toxicity studies using rats, guinea pigs and mice indicate that the extract is relatively non-toxic, mixtures containing the extract and oil were not irritants or sensitizers in animals and produced minimal/no ocular irritation in rabbits and was not irritating in clinical studies. Also, hypericum perforatum extract is used in over 50 cosmetic foundations across a wide range of product types, International Journal of Toxicology 20(S2): 31-39, 2001. As there is no data available on the efficacy and safety of the extract in children and adolescents, use below the age of 18 is not recommended. The use of Hypericum has been documented for a long period and beside the risk of increased photosensitivity of the treated skin (the label will contain a suitable warning, see Section B.2 of this PIF) no concerns are known. The risk has been deemed an acceptable level for traditional herbal medicinal products, Assessment Report on Hypericum Perforatum L., Herba, Doc. Ref.: EMA/HMPC/101303/2008.
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
Ascorbic Acid 50-81-7	A									2014 CIR Compendium, safe when used up to 10%, International Journal of Toxicology 24(2): 51-111, 2005
Pyrus Malus (Apple) Fruit Extract 85251-63-4	A									Safe (concentration of use not reported) CIR Compendium, 2014, Food item GRAS
Rubus Idaeus (Raspberry) Fruit Extract	##									Rubus Idaeus (Raspberry) <b>Seed Oil</b> - is safe up to 5%, 2014 CIR Compendium. In addition, raspberries are food items and raspberry leaf is a well-known herb that has been used orally for decades against various ailments according to handbooks and articles. Raspberry leaf preparations are generally recognized as safe. In mice an oral

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
84929-76-0			dose of extract equivalent to 10% of body weight of dried raspberry leaves was considered non-toxic. Neither the chemical composition nor the long-term widespread use in the European Union suggest that there is a high risk associated with the use of raspberry leaf preparations, Reference: EMA/HMPC/44209/2012.							

<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 The reference 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 related ingredient as presented

### **Fragrances:**

Zone 50 Power Peel Natural Exfoliating Gel - Advanced Masque does not contain a fragrance.

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

A letter describing in-salon use of this product and its immediate effects is included in Appendix 4 and described here.

'On application of the Power Peel Masque there may be a tingling, itching sensation. The tingling is alleviated by the application of Laser Azu-Gel, which is massaged around the face. There is rarely erythema, unless the skin is dehydrated or there are extensive solar keratosis. Over the next few days following the in-Rooms application there may be slight flaking or peeling of the skin which subsides quickly and the patient applies Scar Forte Serum and day protection as desired. The patients tolerate these treatments extremely well, are very happy with the results and attend the Rooms regularly for these Power Peel Masques.

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

### **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 50 Power Peel NE Gel- Advanced Masque was released in 2013. Over the period October 2014 to May 2016, 1388 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

Ingredients no. 1 (a mixture containing Lactic Acid), 2 (Malic Acid) and 4 (Citric Acid) and declare up to 24.5%, 22.5% and 5% alpha hydroxyl acid (AHA) content respectively, which would equate to a maximum of 52% content in the formulated product which has a pH of 1.03. According to the criteria on the FDA web-site about the use of AHAs in cosmetic products, they 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.

In this product the concentration of AHA is greater than 10 percent and the pH is less than 3.5. Consequently the product is for strictly in-salon use by professional therapists who have been trained according to the RegimA training scheme. Additionally the product insert and labelling contain the advice to use daily protection from the sun.

When used according to the label and product insert directions, it is not expected that Zone 50 Power Peel Natural Exfoliating Gel - Advanced Masque will cause lasting damage to human health. This is supported by a letter from Richard J Van Der Poel MB ChB FRCS (Edin.) Plastic and Reconstructive Surgeon who has supervised the use of this product in-salon in South Africa (see below).

It is therefore concluded that Zone 50 Power Peel NE Gel - Advanced Masque can be placed on the market in the EU as an exfoliating masque, under the condition **that it is only to be applied in-salon by a RegimA trained professional skin care therapist.**

#### 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, whose patients have tolerated the 50% AHA formulation without lasting adverse irritating effects being reported.

Richard J Van Der Poel reports ‘On application of the Power Peel Masque there may be a tingling, itching sensation. The tingling is alleviated by the application of Laser Azu-Gel, which is massaged around the face. There is rarely erythema, unless the skin is dehydrated or there are extensive solar keratosis. The Power Peel Gel is then thoroughly cleansed with RégimA Derma Zest Cleansing + Toning Gel ensuring all masque has been removed. Following cleansing Scar Forte Serum and a RégimA product containing sun protection is always applied.

Over the next few days following the in-Rooms application there may be slight flaking or peeling of the skin which subsides quickly and the patient applies Scar Forte Serum and day protection as desired.

The patients tolerate these treatments extremely well, are very happy with the results and attend the Rooms regularly for these Power Peel Masques.

I feel that these products and treatments offer safe, continuity of care at home and in-Rooms for my patients pre and post-op.’ The statement is included in Appendix 4.

## B.2 Label Warnings and Instructions for Use

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

Directions for use: In-salon: Cleanse with RegimA products. Apply 2 pump depressions to the face, avoiding the eye area and neck. Allow 10 to 15 minutes before removing by cleansing thoroughly with RegimA cleanser. This is an in-salon masque applied as part of a RegimA facial ideally every 4-6 weeks. Follow with RegimA home care products, which must include a product containing sun protection.

Label warnings:

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

‘All skin types- except sensitive’

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

‘Keep out of reach of children’.

‘Protect from temperatures above 25°C’.

‘Suitable for adults only’.

### B.3 Reasoning

This product contains many ingredients with a positive reputation for its exfoliating properties. There are no reasons to anticipate tolerance problems with intermittent 4-6 week use. Supporting evidence has been given by Richard J Van Der Poel, plastic and reconstructive surgeon, who has used this product as an in-salon treatment. Clients have tolerated the 50% AHA formulation without lasting adverse irritating effects being reported.

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". It is written in a cursive style with a long horizontal stroke extending from the right side of the letter "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**

## **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 ‘Acne Attack’ Pro-  
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 ‘Acne Attack’ Pro-Masque

Product type	Masque to help congested skins
Form	Cream
Colour	Off white
Pack size	50ml
Pack type	WO Jar
Dispenser type	N/A
Part of a set	No
Manufacturer code	AAP 003
Normal use	<b>In-salon use only.</b> Cleanse face and neck with RegimA Cleanser. Apply a pea size amount of ‘Acne Attack’ Pro-Masque, using fingertips, to face, and neck if also problematic, 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 safely help congested, problematic skins. Selected botanicals, work synergistically providing particular benefits for oily problem skins.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Zone 'Acne Attack' Pro-Masque base formula

No	Raw Ingredient (INCI Name)	%	% (w/w)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Salicylic Acid	30	30	69-72-7	200-712-3	Keratolytic/ Masking/ Preservative/ Skin Conditioning	Salicylates & Chemicals (Fourchem)	Salicylic Acid 99%
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	Hydrogenated Polydecene	10	10	68037-01-4	500-183-1	Emollient/ Masking/ Perfuming/ Skin Conditioning	BP (Lipo Chemicals)	Silkflo 364 NF
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)	Meadowsweet Medulat
	Propylene Glycol	2.47		57-55-6	200-338-0			
	Spiraea Ulmaria Flower Extract	0.055		84775-57-5	283-886-3			

No	Raw Ingredient (INCI Name)	%	% (w/w)	CAS	EC	Function	Supplier (Agent)	Tradename
6	Butylene Glycol	2.625	5	107-88-0	203-529-7	Solvent/ Skin Conditioning/ Astringent/ Soothing/ Tonic/ Antimicrobial Cleansing/ Perfuming	Greentech (Natchem)	Phytelene Complex EGX 247 BG
	Aqua (Water)	2.345		7732-18-5	231-791-2			
	Nasturtium Officinale Extract	0.0106 5		84775-70-2	283-899-4			
	Arctium Lappa Root Extract	0.0021 75		84012-13-5	281-658-8			
	Salvia Officinalis (Sage) Leaf Extract	0.0021 75		84082-79-1	282-			
	Citrus Limon (Lemon) Fruit Extract	0.0106 5		84929-31-7	284-515-8			
	Hedera Helix (Ivy) Extract	0.0021 75		84082-54-2	282-000-2			
	Saponaria Officinalis Extract	0.0021 75		84775-97-3	283-921-2			
7	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						
	Aqua (Water)	0.0075		7732-18-5				
	Glucose	0.005		50-99-7				
				200-075-1				

No	Raw Ingredient (INCI Name)	%	% (w/w)	CAS	EC	Function	Supplier (Agent)	Tradename
8	Panthenol	2	2	81-13-0	201 327 3	Skin Conditioning	DSM Nutritional Products (Chempure)	D-Panthenol
9	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		#	#			
10	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			
11	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			

No	Raw Ingredient (INCI Name)	%	% (w/w)	CAS	EC	Function	Supplier (Agent)	Tradename
12	Xanthan Gum	0.3	0.3	11138-66-2	234-394-2	Binding/ Emulsifying/ Emulsion Stabilising/ Gel forming/ Skin Conditioning/ Surfactant/ Viscosity Controlling	CP Kelco (Tranarc)	Keltrol CG-T
13	Aqua (Water)	23.7	23.7	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

# not assigned

Ingredient order for the label: Salicylic Acid, Aqua (Water), Lactic Acid, Hydrogenated Polydecene, Butylene Glycol, Propylene Glycol, Panthenol, C14-22 Alcohols, Polyacrylate Crosspolymer-6, Phenoxyethanol, Palmitic Acid, Caprylyl Glycol, C12-20 Alkyl Glucoside, Stearic Acid, Xanthan Gum, T-Butyl Alcohol, Spiraea Ulmaria Flower Extract, 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 ‘Acne Attack’ Pro-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)	Characteristic odour
4 pH (at 25°C)	2.08
5 viscosity (at 25°C)	44000 cPs
6 thermal stability (glass bottle)	Stable for 12 weeks at 25°C
7 Specific gravity	0.987 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 an increase in pH of around 20% was noted at 40°C at week 8 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 ‘Acne Attack’ is a product designed to safely help congested, problematic skins. 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 (if also problematic), 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)
Salicylic Acid 69-72-7	30	4.17	1	1.25
Lactic Acid 79-33-4	10.8	4.17	1	0.45
Hydrogenated Polydecene 68037-01-4	10	4.17	1	0.42
Butylene Glycol 107-88-0	7.625	4.17	1	0.32
Propylene Glycol 57-55-6	2.47	4.17	1	0.10
Panthenol 81-13-0	2	4.17	1	0.083
C14-22 Alcohols 67762-30-5	1.9875	4.17	1	0.083
Polyacrylate Crosspolymer-6 <sup>#1</sup>	1.9	4.17	1	0.079
Phenoxyethanol 122-99-6	0.975	4.17	1	0.041
Palmitic Acid 57-10-3	0.543	4.17	1	0.023
Caprylyl Glycol 1117-86-8	0.525	4.17	1	0.022
C12-20 Alkyl Glucoside 67762-30-5	0.5	4.17	1	0.021
Stearic Acid 57-11-4	0.449	4.17	1	0.019
Xanthan Gum 11138-66-2	0.3	4.17	1	0.013
T-Butyl Alcohol 75-65-0	0.08	4.17	1	0.0033
Spiraea Ulmaria Flower Extract 84775-57-5	0.055	4.17	1	0.0023
Citrus Limon (Lemon) Fruit Extract	0.01065	4.17	1	0.00044

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)
84929-31-7				
Nasturtium Officinale Extract 84775-70-2	0.01065	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	0.002175	4.17	1	0.000091
Hedera Helix (Ivy) Extract 84082-54-2	0.002175	4.17	1	0.000091
Salvia Officinalis (Sage) Leaf Extract 84082-79-1	0.002175	4.17	1	0.000091
Saponaria Officinalis Extract 84775-97-3	0.002175	4.17	1	0.000091

# 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.

<sup>#1</sup> Not assigned

## 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
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).								
Lactic Acid 79-33-4	B	2014 CIR compendium, αHAs included at ca. 15% - safe up to $\leq$ 10%, at final formulation pH $\geq$ 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 $\leq$ 30%, at final formulation pH $\geq$ 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)								
Hydrogenated Polydecene 68037-01-4	C	-	Non- irritant	Not a primary irritant/non- corrosive	Non- sensitizing	Non- irritant, non- genotoxic	1000- 6771 4620 for females in a 90-day study	0.209	22105	Safety assessment of polyene group as used in cosmetics, CIR, 2014
Butylene Glycol 107-88-0	A	Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006								
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. <i>et al.</i> , International Journal of Toxicology 31(S 2), 2012								
Panthenol 81-13-0	A	Safe up to 25%, JAQCT 6(1): 139-62, 2006								
C14-22 Alcohols	## <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								

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
67762-30-5			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 <sup>#1</sup>	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
Phenoxyethanol	B	2014 CIR Compendium safe up to 1%, JACT 9(2):259-77, 1990								

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
122-99-6										
Palmitic Acid 57-10-3	A									
Caprylyl Glycol 1117-86-8	A									
C12-20 Alkyl Glucoside 67762-30-5	A									
Stearic Acid 57-11-4	A									
Xanthan Gum 11138-66-2	A									
T-Butyl Alcohol 75-65-0	A									
Spiraea Ulmaria Flower Extract 84775-57-5	A									
Citrus Limon (Lemon) Fruit Extract 84929-31-7	#									
Nasturtium Officinale Extract	#									

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
84775-70-2										
Glucose 50-99-7	A									
Arachidic Acid 506-30-9	A									
Myristic Acid 544-63-8	A									
Arctium Lappa Root Extract 84012-13-5	## <sup>1</sup>									
Hedera Helix (Ivy) 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
84082-54-2										<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.

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

**Fragrances:**

Zone ‘Acne Attack’ Pro-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, 2563 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 ‘Acne Attack’ Pro Masque will cause damage to human health when used as directed.

It is therefore concluded that Zone ‘Acne Attack’ Pro Masque can be placed on the market in the EU as an in-salon use masque to help congested skins.

#### 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 ‘Acne Attack’ Pro-Masque, using fingertips, to face, and neck if also problematic, 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 ‘Acne Attack’ Rescue  
Serum

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 ‘Acne Attack’ Rescue Serum

Product type	Post-peel gel
Form	Cream gel
Colour	Off white
Pack size	50ml
Pack type	WSZ Airless Bottle
Dispenser type	N/A
Part of a set	No
Manufacturer code	RPPG 002
Normal use	Leave-on face cream gel

**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 help alleviate the difficulties associated with a problematic skin. An abundance of plants, including Meadowsweet, help control oil production, visibly reducing pore size and minimizing the appearance of blackheads and spots for a more refined appearance.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Zone 'Acne Attack' Rescue Serum base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Isostearyl Alcohol	3.06	6	27458-93-1	248-470-8	Emollient/ Skin Conditioning/ Viscosity Controlling/ Binding	Gattfossé (Inc cosmetics)	Emulfree CBG
	Butylene Glycol Cocoate	2.646		73138-39-3/ 32074-61-6	277-288-1			
	Ethylcellulose	0.294		9004-57-3	#			
2	Butylene Glycol	2.75	5	107-88-0	203-529-7	Humectant/ Masking/ Viscosity Controlling/ Skin Conditioning/ Skin Protecting	Greentech (Natchem)	Cosmelene Passion Flower
	Aqua (Water)	2.1		7732-18-5	231-791-2			
	Passiflora Incarnata Flower Extract	0.15		84012-31-7/ 72968-47-9	277-142-7			
3	Capryloyl Glycine	1.1	4	14246-53-8	238-122-3	Cleansing/ Surfactant/ Skin Conditioning/ Antimicrobial /Antioxidant / Astringent/ Emollient/ Humectant/ Perfuming/ Skin Conditioning/ Skin Protecting	Seppic (CJP)	Sepicontrol A5
	Sarcosine	0.38		107-97-1	203-538-6			
	Cinnamomum Zeylanicum Bark Extract	0.12		84649-98-9	283-479-0			
	Hexylene glycol	0.88		107-41-5	203-489-0			
	Aqua (Water)	1.52		7732-18-5	231-791-2			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
4	Aqua (Water)	1.924	4	7732-18-5	231-791-2	Astringent/ Skin Conditioning/ Tonic/ Humectant/ Masking/ Viscosity Controlling	Silab (Mehanede)	Dermapur HP
	Butylene Glycol	2		107-88-0	203-529-7			
	Spiraea Ulmaria Extract	0.076		84775-57-5	283-886-3			
5	Decyl Isostearate	1.53	3	84605-08-3	283-388-6	Emollient/ Skin Conditioning/ Binding	Croda Chemicals	Crodamol SSA
	Isostearyl Isostearate	1.47		41669-30-1	255-485-3			
6	Caprylyl Methicone	2.997	3	17955-88-3	241-881-3	Skin Conditioning/ Solvent	Momentive (Savannah Fine Chemicals)	Silsoft 034
	Octene	0.003		111-66-0	203-893-7			
7	Rosa Canina Fruit Oil	3	3	84696-47-9/ 84603-93-0	283-652-0	Emollient/ Skin Conditioning	Seatons (Croda)	Rosehip Oil
8	Ribes Nigrum (Black Currant) Seed Oil	3	3	68606-81-5/ 97676-19-2	271-749-0	Emollient	Sharon Bolel Chemical Marketing	Blackcurrant Oil
9	Octyldodecyl Myristate	1.02	2	22766-83-2	245-205-8	Emollient/ Skin Conditioning	Gatlefossé (Carst & Walker)	Gatuline Derma-Sensitive
	Capparis Spinosa Fruit Extract	0.98		89958-23-6	289-646-4			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
10	Glycerin	2	2	56-81-5	200-289-5	Humectant/Perfuming/Skin Conditioning/Viscosity Controlling	Various	Glycerine CP
11	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		#	#			
12	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			
13	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
14	Aqua (Water)	61	61	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

# not assigned

Ingredient order for the label: Aqua (Water), Butylene Glycol, Isostearyl Alcohol, Ribes Nigrum (Black Currant) Seed Oil, Rosa Canina Fruit Oil, Caprylyl Methicone, Butylene Glycol Cocoate, Glycerin, Polyacrylate Crosspolymer-6, Decyl Isostearate, Isostearyl Isostearate, Capryloyl Glycine, Octyldodecyl Myristate, **Capparis Spinosa** Fruit Extract, Phenoxyethanol, Hexylene glycol, Caprylyl Glycol, Xanthan Gum, Sarcosine, Ethylcellulose, Passiflora Incarnata Flower Extract, Cinnamomum Zeylanicum Bark Extract, T-Butyl Alcohol, Spiraea Ulmaria Extract, Octene

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 ‘Acne Attack’ Rescue Serum 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 gel
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Cream gel
3 organoleptic properties (colour, odour, whenever relevant)	Off white, characteristic odour
4 pH (at 25°C)	5.55
5 viscosity (at 25°C)	65,600 cPs
6 thermal stability (glass bottle)	12 weeks at 50°C
7 Specific gravity	0.974 /ml

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

A shelf-life of six 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. At this time and at an elevated temperature, the product appeared slightly darker and the pH, viscosity and specific gravity dropped slightly, however this is thought not to effect the functionality 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 ‘Acne Attack’ Rescue Serum is a product designed to help alleviate the difficulties associated with a problematic skin. It is a leave-on product that in normal circumstances will be used twice daily on the face and neck if affected, avoiding the eye area.

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

Site of application	Face and neck (avoiding the eye area)
Surface area of application (cm <sup>2</sup> )	565 cm <sup>2</sup>
Volume of product applied (ml)	0.5 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)	0.5ml exposure daily Estimated exposure based on 60 kg adult =8.34 mg/kg bw/day
Dermal absorption information	Unknown
other	Face and neck (avoiding the eye area)

### **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	4.75	16.67	1	0.79
Isostearyl Alcohol	3.06	16.67	1	0.51
Ribes Nigrum (Black Currant) Seed Oil	3	16.67	1	0.50
Rosa Canina Fruit Oil	3	16.67	1	0.50
Caprylyl Methicone	2.997	16.67	1	0.50
Butylene Glycol Cocoate	2.646	16.67	1	0.44
Glycerin	2	16.67	1	0.33
Polyacrylate Crosspolymer-6	1.9	16.67	1	0.32
Decyl Isostearate	1.53	16.67	1	0.26
Isostearyl Isostearate	1.47	16.67	1	0.25
Capryloyl Glycine	1.1	16.67	1	0.18
Octyldodecyl Myristate	1.02	16.67	1	0.17
Capparis Spinosa Fruit Extract	0.98	16.67	1	0.16
Phenoxyethanol	0.975	16.67	1	0.16
Hexylene glycol	0.88	16.67	1	0.15
Caprylyl Glycol	0.525	16.67	1	0.088
Xanthan Gum	0.5	16.67	1	0.083
Sarcosine	0.38	16.67	1	0.063
Ethylcellulose	0.294	16.67	1	0.049
Passiflora Incarnata Flower Extract	0.15	16.67	1	0.025
Cinnamomum Zeylanicum Bark Extract	0.12	16.67	1	0.020

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)
T-Butyl Alcohol	0.08	16.67	1	0.013
Spiraea Ulmaria Extract	0.076	16.67	1	0.013
Octene	0.003	16.67	1	0.0005

# 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 CAS:107-88-0	A									Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006
Isostearyl Alcohol 27458-93-1	A									2014 CIR Compendium, safe at use up to 50%, JACT 7(3):359-413, 1988 confirmed 12/05
Ribes Nigrum 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.
Rosa Canina Fruit Oil 84696-47-9	A									2014 CIR Compendium, safe up to 19%, Final report 03/2013 (CIR)
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.
Butylene Glycol Cocoate 73138-39-3	A									2014 CIR Compendium, Safe for use up to 2%, IJT 30(S1):5S-16S, 2011
Glycerin 56-81-5	A									Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin
Polyacrylate Crosspolymer-6 No CAS number available	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

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
										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
Decyl Isostearate 84605-08-3	A	2014 CIR Compendium, Safe for use when formulated to be non-irritating, Final report 03/2013 available from CIR								
Isostearyl Isostearate 41669-30-1	A	2014 CIR Compendium, Safe (when formulated to be non-irritating), Final report 03/2013 (CIR)								
Capryloyl Glycine	A	2014 CIR Compendium, Safe (when formulated to be non-irritating), Final report 12/2013 (CIR)								
Octyldodecyl Myristate	A	2014 CIR Compendium, Safe (when formulated to be non-irritating), Final report 12/2013 (CIR)								
Capparis Spinosa Fruit Extract	#	Capers are a food item and systemic toxicity is acceptable. Considering its food item status, it can be assumed safe systemically when applied dermally. Whilst dermal tolerance when applied topically is unknown the label carries the warning 'if irritation occurs, discontinue use'								
Phenoxyethanol	B	2014 CIR Compendium safe up to 1%, JACT 9(2):259-77, 1990								

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
122-99-6										
Hexylene glycol	A									
Caprylyl Glycol 1117-86-8	A									
Xanthan Gum 11138-66-2	A									
Sarcosine	A									
Ethylcellulose 9004-57-3	A									
Passiflora Incarnata Flower Extract	A									
Cinnamomum Zeylanicum Bark Extract	#									
T-butyl alcohol	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
75-65-0										
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 considering 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 unknown, however, the label carries the warning 'if irritation occurs, discontinue use'.								
Octene	A	No safety concern when ingested through diet at up to 1800 ug/day (= 1.8 mg/day). Exposure to octane in this formulation is 0.005 mg/day. Dermal absorption is unknown, however even considering a 100% absorption rate, the concentration within this product is 360 times less than the dietary threshold of concern; WHO Technical Report Series, Evaluation of certain food additives, seventy-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. <a href="http://apps.who.int/iris/bitstream/10665/150883/1/9789241209908_eng.pdf#page=74">http://apps.who.int/iris/bitstream/10665/150883/1/9789241209908_eng.pdf#page=74</a> Topical tolerance of this ingredient is unknown, however, the label carries the warning 'if irritation occurs, discontinue 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 ‘Acne Attack’ Rescue 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 on the face twice daily.

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

Zone ‘Acne Attack’ Rescue Serum was released in 2016. Over the period August 2016 to May 2016, 1927 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 ‘Acne Attack’ Rescue Serum will cause damage to human health when used as directed.

It is therefore concluded that Zone ‘Acne Attack’ Rescue Serum can be placed on the market in the EU as a serum.

#### Review of human data on the product

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

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

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

AM and PM: Cleanse with RegimA. Apply 2 pump depressions of ‘Rescue’ Serum to the face and neck if affected, avoiding the eye area. To be followed by appropriate RegimA day and night care, which must always include a RegimA day product containing sun protection. [if irritation occurs, discontinue use].

Warnings: ‘If irritation occurs, discontinue use’.

‘Avoid contact with eyes’

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their properties which help alleviate the difficulties associated with a problematic skin 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 flourish at the end of the "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/>  
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## 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.

## **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 Age Reversal Night  
Complex

Prepared: 19 November 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**

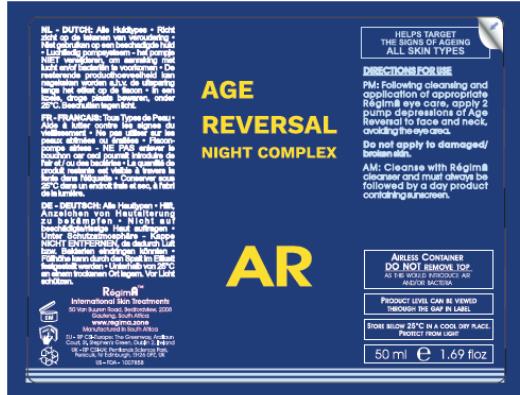
**Product Name: Zone Age Reversal Night Complex**

Product type	Anti-Ageing Night 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	NBN005
Normal use	Leave-on face cream

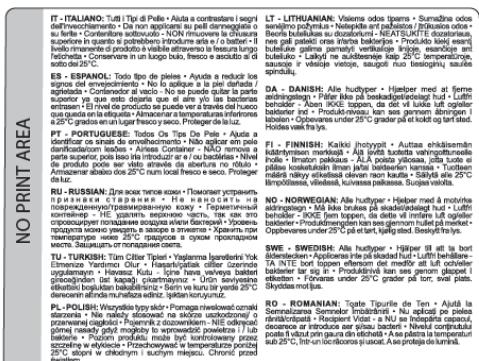
**Pictures of the Item: On following page**

## Container label

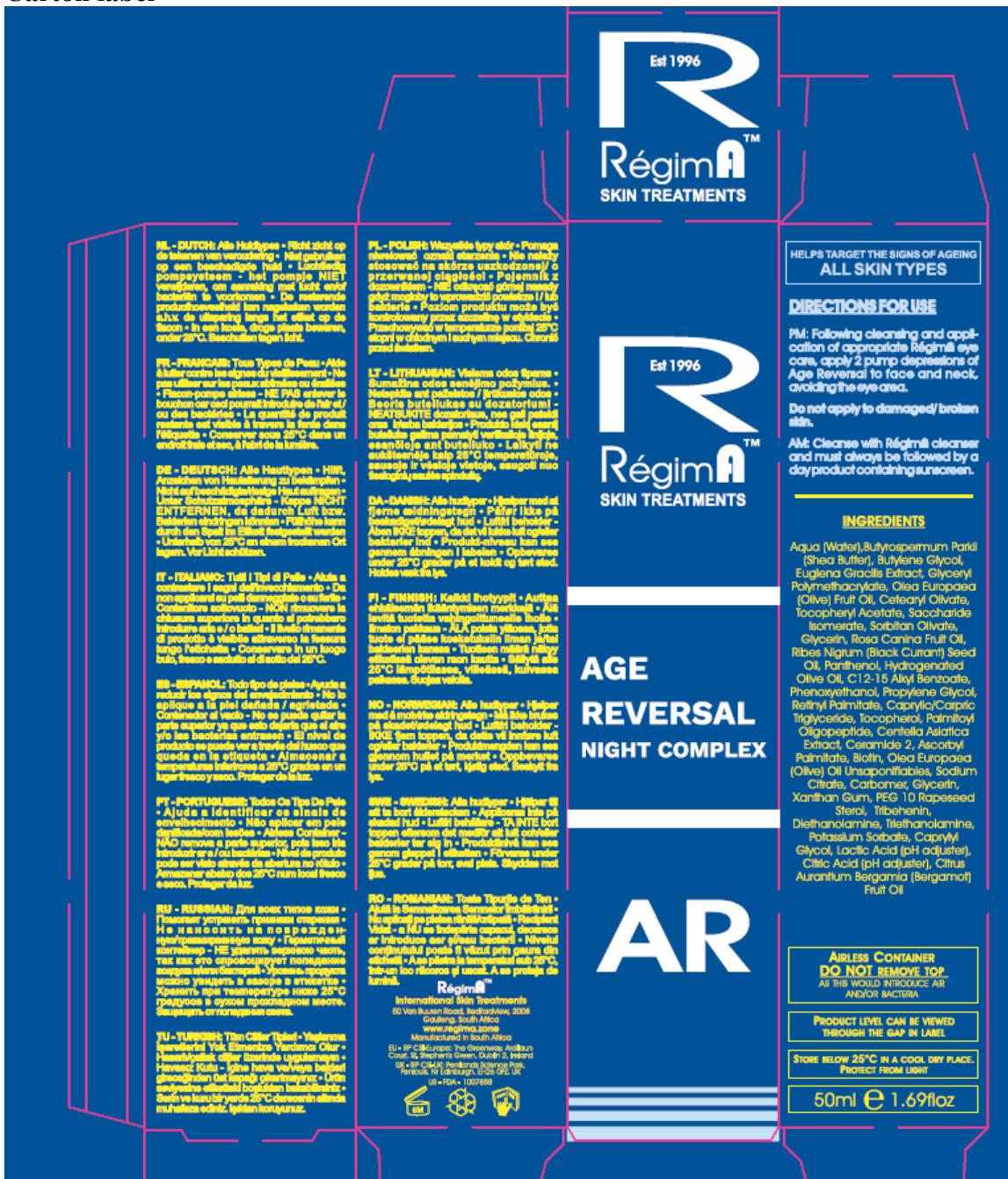
Top layer



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 target the signs of ageing.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Zone Age Reversal Night Complex base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Sorbitan Olivate	2.400	6.000	92202-01-2 223706-40-9	296-033-5	Primary Emulsifier	Hallstar	Olivem 1000
	Cetearyl Olivate	3.600		85116-80-9	285-532-3			
2	Butyrospermum Parkii (Shea Butter)	5.000	5.000	68920-03-6 194043-92-0 91080-23-8	293-515-7	Skin Conditioning	AA Fratelli Parodi	Cetiol SB-45
3	Centella Asiatica Extract	0.0875	5.000	84696-21-9	283-640-5	Skin Conditioning	Greentech (Natchem)	Cosmelene of Centella
	Butylene Glycol	4.9125		107-88-0	203-529-7			
4	Palmitoyl Oligopeptide	0.0005	5.000	147732-56-7 171263-26-6	#	Skin Conditioning/ Viscosity controlling	Sederma	Biopeptide CL
	Propylene Glycol	1.000		57-55-6	200-338-0			
	Glyceryl Polymethacrylate	3.9995		146126-21-8 28474-30-8	#			
5	Citric Acid	0.050	5.000	77-92-9	201-069-1	Humectant	DSM Nutritional Products (Chempure)	Pentavitin
	Sodium Citrate	0.050		68-04-2	200-675-3			
	Aqua	2.400		7732-18-5	231-791-2			
	Saccharide Isomerate	2.500		100843-69-4	-			
6	Biotin	0.00006	3.000	58-85-5	200-399-3	Skin Conditioning	Sederma	Chronodyn
	Tocopherol	0.001		54-28-4	200-201-5			
	Potassium Sorbate	0.003		24634-61-5 590-00-1	246-376-1			
	Phenoxyethanol	0.030		122-99-6	204-589-7			
	Glycerin	0.150		56-81-5	200-289-5			
	Euglena Gracilis Extract	2.816		100085-62-9	309-204-7			
7	Olea Europaea (Olive) 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	Olea Europaea (Olive) Fruit Oil	3.000	3.000	8001-25-0	232-277-0	Skin Conditioning	Textron	Extra Virgin Olive Oil
9	Tocopheryl Acetate	3.000	3.000	7695-91-2	231-710-0	Antioxidant	DSM Nutritional Products (Chempure)	DL-Alpha-Tocopheryl Acetate
10	Glycerin	2.0000	2.000	56-81-5	200-289-5	Humectant	Organic Chemical Corporation	Glycerine BP
11	Palmitoyl Oligopeptide	0.0004	2.000	171263-26-6	#	Skin Conditioning	Sederma	Dermaxyl

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Lactic Acid	0.018		50-21-5	200-018-0			
	PEG 10 Rapeseed Sterol	0.050		68441-03-2	#			
	Ceramide 2	0.070		100403-19-8	309-560-3			
	Tribehenin	0.400		18641-57-1	242-471-7			
	C12-15 Alkyl Benzoate	1.4616		68411-27-8	270-112-4			
12	Rosa Canina Fruit Oil	2.000	2.000	84603-93-0	283-652-0	Emollient	Seatons (Croda)	Rose Hip Oil
13	Ribes Nigrum (Black Currant) Seed Oil	2.000	2.000	68606-81-5	271-749-0	Emollient	Goerlich Pharma	Blackcurrant Seed Oil
14	Panthenol	2.000	2.000	81-13-0	201-327-3	Skin Conditioning	Zhejiang Xinfu Biochemical	D-Panthenol
15	Caprylyl Glycol	0.5250	1.500	1117-86-8	214-254-7	Preservative	Acti-Chem	Microcare PHG
	Phenoxyethanol	0.9750		122-99-6	204-589-7			
16	Citrus Aurantium Bergamia (Bergamot) Fruit Oil	0.600	0.600	8008-31-9 93686-22-7 8007-75-8	297-672-2 616-915-9	Perfuming	FD Copeland and Sons	Bergamot Oil
17	Diethanolamine	0.0025	0.500	111-42-2	203-868-0	pH Adjuster	DOW	TEA 99%
	Triethanolamine	0.4975		102-71-6	203-049-8			
18	Retinyl palmitate	0.2775	0.500	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			
19	Carbomer	0.250	0.250	9003-01-4	#	Emulsion stabilizing	Lubrizol (Carst & Walker)	Carbopol Ultrez 30
20	Ascorbyl Palmitate	0.200	0.200	137-66-6	205-305-4	Antioxidant	DSM Nutritional Products (Chempure)	Ascorbyl Palmitate
21	Xanthan Gum	0.200	0.200	11138-66-2	234-394-2	Binding/Emulsifying/ Emulsion Stabilizing	Jungbunzlauer	Xanthan Gum
22	Aqua	48.2500	48.250	7732-18-5	200-338-0	Vehicle	In-House	Deionised Water

# not assigned

Ingredient order for the label: Aqua, Butyrospermum Parkii (Shea Butter), Butylene Glycol, Euglena Gracilis Extract, Glyceryl Polymethacrylate, Olea Europaea (Olive) Fruit Oil, Cetearyl Olivate, Tocopheryl Acetate, Saccharide Isomerase, Sorbitan Olivate, Glycerin, Rosa Canina Fruit Oil, Ribes Nigrum (Black Currant) Seed Oil, Panthenol, Hydrogenated Olive Oil, C12-15 Alkyl

Benzoate, Phenoxyethanol, Propylene Glycol, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Caprylyl Glycol, Triethanolamine, Tribehenin, Retinyl Palmitate, Glycerin, Carbomer, Olea Europaea (Olive) Oil Unsaponifiables, Tocopherol, Ascorbyl Palmitate, Xanthan Gum, Centella Asiatica Extract, Ceramide 2, Citric Acid, Sodium Citrate, PEG 10 Rapeseed Sterol, Lactic Acid, Potassium Sorbate, Caprylic/Capric Triglyceride, Diethanolamine, Palmitoyl Oligopeptide, 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

<b>INCI (EU) Name</b>	<b>CAS number</b>	<b>EC number</b>	<b>Concentration % w/w</b>
Citral	5392-40-5	226-394-6	0.018
Linalool	78-70-6	201-134-4	0.060
d-Limonene (p-Mentha-1,8-diene)	5989-27-5	227-813-5	0.164

### 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. 5.80
5 viscosity (at 25°C ) for liquid forms	ca. 65000 cPs
6 thermal stability (glass bottle)	Stable at 50°C for 12 weeks
7 Specific gravity	ca. 0.971 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 at which time point the cream was slightly darker in appearance with a slightly stronger odour. The pH has also reduced slightly from an initial pH of 5.80 to 5.63.

### **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 Age Reversal Night Complex is an anti-aging product designed to visibly improve the appearance of the hydration of the skin 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 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 = 8.34 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)
Butyrospermum Parkii (Shea Butter)	5.0000	8.34	1	0.4170
Butylene Glycol	4.9125	8.34	1	0.4097
Glyceryl Polymethacrylate	3.9995	8.34	1	0.3336
Olea Europaea (Olive) Fruit Oil	3.8250	8.34	1	0.3190
Cetearyl Olivate	3.6000	8.34	1	0.3002
Tocopheryl Acetate	3.0000	8.34	1	0.2502
Euglena Gracilis Extract	2.8160	8.34	1	0.2349
Saccharide Isomerate	2.5000	8.34	1	0.2085
Sorbitan Olivate	2.4000	8.34	1	0.2002
Glycerin	2.2500	8.34	1	0.1877
Panthenol	2.0000	8.34	1	0.1668
Ribes Nigrum (Black Currant) Seed Oil	2.0000	8.34	1	0.1668
Rosa Canina Fruit Oil	2.0000	8.34	1	0.1668
Hydrogenated Olive Oil	1.9500	8.34	1	0.1626
C12-15 Alkyl Benzoate	1.4616	8.34	1	0.1219
Phenoxyethanol	1.0050	8.34	1	0.0838
Propylene Glycol	1.0000	8.34	1	0.0834
Citrus Aurantium Bergamia (Bergamot) Fruit Oil	0.6000	8.34	1	0.0500
Caprylyl Glycol	0.5250	8.34	1	0.0438
Triethanolamine	0.4975	8.34	1	0.0415

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)
Tri behenin	0.4000	8.34	1	0.0334
Retinyl Palmitate	0.2775	8.34	1	0.0231
Carbomer	0.2500	8.34	1	0.0209
Olea Europaea (Olive) Oil Unsaponifiables	0.2250	8.34	1	0.0188
Tocopherol	0.2185	8.34	1	0.0182
Ascorbyl Palmitate	0.2000	8.34	1	0.0167
Xanthan Gum	0.2000	8.34	1	0.0167
Centella Asiatica Extract	0.0875	8.34	1	0.0073
Ceramide 2	0.0700	8.34	1	0.0058
Citric Acid	0.0500	8.34	1	0.0042
PEG 10 Rapeseed Sterol	0.0500	8.34	1	0.0042
Sodium Citrate	0.0500	8.34	1	0.0042
Lactic Acid	0.0180	8.34	1	0.0015
Caprylic/Capric Triglyceride	0.0050	8.34	1	0.0004
Potassium Sorbate	0.0030	8.34	1	0.0003
2,2'-Iminodiethanol; diethanolamine	0.0025	8.34	1	0.0002
Palmitoyl Oligopeptide	0.0009	8.34	1	0.0001
Biotin	0.00006	8.34	1	0.0000

# 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
Butyrospermum Parkii Butter (Shea Butter) 68920-03-6	A					Safe when used up to 60% , Final report 03/11 CIR Compendium, 2014				
Butylene Glycol 107-88-0	A					Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006				
Cetearyl Olivate 85116-80-9	A					2014 CIR Compendium Safe (when formulated to be non-irritating), Final report 03/2013 (CIR)				
Euglena Gracilis Extract 100085-62-9	A					GRAS#, FDA approved food source/additive (considered safe because; it contains nutrients such as proteins, lipids and carbohydrates, it is non toxogenic and nonpathogenic, has no traces of biotoxins and there are companies selling Euglena Gracilis for human consumption with no untoward effects)				
Glycerin 56-81-5	A					GRAS#, FDA approved food additive, FDA approved over the counter (OTC) for skin				
C12-15 Alkyl Benzoate 68411-27-8	A					Safe up to 59%, International Journal of Toxicology 31(3), 342-372, 2012				
Citrus Aurantium Bergamia (Bergamot) Fruit Oil 8008-31-9	B					Safe up to 0.4%, IFRA Standards- Annex I to the 46 <sup>th</sup> Amendment- Current concentration in the product is 0.6%. As phototoxicity may be associated with higher concentrations a label recommendation to apply sunscreen after use of this product will be implemented.				
Caprylyl glycol 1117-86-8	A					Safe when used up to 5%, Safety assessment of 1,2-glycols as used in cosmetics, International Journal of Toxicology 31 (S2), 1475-1685, 2012				
Carbomer 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				
Ascorbyl Palmitate 137-66-6	A					Safe up to 0.2%; International Journal of Toxicology 18(S3), 1-26, 1999				
Ceramide 2 100403-19-8	A					Maximum use of up to 0.2%. Safety Assessment of Ceramides as Used in Cosmetics, 2014				
Citric Acid	A					2014 CIR Compendium, safe for use up to 39%, IJT 33 (S2): 16-46, 2014				

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
77-92-9										
Diethanolamine 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%, International Journal of Toxicology 20(S4), 1-12, 2001								
Glyceryl Polymethacrylate 146126-21-8	D	GRAS. Is not considered inherently toxic to humans and does not meet the human health categorization criteria on the Domestic Substances List (DSL) Categorization. Canadian Environmental Protection Act (CEPA) Environmental Registry. In addition it has a long history of safe use in cosmetic products.								
Hydrogenated Olive Oil 68334-28-1	A	2014 CIR Compendium safe up to 12%, Final report 03/2011 (CIR)								
Lactic acid 50-21-5	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 0.018%.								
Olea Europaea (Olive) Fruit Oil 8001-25-0	A	2014 CIR Compendium safe up to 100%, Final report 03/2011 (CIR)								
Olea Europaea (Olive) Fruit Oil Unsaponifiables 8001-25-0	A	2014 CIR Compendium safe up to 3%, Final report 03/2011 (CIR)								
Palmitoyl Oligopeptide 171263-26-6	B	Safe in present practices of use and concentration in cosmetics (maximum 1%). Safety Assessment of Tripeptide-1, Hexapeptide-12, their Metal Salts and Fatty Acyl Derivatives, and Palmitoyl Tetrapeptide-7 as Used in Cosmetics, 2014								
Panthenol 81-13-0	A	Safe up to 25%, JAQCT 6(1): 139-62, 2006								
PEG 10- Rapeseed Sterol 68441-03-2	B	PEG's are considered safe for use in cosmetics when not applied to damaged/broken skin. They produce little or no ocular or dermal irritation and have extremely low acute and chronic toxicities. Safety Assessment on polyethylene glycols (PEGs) and their derivatives as used in cosmetic products, Toxicology 214 (1-2), 1-38, 2005								
Phenoxyethanol 122-99-6	B	2014 CIR Compendium safe up to 1%, JACT 9(2):259-77, 1990								
Potassium Sorbate	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
24634-61-5										
Propylene glycol, 57-55-6	A									
Retinyl palmitate 79-81-2	A									
Ribes Nigrum (Black Currant) Seed Oil 68606-81-5	A									
Rosa Canina Fruit Oil 84603-93-0	A									
Saccharide Isomericate 100843-69-4	A									
Sodium Citrate 68-04-2	A									
Sorbitan Olivate 92202-01-2	A									
Tocopherol 54-28-4	A									
Tocopheryl Acetate 7695-91-2	A									
Tri behenin 18641-57-1	A									
Triethanolamine 102-71-6	A									
Xanthan Gum 11138-66-2	A									
Caprylic/Capric Triglyceride 73398-61-5	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
Centella asiatica extract 84696-21-9	-	-	Non-irritant	Non-irritant	Safe at 0.024% inclusion rate	Not genotoxic	10	9.60x10 <sup>-6</sup>	1.04x10 <sup>6</sup>	NOAEL based on reproduction toxicity effects in male rats

<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. D specific toxicity data not available, safe use from other sources listed.

<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 Age Reversal Night Complex contains Bergamot oil as 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**

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 Age Reversal Night Complex was released in 2014. Over the period October 2014 to February 2015 1413 units have been sold and there have been no adverse reactions reported to RégimA International Skin Treatments.

This product is one of the Zone range and has been recommended for use in clinics under the supervision of Dr. Richard Van Der Poel who has confirmed good feedback from patients using this product. A letter from Dr. Van Der Poel is included n Appendix 4.

## **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 Age Reversal Night Complex will cause damage to human health when used as directed.

It is therefore concluded that Zone Age Reversal Night Complex 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**

‘Do not apply to damaged/broken skin’

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

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

PM: Following cleansing and application of appropriate RegimA eye care, apply 2 pump depressions of Zone Age Reversal Night Complex to face and neck, avoiding the eye area.

AM: Cleanse with RegimA cleanser and must always be followed by a day product containing sunscreen.

Must not be combined with any other product range.

### **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, reading "Shirley H", is placed over a yellow rectangular box. A thin horizontal yellow line extends from the bottom left corner of the box to the left edge of the page.

## **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**



### **Allergen Analysis**

Compound Name : BERGAMOT OIL {BOL-BE01}

Code Number : RCP-76695

Flavour Ingredient	CAS No.	Concentration present as a percentage (%) or 'A' for absent in flavour		
		Added as such	From natural & other sources	Total
alpha-Iso-Methylionone	127-51-5	A	A	A
Amyl Cinnamal	122-40-7	A	A	A
Amylcinnamyl Alcohol	101-85-9	A	A	A
Anise Alcohol	105-13-5	A	A	A
Benzyl Alcohol	100-51-6	A	A	A
Benzyl Benzoate	120-51-4	A	A	A
Benzyl Cinnamate	103-41-3	A	A	A
Benzyl Salicylate	118-58-1	A	A	A
Butylphenyl Methylpropional (Linal)	80-54-6	A	A	A
Cinnamal	104-55-2	A	A	A
Cinnamyl Alcohol	104-54-1	A	A	A
Citral	5392-40-5	3.00	0.05	3.05
Citronellol	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-53-0	A	A	A
Evernia Furfuracea (Tree Moss) Extract	90028-67-4	A	A	A
Evernia Prunastri (Oak Moss) Extract	90028-69-5	A	A	A
Farnesol	4602-84-0	A	A	A
Geraniol	106-24-1	A	A	A
Hexyl Cinnamal	101-86-0	A	A	A
Hydrocinnamal	107-75-5	A	A	A
Hydroxyisobutyl 3-Cyclohexene Carboxaldehyde (Lyral)	31-908-04-4	A	A	A
Isoeugenol	97-54-1	A	A	A
Limonene	5989-27-5	A	27.35	27.35
Unisol	78-70-6	10.00	0.05	10.05
Methyl 2-Octynoate	111-12-6	A	A	A

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

Page 1 of 1

## **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

Anti-Inflamm-Ageing

Prepared: April 2019  
9Label and Packaging update August 2021)

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

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## **INTRODUCTION**

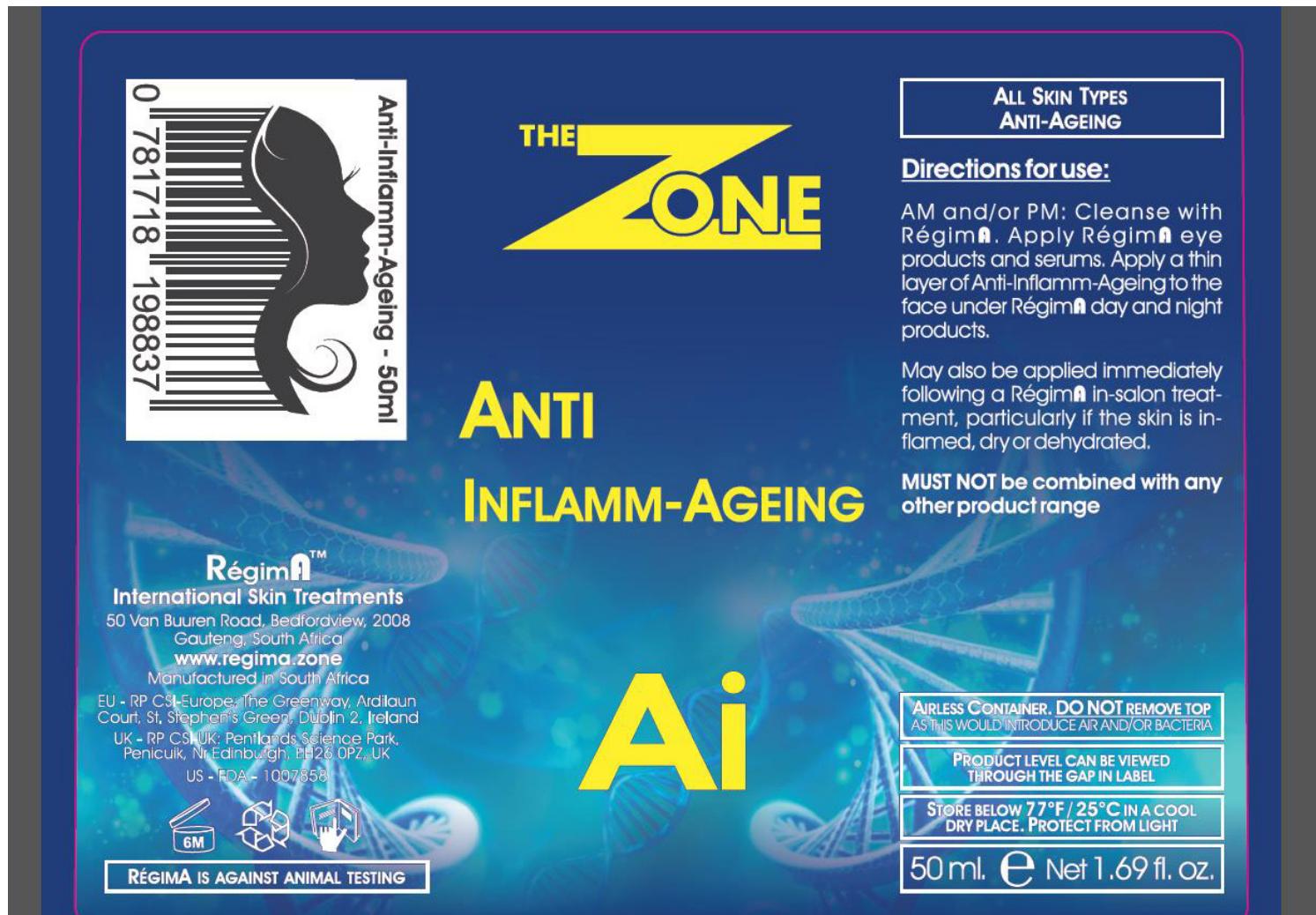
### **PRODUCT DESCRIPTION**

**Product Name:** Anti-inflamm-Ageing

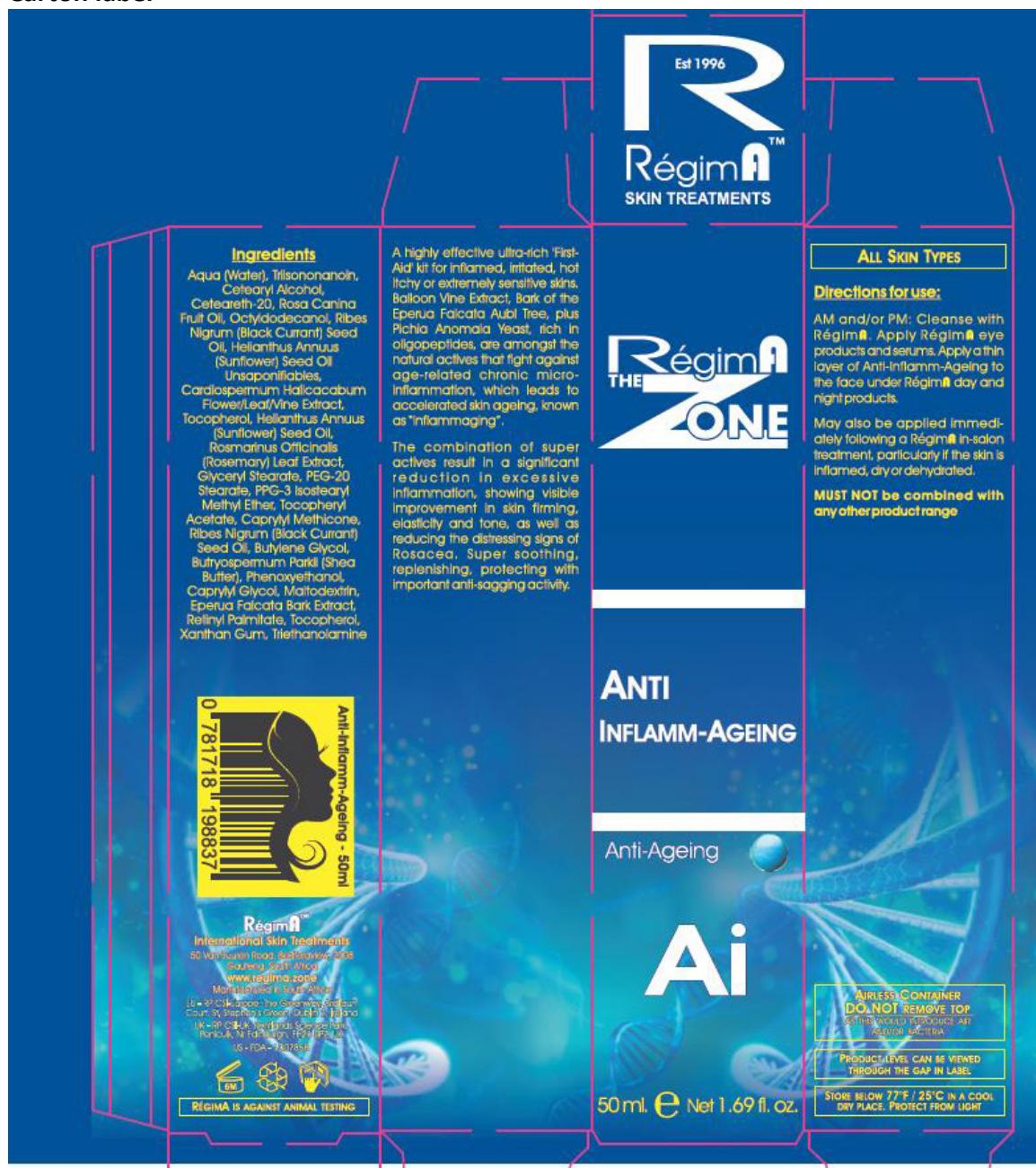
Product type	Skin cream
Form	Cream
Colour	Beige
Pack size	50ml (1.69 fl. Oz)
Pack type	Acrylonitrile-styrene resin (SAN) with a polyethylene liner. The pump is polypropylene.
Dispenser type	Polypropylene pump
Part of a set	No
Manufacturer code	RIC 001
Normal use	<b>Directions:</b> AM and/or PM: cleanse with RégimA. Apply RégimA eye products and serums. Apply a thin layer of Anti-inflamm-Ageing to the face under RégimA day and night products. May also be applied immediately following a RégimA in-salon treatment, particularly if the skin is inflamed, dry or dehydrated.

**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 has no claims associated with it.

## **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Anti-inflamm-Ageing base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Triisononanoin	7	7	56554-53-1/ 206354-95-2	260-257-1	Skin Conditioning/ Viscosity Controlling	Industria Quimca Lasem (Savannah Fine Chemicals)	2451-Waglinol 3/929
2	Cetearyl Alcohol	3.5	5	67762-27-0/ 8005-44-5	267-008-6	Emollient/ Emulsifying/ Emulsion Stabilising/ Foam Boosting/ Opacifying/ Surfactant/ Viscosity Controlling/ Cleansing/ Emulsifying/ Surfactant	Croda Chemicals	Cosmowax™ D- PA-SG
	Ceteareth-20	1.5		68439-49-6	#			
3	Water (Aqua)	5	5	7732-18-5	231-791-2	Solvent	In House	Deionised Water
4	Rosa Canina Fruit Oil	5	5	84696-47-9/ 84603-93-0	283-652-0	Emollient/ Skin Conditioning	Seatons (Croda)	Rose Hips Oil
5	Octyldodecanol	4.1955	5	5333-42-6	226-242-9	Emollient/ Masking/ Perfuming/ Skin Conditioning/ Solvent	Rahn (Sizeya Chemicals)	Defensil-Plus
	Echium Plantagineum Seed Oil	0.5		84988-87-4	284-877-7			
	Helianthus Annuus Seed Oil Unsaponifiables	0.25		8001-21-6	232-273-9			
	Cardiospermum Halicacabum Flower/Leaf/Vine Extract	0.05		89958-27-0	289-651-1			
	Tocopherol	0.0045		54-28-4 (gamma)/	200-201-5/ 240-747-1/			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
				16698-35-4 (beta)/ 10191-41-0 (DL)/ 119-13-1/ 1406-18-4/ 1406-66-2/ 2074-53-5 (DL)/ 59-02-9 (D)/ 7616-22-0	233-466-0/ 204-299-0/ 215-798-8/ 218-197-9/ 200-412-2			
6	Glyceryl Stearate	2	4	31566-31-1	250-705-4/ 286-490-9	Emollient/ Emulsifying/ Surfactant	Croda Chemicals	Arlacel 165 FP (CB 07312)
	PEG-100 Stearate	2		9004-99-3				
7	PPG-3 Isostearyl Methyl Ether	4	4	1429060-56-9	#	Emollient/ Skin Conditioning	Croda Chemicals	Arlamol LST-LQ-(MH)
8	Water (Aqua)	2.937	3	7732-18-5	231-791-2	Solvent / Skin Conditioning/ Skin Protecting/ Preservative	Silab (Meganede)	Unflamagyl
	Yeast Extract	0.042		8013-01-2/ 68876-77-7	232-387-9			
	Phenoxyethanol	0.015		122-99-6	204-589-7			
	Ethylhexylglycerin	0.006		70445-33-9	408-080-2			
9	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
10	Caprylyl Methicone	3	3	17955-88-3	241-881-3	Skin Conditioning	Momentive (Savannah Fine Chemicals)	Silsoft 034
11	Ribes Nigrum Seed Oil	3	3	68606-81-5/	271-749-0	Emollient	Sharon Bolel	Blackcurrant

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
				97676-19-2			Chemical Marketing	Seed Oil
12	Butylene Glycol	2	2	107-88-0	203-529-7	Humectant/ Masking/ Skin Conditioning/ Solvent/ Viscosity Controlling	Various	1,3-Butylene Glycol
13	Butyrospermum Parkii Butter	2	2	194043-92-0/ 91080-23-8/ 67701-30-8	293-515-7/ 266-948-4	Viscosity Controlling	BASF	Cetiol SB45
14	Phenoxyethanol	0.975	1.5	122-99-6	204-589-7	Preservative/ Emollient/ Humectant/ Skin Conditioning	Acti-Chem	Microcare® PHG
	Caprylyl Glycol	0.525		1117-86-8	214-254-7			
15	Eperua Falcata Bark Extract	0.15	1	999999-99-4	310-127-6	Absorbent/ Binding/ Emulsion Stabilising/ Film Forming/ Skin Conditioning	BASF Beauty Care (Botanichem)	Eperuline® PW LS 9627
	Maltodextrin	0.85		9050-36-6	232-940-4			
16	Triethanolamine	0.49755	0.5	102-71-6	230-049-8	Buffering/ Emulsifying/ Masking/ Surfactant	Dow Europe	Triethanolamine 99%
	Secondary alkyl- and alkanolamines and their salts*	0.00245		111-42-2/ 110-97-4	203-868-0/ 203-820-9			
17	Retinyl Palmitate	0.2775	0.5	79-81-2	201-228-5	Skin Conditioning/ Antioxidant/ Masking/ Skin Conditioning/	DSM Nutritional Products	Vitamin A Palmitate/M 1.0 MIU/g
	Tocopherol	0.005		54-28-4	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		(gamma)/ 16698-35-4 (beta)/ 10191-41-0 (DL)/ 119-13-1/ 1406-18-4/ 1406-66-2/ 2074-53-5 (DL)/ 59-02-9 (D)/ 7616-22-0	240-747-1/ 233-466-0/ 204-299-0/ 215-798-8/ 218-197-9/ 200-412-2	Masking/ Perfuming/ Skin Conditioning		
				73398-61-5/ 25381-09-1	277-452-2/ 265-724-3			
18	Xanthan Gum	0.3	0.3	11138-66-2	234-394-2	Binding/ Emulsifying/ Emulsion Stabilising/ Gel Forming/ Skin Conditioning/ Surfactant/ Viscosity Controlling	CP Kelco (Tranarc)	Xanthan Gum
19	Tocopherol	0.2	0.2	54-28-4 (gamma)/ 16698-35-4 (beta)/ 10191-41-0 (DL)/ 119-13-1/	200-201-5/ 240-747-1/ 233-466-0/ 204-299-0/ 215-798-8/ 218-197-9/ 200-412-2	Antioxidant/ Skin Conditioning/ Masking	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
				1406-18-4/ 1406-66-2/ 2074-53-5 (DL)/ 59-02-9 (D)/ 7616-22-0				
20	Water (Aqua)	45	45	7732-18-5	231-791-2	Solvent	In House	Deionised Water

# not assigned

\* Secondary alkyl- and alkanolamines and their salts is included in the compositional breakdown however it is not included in the ingredients list, see justification presented in Appendix 4.

Ingredient order for the label: Water (Aqua), Triisononanoin, Rosa Canina Fruit Oil, Octyldodecanol, PPG-3 Isostearyl methyl Ether, Cetearyl Alcohol, Caprylyl Methicone, Ribes Nigrum Seed Oil, Tocopheryl Acetate, Butylene Glycol, Butyrospermum Parkii Butter, Glyceryl Stearate, PEG-100 Stearate, Ceteareth-20, Phenoxyethanol, Maltodextrin, Caprylyl Glycol, Echium Plantagineum Seed oil, Triethanolamine, Xanthan Gum, Retinyl Palmitate, Helianthus Annuus Seed Oil Unsaponifiables, Caprylic/Capric Triglyceride, Tocopherol, Eperua Falcata Bark Extract, Cardiospermum Halicacabum Flower/Leaf/Vine Extract, Yeast extract, Ethylhexylglycerin.

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

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

#### **Fragrance allergens\***

<i>INCI (EU) Name</i>	<i>CAS number</i>	<i>EC number</i>	<i>Concentration % w/w</i>

\*Anti-Inflamm-Ageing 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 ...)	Emulsion
3 organoleptic properties (colour, odour, whenever relevant)	Beige smooth cream with characteristic odour.
4 pH (at 25°C)	5.95
5 viscosity (at 25°C)	30,000 cPs
6 thermal stability (glass bottle)	40°C for 12 weeks
7 Specific gravity (at 25°C)	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 jars has confirmed stability at ambient temperature of 25°C for 12 weeks.

### Stability testing at 25°C

During testing at 25°C a change in the viscosity was noted in week 2, week 8 and week 12 where the decrease was noted as 20%, 24%, and 23% respectively.

### Stability testing at 5°C

Additionally stability testing was performed at 5°C where a decrease in viscosity was noted in week 1; 15%, week 3; 15% and week 8 through to week 12; 44% and 63% respectively.

### Stability testing at 40°C

Additional stability testing was performed at 40°C, where the appearance was noted to have become slightly darker on week 12. At this time point there was a noticeable decrease in the pH where there was a 15% decrease.

Also at the week 8 time point the odour was noted to have changed, where the change was noted to be '*slight base odour*'.

A decrease in viscosity was noted from week 2 through to week 8 where the decreases were noted as 20%, 26%, 31%, 52% respectively.

### Stability testing at 50°C

Accelerated stability testing was performed at a temperature of 50°C. Testing of the products appearance was noted to have changed from beige to slightly darker to darker from week 8 through to week 12.

The characteristic odour noted in the product was described as '*slight base odour*' from week 8 through to week 12.

The pH of the product was noted to have significantly changed in week 12 where there was a decrease of 14% noted.

A decrease in viscosity was noted from week 1 and week 8 through to week 12; 15%, 55% and 64% respectively.

### Accelerated Ageing Rate (AAR)

The Accelerated Aging Rate (AAR) is a calculation that is used to estimate the shelf life of the product. The calculation used is  $Q10^{((\text{Accelerated Aging Temp.} - \text{Ambient Temp.})/10)}$  where Q10 is the Accelerated Aging Factor with an industry standard of 2.

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

The study was performed over 12 weeks, 84 days, therefore  $84 \times 5.66 =$  approximately 475 days using the Accelerated Aging scenario.

The AAR calculated confirms the 6 month shelf life 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**

Triethanolamine contains an impurity called Secondary alkyl-and alkanolamines and their salts. Further details on safety and compliance with Regulation 1223/2009 is provided in Appendix 4. In consideration of the requirements outlined in Regulation 1223/2009, safety considerations of the impurity and the evidence of its technical unavoidability in the manufacturing process, this impurity is not expected to be unsafe under the use directions outlined on the label.

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

The WSZ Airless Bottle is made from acrylonitrile-styrene resin (SAN) with a polyethylene liner. The pump is composed of 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**

Anti-Inflamm-Ageing is a product designed as a moisturizer that is typically applied to the face. It is a leave-on product that in normal circumstances will be used twice daily.

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

Site of application	Face
Surface area of application (cm <sup>2</sup> )	565*
Volume of product applied (mg)	1540**
Frequency of application/use per day	Twice daily
Target population	Adults
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	A relative daily exposure of 25.67 mg/kg bw/day when 1.54g of product is applied daily by a 60kg human.
Dermal absorption information	None

other	NA
-------	----

\*Surface area of application = 565cm<sup>2</sup>. The surface area has been established following application to the face surface area = 565cm<sup>2</sup>, Table 1; Mean exposed skin surface area per product type and frequency of application per product type, page 76, SCCS notes of Guidance for the testing of Cosmetic Ingredients and their safety Evaluation, 9<sup>th</sup> revision.

\*\* Volume of product applied = 1540mg. The volume of application applied has been adapted from the surface area to which the product is applied in normal and foreseeable uses. Face cream 1.54g, Table 2; Estimated daily exposure levels for different cosmetic product types according to Cosmetics Europe Data (SCCNFP/0321/00; Hall et al., 2007, 2011)

#### 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)
Triisononanoin 56554-53-1	7	25.67	1	1.80
Rosa Canina Fruit Oil 84696-47-9	5	25.67	1	1.28
Octyldodecanol 5333-42-6	4.1955	25.67	1	1.08
PPG-3 Isostearyl Methyl Ether 1429060-56-9	4	25.67	1	1.03
Cetearyl Alcohol 67762-27-0	3.5	25.67	1	0.90
Caprylyl Methicone 17955-88-3	3	25.67	1	0.77
Ribes Nigrum Seed Oil 68606-81-5	3	25.67	1	0.77
Tocopheryl Acetate 7695-91-2	3	25.67	1	0.77
Butylene Glycol 107-88-0	2	25.67	1	0.51
Butyrospermum Parkii Butter 194043-92-0	2	25.67	1	0.51
Glyceryl Stearate 31566-31-1	2	25.67	1	0.51
PEG-100 Stearate 9004-99-3	2	25.67	1	0.51

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	1.5	25.67	1	0.39
Phenoxyethanol 122-99-6	0.99	25.67	1	0.25
Maltodextrin 9050-36-6	0.85	25.67	1	0.22
Caprylyl Glycol 1117-86-8	0.525	25.67	1	0.135
Echium Plantagineum Seed Oil 84988-87-4	0.5	25.67	1	0.128
Triethanolamine 102-71-6	0.49755	25.67	1	0.128
Xanthan Gum 11138-66-2	0.3	25.67	1	0.077
Retinyl Palmitate 79-81-2	0.2775	25.67	1	0.071
Helianthus Annuus Seed Oil Unsaponifiables 8001-21-6	0.25	25.67	1	0.064
Caprylic/Capric Triglyceride 73398-61-5	0.2175	25.67	1	0.056
Tocopherol 54-28-4	0.2095	25.67	1	0.054
Eperua Falcata Bark Extract 999999-99-4	0.15	25.67	1	0.039
Cardiospermum Halicacabum Flower/Leaf/Vine Extract 89958-27-0	0.05	25.67	1	0.013
Yeast Extract 8013-01-2	0.042	25.67	1	0.011
Ethylhexylglycerin 70445-33-9	0.006	25.67	1	0.002

# No dermal absorption data is available; 100% dermal absorption is used as this is a leave on product.

2# No CAS number assigned.

## 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
Triisononanoic acid 56554-53-1	A	For use up to 23.5%, In Vitro dermal irritation and sensitization studies evaluated Triisononanoic acid undiluted on EpiSkin™ reconstructed human epidermis model according to OECD TG 439 where it was predicted not to be irritating. Final report 12/05/2017 available from CIR								
Rosa Canina Fruit Oil 84696-47-9	A	2014 CIR compendium. For use up to 19%, Final report 03/11 available from CIR.								
Octyldodecanol 5333-42-6	A	2014 CIR compendium. For use up to 85%, JACT 4(5):1-29, 1985 confirmed 03/04; IJT 25(S2), 2006.								
PPG-3 Isostearyl Methyl Ether 1429060-56-9	B	Limited data is available publicly for PPG -3 Isostearyl Methyl Ether. Limited publicly available information is available on PPG-3 Isostearyl Methyl Ether this includes ADI, NOAEL or any toxicological data. Therefore, the information provided on the SDS was initially used to evaluate the safety of the ingredient. The GHS Classification states that it is not a hazardous substance or mixture however it is stated that it may irritate eyes and the skin along with potential irritation of the respiratory tract, the SDS is presented in Appendix 1.  To ensure full safety of PPG-3 Isostearyl Methyl Ether a read across was performed to Polypropylene Glycol Methyl Ether (PPGME) where a Toxtree assessment was carried out. The read across was justified due to the close nature of the two compounds structures. Polypropylene glycol has a standard structure where n indicates the average propylene oxide chain length and therefore this is relative in the name, Image 1.								
		Image 1: Polypropylene glycol structure.								
		Therefore, PPG-3 would have n=2 with additional Isostearyl Methyl Ether groups attached in comparison PPGME has n=1 with an additional Methyl Ether group attached. Due to the limited differences in the two								

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
										structures the read across was justified.

The Toxtree assessment was performed using the Cramer rules and the revised Cramer decision tree which have both classed PPGME as High (Class III). The Cramer Rules describes a High (Class III) substance as a substance with chemical structure that permits no strong initial impression of safety and may even suggest a significant toxicity, a threshold of toxicological concern was established as 90 µg/day (1.5µg/kg bw/day). The Revised Cramer decision tree High (Class III) substance describes a substance with a chemical structures that permits no strong initial presumption of safety or may even suggest significant toxicity or have reactive functional groups, the 5<sup>th</sup> percentile NOEL is established as 0.15mg/kg bw/day with a human exposure threshold of 0.09 mg/person/day.

A further Toxtree assessment was performed to evaluate the skin irritation/corrosion potential of PPGME which concluded in an 'irritating to skin' classification. All assessments are presented in Appendix 4.

Human health data available on Polypropylene ethers has indicated that dermal absorption is slower than oral or inhalation where excretion is via the urine and expired air. To determine the penetration potential of PPGME an evaluation of the Log K<sub>ow</sub> values was performed and it was established as -0.437 ([Propylene Glycol Ethers OECD SIDS, November 2003](#)). The K<sub>ow</sub>; Octanol-water Partition coefficient is a measure of the compounds hydrophilicity or lipophilicity, the Log K<sub>ow</sub> values are between -3 (very hydrophilic) and +10 (extremely hydrophobic) ([Octanol-Water Partition Coefficient](#)) therefore it was determined that PPGME was a hydrophilic compound. With this it was concluded that dermal penetration would be limited due to the skin being primarily hydrophobic.

Skin irritation studies performed on rabbits skin indicated that PPGME was slightly irritating with a negative result in Skin Sensitization (Guinea Pig) studies [Propylene Glycol Ethers OECD SIDS, November 2003, Section 3 Human Health, Table 8; Eye/Skin irritation \(Rabbits\)](#) and [Sensitization \(Guinea Pigs\)](#). A Dermal NOAEL for PPMG was established as >1000 mg/kg day where no systemic toxicity but limited dermal irritation was observed [Propylene Glycol Ethers OECD SIDS, November 2003, Section 3 Human Health, Table 9; Repeated Dose Mammalian Toxicity](#).

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment	
			<p>Using the derma NOAEL was used to calculate a MoS, the MoS was calculated to be 160 (Dermal NOAEL 1000mg/kg ÷ SED 6.24 mg/kg bw/day) A MoS of greater than 100 is generally considered safe.</p> <p>PPG -3 Isostearyl Methyl Ether is presented on formulation at 4%, 6.24 mg/kg bw/day higher than that outlined in the Cramer Rules and Revised Cramer Decision. The additional data provided in the read across had confirmed the safety of the ingredient.</p> <p>It was therefore concluded that PPG -3 Isostearyl Methyl Ether is expected safe for use in Anti-inflamm-agein when used as directed.</p>								
Cetearyl Alcohol 67762-27-0	A		2014 CIR Compendium. For use up to 25%, JACT 7(3):359-413, 1998 confirmed 12/05.								
Caprylyl Methicone 17955-88-3	A		<p>Limited public information is available on Caprylyl Methicone. Therefore, the safety assessment of Caprylyl Methicone used information that was obtained from REACH Dossier. The information used was performed for the purposes of REACH and not for the purposes of EC 1223/2009.</p> <p>The Log K<sub>ow</sub> value was determined as 9, indicating that the compound is hydrophobic. The K<sub>ow</sub> (octanol-water partition coefficient) is the measure of hydrophilicity/lipophilicity of the compound, the K<sub>ow</sub> values are typically between -3 (very hydrophilic) and + 10 (extremely hydrophobic). Caprylyl Methicone is very hydrophobic therefore there is the potential of bio-accumulation due to the compound's affinity for lipids.</p> <p>Skin irritation/Corrosion evaluation was performed according to OECD Guidelines 404 (Acute Dermal Irritation/Corrosion) where 0.5ml of Caprylyl Methicone was applied to the clipped dorsal region of New Zealand White rabbits where a semi occlusive patch was then applied. The site was observed at 30 and 60 minutes and then 24, 48 and 72 hours post application. No signs of irritation was observed in any of the animals during the study and it was therefore concluded not to be irritating to rabbit skin.</p> <p>The skin sensitization potential was evaluated according to OECD Guidelines 406 (Skin Sensitization) using the</p>								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
		Buehler test. Crl: HA Guinea Pigs (20 in the test group) were used in the evaluation where 100% concentration was applied directly to the skin once a week for 6 hours for 3 weeks where an occlusive patch was applied. The challenge test comprised of the application of 0.75% concentration test material directly to the skin for a single 6-hour application. It was concluded that Caprylyl Methicone was not sensitizing to the skin of guinea pigs.  A NOAEL was established as >1,000mg/kg bw following repeated dose toxicity testing on Crl: WI(Han) rats. <a href="#">REACH Dossier CAS no. 17955-88-3</a> Caprylyl Methicone is present in formulation at 3%, 4.68 mg/kg bw/day where a MoS was calculated to be 214. A MoS of greater than 100 is considered to represent safe use.  It was therefore concluded that Caprylyl Methicone is expected to be safe for use in RégimA Anti-inflamm-Ageing when used as directed.								
Ribes Nigrum Seed Oil 68606-81-5	A	2014 CIR Compendium. For use up to 0.3%, Final report 03/11 available from CIR. Present in formulation at 3%, however Ribes Nigrum Seed Oil described by the FDA as a food item with a GRAS label. It was therefore concluded safe for use.								
Tocopheryl Acetate 7695-91-2	A	2014 CIR Compendium. For use <=36% (10% in Vitamin E oil), IJT 21(S3):51-116, 2002; Final report 03/2014 available from CIR.								
Butylene Glycol 107-88-0	A	2014 CIR Compendium. For use up to 89%, JACT 4(5):223-48, 1985 confirmed 02/04 IJT 25(S2), 2006.								
Butyrospermum Parkii Butter 194043-92-0	A	2014 CIR Compendium. For use up to 60%, Final report 03/11 available from CIR.								
Glyceryl Stearate 31566-31-1	A	2014 CIR Compendium. For use up to 50%, JACT 1(4):169-92, 1982.								
PEG-100 Stearate 9004-99-3	A	2014 CIR Compendium. For use up to 6%, IJT 24(S1):1-102, 2005.								
Ceteareth-20 68439-49-6	A	2014 CIR Compendium. Safe as used in cosmetics when formulated to be non-irritating, IJT 18 (S3):41-49, 1999; IJT 31(S2):169-244 (2012)								
Phenoxyethanol	A	2014 CIR Compendium. For use up to 1%, JACT 9(2):259-77, 1990.								

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
122-99-6										
Maltodextrin 9050-36-6	A									For use up to 4%, Final report 09/22/2015 available from CIR website
Caprylyl Glycol 1117-86-8	A									2014 CIR Compendium. For use up to 5% IJT 31(S2):147-168, 2012.
Echium Plantagineum Seed Oil 84988-87-4	A									For use up to 4%, Final report 09/22/2015 available from the CIR.
Triethanolamine 102-71-6	A									Safe for use in rinse-off products; but 5% in leave on cosmetic products; and should not be used in products containing N-nitrosating agents, JACT 2(7):183-235, 1983; IJT 32(S1): 59-81, 2013
Xanthan Gum 11138-66-2	A									2014 CIR Compendium. For use up to 6%, Final report 09/12 available from CIR.
Retinyl Palmitate 79-81-2	A									2014 CIR Compendium. For use up to 5%, JACT 6(3):279-320, 1987 confirmed 06/06
Helianthus Annuus Seed Oil Unsaponifiables 8001-21-6	A									2014 CIR Compendium. For use up to 2%, Final report 03/11 available from CIR.
Caprylic/Capric Triglyceride 73398-61-5	A									2014 CIR Compendium. For use up to 84%, JEPT 4(4):105-20, 1980 confirmed 06/01 IJT 22(S1):1-35, 2003.
Tocopherol 54-28-4	A									2014 CIR Compendium. For use <=5%, IJT 21(S3);51-116, 2002; Final report 03/2014 available from CIR.
Eperua Falcata Bark Extract 999999-99-4	A									Limited publicly available information is available on Eperua Falcata Bark Extract. The Eperua plant is a genus of the flowering plant Fabaceae, Wikipedia document presented in Appendix 4.  Eperua Falcata Bark Extract is a species in the genus Eperua is in the family Leguminosae (or known as Fabaceae) in the major group Angiosperms ( <a href="#">Eperua Taxonomy</a> ). Some of the most important commercial species including soyabean ( <i>Glycine max</i> ), garden peas ( <i>Pisum Sativum</i> ), peanuts ( <i>Arachis hypogaea</i> ) and alfalfa ( <i>Medicago sativa</i> ), <a href="#">Fabaceae Family</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
		<p>A read across was performed to Alfalfa (<i>Medicago sativa</i>) as they are both present in the family Leguminosae (Fabaceae) where limited information is available on the plant in question. An assessment was performed on An EFSA report has evaluated Alfalfa Protein Concentrate (APC) which is extracted from <i>Medicago sativa</i> spp. <i>Sativa</i>) known as Alfalfa. Alfalfa is a source of protein concentrate and parts of the plant (seeds and sprouts) have been used for human consumption in the European Community.</p> <p>APC at a dose of 10 g/day has been tested for its nutritional value in several clinical trials carried out in some countries. APC has been used since 1992 as a food supplement to combat malnutrition in several non-EU countries in the world with no reported deleterious effects.</p> <p>There are no reported cases of allergic reactions to alfalfa in man. However, given the fact that alfalfa is a leguminous plant, cross-reactivity could potentially cause adverse effects in persons who are allergic to foods from the leguminous plant family in particular, peanuts. The EFSA report has analyzed the sequence homology that might exist between alfalfa proteins and known allergens. The Panel concludes that the risk of cross-reactivity in subjects allergic to peanuts cannot be excluded.</p> <p style="text-align: center;"><a href="#">EFSA Opinion on the Safety of Alfalfa Protein Concentrate</a></p> <p>Using the dose of 10g/day which was outlined for APC was applied to Eperua Falcata Bark Extract.  Therefore:  10g/day - 10,000mg/day  10,000 mg/day ÷ 60kg bw (nominal human weight used)  = 166.6 mg/kg bw/day</p> <p>Eperua Falcata Bark Extract is present in formulation at 0.234 mg/kg bw/day 712 times less than that outlined as the daily dose by EFSA</p> <p>Eperua Falcata Bark Extract is not present on the FDA Poisonous Plant Database</p>								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
										<p>It was therefore concluded that Eperua Falcata Bark Extract was safe for use when used as directed.</p>
Cardiospermum Halicacabum Flower/Leaf/Vine Extract 89958-27-0										<p>Cardiospermum Halicacabum Flower/Leaf/Vine Extract is also known as the Balloon Vine where there was limited publicly available information available.</p> <p>A controlled blind trial in human subjects evaluated the activity of Cardiospermum 10% water-in-oil emulsion. The extract and corresponding base preparations were applied at random to the forearms and kept occluded in a Finn chamber for 16 hours. Blanching and reddening was observed in both preparations. Authors of the report indicate that no adverse effects were seen and that only desirable effects were seen during the trial.</p> <p>In additional clinical trials Halicar® (an ointment preparation that is based on the fresh parts of the flowering plant) was used in an open trial where it was applied up to three times daily over a fortnight to various inflammatory skin diseases where it was noted that the skin improved.</p> <p>Finally in an uncontrolled trial 19/24 subjects whom had itching inflammatory dermatoses skin had improved following the application of 10% Cardiospermum water-in-oil type ointment. <i>Evidence for the Efficacy and Safety of Topical Herbal Drugs in Dermatology: Part I: Anti-inflammatory agents</i> is available in Appendix 4.</p> <p>Additional information available on Cardiospermum Halicacabum Flower/Leaf/Vine Extract provide limited information on its toxicological potential.</p> <p>The studies indicate that a moistened crushed leaf was applied topically to rabbit (20-30 g/animal), in a skin irritability model using the Draize method where the results indicated that it did not cause irritation.</p> <p>The hydroalcoholic extract (95%) from the fresh aerial parts in external application did not induce allergenic activity in human beings.</p> <p style="color: blue;"><a href="#">Cardiospermum Halicacabum</a></p>

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
			Using 30g as a worst-case dose of Cardiospermum Halicacabum Flower/Leaf/Vine Extract, which equates to 30,000mg, the toxicity was assessed using a 60kg human, the nominal human default body weight is set at 60kg. Therefore, 30,000mg ÷ 60kg = 500mg/kg. Cardiospermum Halicacabum Flower/Leaf/Vine Extract is present in formulation at 0.05%, 0.078 mg/kg bw/day 6,410 times less than stated in the dermal irritation study.  It was therefore concluded that Cardiospermum Halicacabum Flower/Leaf/Vine Extract was safe for use when used as directed.							
Yeast Extract 8013-01-2	B		The yeast strain that is present in the ingredient Unflamagyl is noted as <i>Pichia anomala</i> . Limited information is available on the toxicological profile of <i>Pichia Anomala</i> so therefore a read across to Baker's Yeast was performed. <i>Pichia anomala</i> and Baker's Yeast descent from the same Genus known as <i>Saccharomyces cervisiae</i> . Baker's Yeast extract is FDA approved as GRAS, 21CFR184.1983. It was therefore concluded that Yeast extract is safe for use as formulated.							
Ethylhexylglycerin 70445-33-9	A						For use up to 8%, IJT 32 (Suppl. 3):5-21, 2013			

<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:**

Anti-Inflamm-Ageing does not contain a fragrance therefore no IFRA certificate is present.

**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 body twice daily.

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

Anti-Inflamm-Aging was released in September 3<sup>rd</sup>, 2018. Over the period September 2018 to February 2019, 900 units have been sold and there have been no adverse reactions reported to RégimA Company.

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

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

#### Review of the ingredients

After analysis of all the available information including:

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

It is not expected that Anti-Inflamm-Ageing will cause damage to human health when used as directed.

It is therefore concluded that Anti-Inflamm-Ageing can be placed on the market in the EU as a face moisturizer.

#### Review of human data on the product

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

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

Directions for use are given on the product label and product outer packaging that is present in Appendix 4.

#### **Directions:**

AM and/or PM: Cleanse with RégimA. Apply RégimA eye products and serums. Apply a thin layer of Anti-Inflamm-Ageing to the face under RégimA day and night products.

May also be applied immediately following a RégimA in-salon treatment, particularly if the skin is inflamed, dry or dehydrated.

#### **Warnings:**

‘Must not be combined with any other product range’

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

‘Product level can be viewed through the gap in label’

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

'If irritation occurs, discontinue use'

### **B.3 Reasoning**

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

This product is intended for external use in adults only.

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

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

*CBiol, MSB*

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

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

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 moisturizer.

### **List of References**

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

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

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Prime Product Manufacturing (Pty) Ltd

Main Site: Necsa Site, Building VB5, Elias Motsoaledi Street Ext (Church Street West), R104 Pelindaba, Madibeng Municipality, North West  
has been registered by Intertek as conforming to the requirements of:

### ISO 22716:2007

The management system is applicable to:

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

**Certificate Number:**  
0072927-00

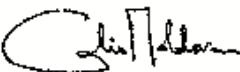
**Initial Certification Date:**  
07 March 2018

**Date of Certification Decision:**  
07 March 2018

**Issuing Date:**  
07 March 2018

**Valid Until:**  
06 March 2021



  
Calin Moldovean

President, Business Assurance



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.

## **PROOF OF EFFECT CLAIMED**

This product 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**

## **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 Daily Radiant Boost  
+  $\beta$ eta-Endorphin Stimulator*

Prepared: May 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 Daily Radiant Boost + βeta-Endorphin Stimulator

Product type	Daytime moisturizer with sun protection
Form	Cream
Colour	Yellow
Pack size	15 and 50ml
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	RBC001
Normal use	Leave-on face cream

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

## Container label



NO PRINT AREA

**IT - ITALIANO:** Pele Mista • Faccia + Collo Crema da Giorno • Contenitore sottovuoto • NON rimuovere la chiusura superiore in quanto si potrebbero introdurre aria e/o batteri • Il livello minimo di prodotto è visibile attraverso la fessura lungo l'etichetta • Conservare a temperature inferiori a 25 gradi in un luogo fresco e secco. Proteggere da luce.

**ES - ESPAÑOL:** Piel mixta • Cara + Cuello Crema de Día • Envase sotovuoto • NÃO remova a parte superior, pois isso irá introduzir ar e/ou bactérias • Nível do produto pode ser visto através da abertura no rótulo • Armazenar a temperatura abaixo de 25°C num local fresco e seco. Proteger da luz.

**PT - PORTUGUÊS:** Pele Mistas • Cara + Pescoço Crema de Dia • Airless Container • NÃO remove a parte superior, pois isso irá introduzir ar e/ou bactérias • Nível do produto pode ser visto através da abertura no rótulo • Armazenar a temperatura abaixo de 25°C num local fresco e seco. Proteger da luz.

**RU - РУССКИЙ:** Комбинированная кожа • Лицо + шея Дневной крем • Герметичный контейнер • НЕ удалять верхнюю часть, так как это спровоцирует попадание воздуха и/или бактерий • Уровень продукта можно увидеть в зазоре в этикете • Хранить при температуре ниже 25° градусов в сухом прохладном месте. Защищать от попадания солнца.

**TU - TÜRK:** Krem Ciltler + yüz + Boyun Gün Hazırlığı • Havuzlu Krem • İğneleme veya bakteri gireceğinden istemeden yüzün üstünü açmayın • Ürün seviyesine etiketin boşluğunundan ulaşın • Sıvı ve kuru bir yerde 25° derecenin altında muhafaza edin. Güneşten korunuz.

**PL - POLSKI:** Cera mieszana • Twarz + Sztyka Krem na dzień • Poxemnik z dozownikiem • NIE odkrywać górnego naskaldu gdyż mogłoby to wprowadzić powietrze i/lub bakterie • Poziom produktu może być kontrolowany przez szczeliny w etykiecie • Przechowywać w temperaturze poniżej 25° stopni w chłodnym i suchym miejscu. Chronić przed światłem.

**LT - LIETUVOS:** Mūšiam odos tipui • Veidas + kaklas Dieninė odos priežiūros priemonė • Beoris buteliukas su dozatoriumi • NEATSUNKITE dozatoriaus, nes gal patekti oras arba baktérijos • Produktui kiekvieną buteliuko galima pamatyti virkelių liniję, esančią ant buteliuko • Laikykite ne aukštis nei kaip 25 °C temperatūroje, sausuje ir visoje vietoje, saugoti nuo iesiočių, saulės spindulių.

**DA - DANSK:** Hud-kombineret • Ansigt + Hals Dagcremeflaske • Lufttørt beholder • Åbent IKKE løssten, da det vil lukke. Utilt oplæsbar bakterier ind • Produktmængden kan ses gennem åbningerne i beholderen • Opbevares under 25° grader på et koldt og tør sted. Holdes væk fra lys.

**FI - SUOMALAINEN:** Yhdistämästi ihu • Kasvo + niska Päivän valmiste • Ilman pakkuksia • ALÄ poista lippaa, ottaa tuote ei pitäisi koskettaa ihmän jalka/bakteeriin kanssa • Tuoteen määrä näkyy etiketissä olevan räätä kautta • Säilytä alle 25 °C lämpötilassa, vähässä, kylissä pakissa. Siitäjää väliä.

**NO - NORSK:** Blandet hudtyp • Ansikt + Hals Dagkrem • Lufttørt beholder • TA INTE åpne toppen efftersom det medfører at luft oplærer bakterier tar sig in • Produktmengden kan ses gjennom hull på merket • Oppbevares under 25° på et tørt, koldt sted. Beskytt fra lys.

**SWE - SVENSKA:** Kombinerade hudtyper • Ansikt + Hals Dagkräm • Lufttørt beholder • TA INTE åpna toppen efftersom det medfører att luft oplærer bakterier tar sig in • Produktmengden kan ses genom hålet på etiketten • Förvaras under 25 grader på torr, sval plats. Skyddas mot ljus.

**RO - ROMÂNĂ:** Ten Mix • Față + Gât Preparat de Zi • Recipient Videt - s NU se îndepărtează capacul deosebit de ar introduce aer și/sau bacterii • Nivelul conținutului poate fi vizat prin gaura din etichetă • A se păstra la temperaturi sub 25°, într-un loc ricoroc și uscat. A se protejea de lumina

## 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 moisturize and protect skin from the drying, aging effects of the sun, giving a natural healthy radiance.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Zone Daily Radiant Boost + βeta-Endorphin Stimulator base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	C12-15 Alkyl Benzoate	8	8	68411-27-8	270-112-4	Emollient	BASF (Chemgrit)	Cetiol AB
2	Diethylamino Hydroxybenzoyl Hexyl Benzoate	8	8	302776-68-7	443-860-6	UV Filter	BASF (Chemgrit)	Uvinul A Plus
3	Propylheptyl Caprylate	8	8	868839-23-0	#	Emollient	BASF (Chemgrit)	Cetiol Sensoft
4	Butylene Glycol	3.675	7	107-88-0	203-529-7	Solvent/ Skin Conditioning	Greentech (Natchem)	Phytelene Complex EGX 247 BG
	Water (Aqua)	3.283		7732-18-5	231-791-2			
	Nasturtium Officinale Extract	0.01491		84775-70-2	283-899-4			
	Arctium Lappa Root Extract	0.003045		84012-13-5	281-658-8			
	Salvia Officinalis (Sage) Leaf Extract	0.003045		84082-79-1	282-025-9			
	Citrus Limon (Lemon) Fruit Extract	0.01491		84929-31-7	284-515-8			
	Hedera Helix (Ivy) Extract	0.003045		84082-54-2	282-000-2			
	Saponaria Officinalis Extract	0.003045		84775-97-3	283-921-2			
5	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	6	6	187393-00-6	425-950-7	UV Absorber/ UV Filter	BASF (Chemgrit)	Tinosorb S
6	Dibutyl Adipate	5	5	105-99-7	203-350-4	Emollient/Skin Conditioning	BASF (Chemgrit)	Cetiol B
7	Ethylhexyl Triazone	5	5	88122-99-0	402-070-1	UV Absorber/ UV Filter	BASF (Chemgrit)	Uvinul T150
8	Niacinamide	5	5	98-92-0	202-713-4	Smoothing	DSM Nutritional Products (Chempure)	Niacinamide PC
9	Cetearyl Alcohol	3	3	67762-27-0 8005-44-5	267-008-6	Emollient/ Emulsifying/ Emulsion Stabilising	PT Musim Mas	Cetyl Stearyl Alcohol
10	Saccharomyces/Xylinum/Black Tea Ferment	2.58294	3	100085-62-9	309-204-7	Skin Conditioning	Sederma (Croda Chemicals)	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	246-376-			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
11			3	590-00-1		Skin Conditioning/ Skin Protecting	Sederma (Croda Chemicals)	Normaseb
	Citric acid	0.012		77-92-9 5949-29-1	201-069-1			
	Sodium citrate	0.027		68-04-2 6132-04-3	200-675-3			
	Biotin	0.00006		58-85-5	200-399-3			
	Aqua (Water)	2.061		7732-18-5	231-791-2			
12	Hydrolyzed milk protein	0.6	3	92797-39-2	296-575-2	Emulsion Stabilising	Seppic (Sharon Bolel Chemical Marketing)	Montanov L
	Glycerin	0.3		56-81-5	200-289-5			
	Phenoxyethanol	0.039		122-99-6	204-589-7			
	C14-22 Alcohols	2.385		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			
	C12-20 Alkyl Glucoside	0.6						
13	Aqua (Water)	0.009	2.5	7732-18-5	231-791-2	Emulsifying/ Surfactant	DSM Nutritional Products (Chempure)	Amphisol K
	Glucose	0.006		50-99-7	200-075-1			
	Potassium Cetyl Phosphate	2.5		84861-79-0 19035-79-1	284-374-2 242-768-			
14	Tocopheryl Acetate	2	2	7695-91-2 58-95-7	231-710-0 200-405-4	Antioxidant/ Skin Conditioning	DSM Nutritional Products (Chempure)	DL-Alpha- Tocopheryl Acetate
15	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			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	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			
16	Butylene Glycol	2	2	107-88-0	203-529-7	Humectant/ Skin Conditioning	Various	Butylene Glycol
17	Hydrogenated Dimer Dilinoleyl/ Dimethylcarbonate Copolymer	2	2	436803-57-5	#	Water Resistance	BASF (Chemgrit)	Cosmedia DC
18	Phenoxyethanol	0.78	1.2	122-99-6	204-589-7	Preservative/ Emollient	Thor (Actichem)	Microcare PHG
	Caprylyl Glycol	0.42		214-254-7	214-254-7			
19	Aqua (Water)	0.8	1	7732-18-5	231-791-2	Buffering	Various 20% Sodium Hydroxide Solution in Water	
	Sodium Hydroxide	0.2		1310-73-2	215-185-5			
21	Xanthan Gum	0.25	0.25	11138-66-2	234-394-2	Binding/ Emulsifying	Jungbunzlauer	Xanthan Gum
22	Disodium EDTA	0.2	0.2	139-33-3	205-358-3	Chelating/ Viscosity Controlling	Trilon BD	EDTA Na2
23	Aqua (Water)	22.55	22.55	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

# not assigned

Ingredient order for the label: Aqua (Water), C12-15 Alkyl Benzoate, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Proheptyl Caprylate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Butylene Glycol, Dibutyl Adipate, Ethylhexyl Triazone, Niacinamide, Cetearyl Alcohol, Saccharomyces/Xylinum/Black Tea Ferment, Potassium Cetyl Phosphate, C14-22 Alcohols, Hydrogenated Dimer Dilinoleyl/ Dimethylcarbonate Copolymer, Tocopheryl Acetate, Glycerin, Phenoxyethanol, C12-20 Alkyl Glucoside, Hydrolyzed milk protein, Caprylyl Glycol, Alcohol, Melissa Officinalis Leaf Oil, Vitex Agnus Castus Extract, Xanthan Gum, Disodium EDTA, Sodium Hydroxide, Lecithin , Hydroxyethylcellulose, Sodium citrate, Vegetable Oil, Citrus Limon (Lemon) Fruit Extract, Nasturtium Officinale Extract, Citric acid, Tocopherol, Glucose, Tetrahexyldecyl Ascorbate, Cyclodextrin, Arctium Lappa Root Extract, Hedera Helix (Ivy) Extract, Salvia Officinalis (Sage) Leaf Extract, Saponaria Officinalis Extract, 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 Daily Radiant Boost + βeta-Endorphin Stimulator 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)	Yellow, characteristic odour
4 pH (at 25°C)	5.65
5 viscosity (at 25°C)	18000 cPs
6 thermal stability (glass bottle)	Stable at 50°C for 4 weeks
7 Specific gravity	0.943 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 4 weeks at which time point there was minor changes in odour and viscosity. 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 Daily Radiant Boost +  $\beta$ -Endorphin Stimulator is a product designed to moisturize the skin, whilst providing protection 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, avoiding the eye area.

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

Site of application	Face and neck (avoiding the 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	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 60kg adult= 8.34 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)
C12-15 Alkyl Benzoate 68411-27-8	8.0	8.34	1	0.6672
Diethylamino Hydroxybenzoyl Hexyl Benzoate 302776-68-7	8.0	8.34	1	0.6672
Propylheptyl Caprylate 868839-23-0	8.0	8.34	1	0.6672
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine 187393-00-6	6.0	8.34	1	0.5004
Butylene Glycol 107-88-0	5.7	8.34	1	0.4733
Dibutyl Adipate 105-99-7	5.0	8.34	1	0.4170
Ethylhexyl Triazone 88122-99-0	5.0	8.34	1	0.4170
Niacinamide 98-92-0	5.0	8.34	1	0.4170
Cetearyl Alcohol 67762-27-0	3.0	8.34	1	0.2502
Saccharomyces/Xylinum/Black Tea Ferment 100085-62-9	2.6	8.34	1	0.2154
Potassium Cetyl Phosphate 84861-79-0	2.5	8.34	1	0.2085
C14-22 Alcohols 67762-30-5/629-96-9/661-19- 8/27836-64-2/54549-26-7/54549-27- 8/27836-65-3/100231-68-3	2.4	8.34	1	0.1989
Hydrogenated Dimer Dilinoleyl/ Dimethylcarbonate Copolymer 436803-57-5	2.0	8.34	1	0.1668
Tocopheryl Acetate 7695-91-2	2.0	8.34	1	0.1668
Glycerin 56-81-5	1.2	8.34	1	0.0984
Phenoxyethanol 122-99-6	0.85	8.34	1	0.0708

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)
C12-20 Alkyl Glucoside 67762-30-5/629-96-9/661-19- 8/27836-64-2/54549-26-7/54549-27- 8/27836-65-3/100231-68-3	0.60	8.34	1	0.0500
Hydrolyzed milk protein 92797-39-2	0.60	8.34	1	0.0500
Caprylyl Glycol 1117-86-8	0.42	8.34	1	0.0350
Alcohol 64-17-5	0.34	8.34	1	0.0284
Melissa Officinalis Leaf Oil 84082-61-1	0.30	8.34	1	0.0250
Vitex Agnus Castus Extract 91722-47-3	0.25	8.34	1	0.0209
Xanthan Gum 11138-66-2	0.25	8.34	1	0.0209
Disodium EDTA 139-33-3	0.20	8.34	1	0.0167
Sodium Hydroxide 1310-73-2	0.20	8.34	1	0.0167
Lecithin 8002-43-5	0.06	8.34	1	0.0052
Hydroxyethylcellulose 9004-62-0	0.05	8.34	1	0.0038
Sodium citrate 68-04-2	0.03	8.34	1	0.0023
Vegetable Oil 68956-68-3	0.02	8.34	1	0.0017
Citrus Limon (Lemon) Fruit Extract 84929-31-7	0.01	8.34	1	0.0012
Nasturtium Officinale Extract 84775-70-2	0.01	8.34	1	0.0012
Citric acid 77-92-9	0.01	8.34	1	0.0010
Tocopherol 59-02-9	0.01	8.34	1	0.0008
Glucose 50-99-7	0.006	8.34	1	0.0005
Tetrahexyldecyl Ascorbate 183476-82-6	0.005	8.34	1	0.0004
Cyclodextrin 7585-39-9	0.005	8.34	1	0.0004
Arctium Lappa Root Extract	0.003	8.34	1	0.0003

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)
84012-13-5				
Hedera Helix (Ivy) Extract 84082-54-2	0.003	8.34	1	0.0003
Salvia Officinalis (Sage) Leaf Extract 84082-79-1	0.003	8.34	1	0.0003
Saponaria Officinalis Extract 84775-97-3	0.003	8.34	1	0.0003
Potassium sorbate 24634-61-5	0.003	8.34	1	0.0003
Biotin 58-85-5	0.0001	8.34	1	0.00001

# 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
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 diethylamino 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.				
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 (applied semi-occlusive	Non-sensitizer (LLNA)	Non-irritant, 48h occlusive application with 50% propylheptyl (0.2ml test material applied)- no dermal effects.	≥1000 mg/mg bw/day	0.6672 mg/kg bw/day	1498.8	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 Cosmetics, 03/2013.

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
				and neat) had no reported irritation (Wistar rats)						
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						
Butylene Glycol 107-88-0	A			Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006						
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						
Ethylhexyl Triazone 88122-99-0	A			Maximum concentration in ready for use concentration 5%, Annex VI of Regulation (EC) 1223/2009						
Niacinamide 98-92-0	A			2014 CIR Compendium, Safe for use up to 3%, International Journal of Toxicology 24(S5): 1-31, 2005						
Cetearyl Alcohol 67762-27-0	A			2014 CIR Compendium, safe at use up to 25% JACT 7(3):359-413, 1988 confirmed 12/05						
Saccharomyces/Xylinum/Black Tea Ferment 100085-62-9	#			Traditional food item, GRAS, contains preservative to control possible bacterial contamination.						
Potassium Cetyl Phosphate 84861-79-0	A			Safe for use when formulated to be non-irritating, Safety Assessment of Alkyl Phosphates as Used in Cosmetics, 09/2014						
C14-22 Alcohols 67762-30-5/629-96-9/661-19- 8/27836-64-2/54549-26- 7/54549-27-8/27836-65- 3/100231-68-3	## <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 <50% of the worst case % presented in the CIR compendium. Therefore it is not expected that any of the other C <sub>n</sub> - alcohols would be present at a % unsafe for use, especially considering there is a mix of 9						

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		
			alcohols in 2.385%.									
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%).										
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										
Glycerin 56-81-5	A	Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin										
Phenoxyethanol 122-99-6	B	Safe for use when included up to 1%, CosIng Annex V/29										
C12-20 Alkyl Glucoside 67762-30-5/629-96-9/661-19- 8/27836-64-2/54549-26- 7/54549-27-8/27836-65- 3/100231-68-3	A	Safe for use in cosmetics when formulated to be non-irritating; International Journal of Toxicology 32 (S3): 22-48, 2013										
Hydrolyzed milk protein 92797-39-2	#	Hydrolyzed Source Proteins as Used in Cosmetics, 05/2012; Milk intended for human consumption, a human skin prick test of 2160 adults showed no adverse reactions, considered non-sensitizing, GRAS.										
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										
Melissa Officinalis Leaf Oil 84082-61-1	A	Assessment report on Melissa officinalis L., folium, EMA/HMPC/196746/2012; Long-standing medicinal use and experience of Melissa officinalis L., folium has been documented within the EU. During this time, no clinical signals that Melissa officinalis L., folium is harmful under the specified conditions of use have been identified (oral doses up to 4.5g taken several times a day identified).										

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	
Vitex Agnus Castus Extract 91722-47-3	A					Well tolerated at the recommended dosage (40-240mg) 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 40mg/kg in a 26 week chronic study, therefore the MoS is 40mg/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 after treatment with 370mg/kg bw/day of the tree for 12 weeks; The Essential Guide to Herbal Safety, Simon Mills and Kerry Bone, pages 333-336					
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					
Disodium EDTA 139-33-3	A					2014 CIR Compendium safe up to 1%, IJT 21(S2):95-142, 2002					
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)					
Hydroxyethylcellulose 9004-62-0	A					Safe when used up to 6%; JACT 5(3):1-59, 1986					
Sodium citrate 68-04-2	A					2014 CIR Compendium, safe for use up to 10%, IJT 33 (S2): 16-46, 2014					
Vegetable Oil 68956-68-3	A					2014 CIR Compendium, safety of vegetable oil as used in cosmetic formulations has been established, GRAS					
Citrus Limon (Lemon) Fruit Extract 84929-31-7	#					Annex II/358 R1, Furocoumarines (e.g. trioxysalen (INN), 8-methoxypsonalen, 5-methoxypsonalen) except for normal content in natural essences used. Restriction does not apply as this 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 a non-irritant and considering its oral consumption, it can be assumed that watercress is safe for dermal use.					
Citric acid 77-92-9	A					Safe up to 39%, International Journal of Toxicology 33(S2), 16-46, 2014					
Tocopherol	A					Safe when used up to 1%; IJT 21(S3):51-116, 2002; Final report 03/2014 CIR Compendium, 2014					

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
59-02-9										
Glucose 50-99-7	A									
Tetrahexyldecyl Ascorbate 183476-82-6	A									
Cyclodextrin 7585-39-9	A									
Arctium Lappa Root Extract 84012-13-5	## <sup>1</sup>									
Hedera Helix (Ivy) Extract 84082-54-2	A									
Salvia Officinalis (Sage) Leaf	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
Extract 84082-79-1										(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.
Potassium sorbate 24634-61-5	A									2014 CIR Compendium safe up to 1%, JACT 7(6):837-80, 1988 confirmed 04/06
Biotin 58-85-5	A									Safe up to 1%, International Journal of Toxicology 20(S4), 1-12, 2001

<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:**

Zone Daily Radiant Boost + βeta-Endorphin Stimulator does not contain a fragrance.

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

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

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

Zone Daily Radiant Boost + βeta-Endorphin Stimulator was released in 2015. Over the period June 2015 to April 2016, 5734 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 Daily Radiant Boost + βeta-Endorphin Stimulator will cause damage to human health when used as directed.

It is therefore concluded that Zone Daily Radiant Boost + βeta-Endorphin Stimulator can be placed on the market in the EU as a moisturizer with added sun protection 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**

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

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

No label warnings are required.

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their moisturising and sun protecting 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 written 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

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**

## **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 Daily Ultra Defence +  
βeta-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**

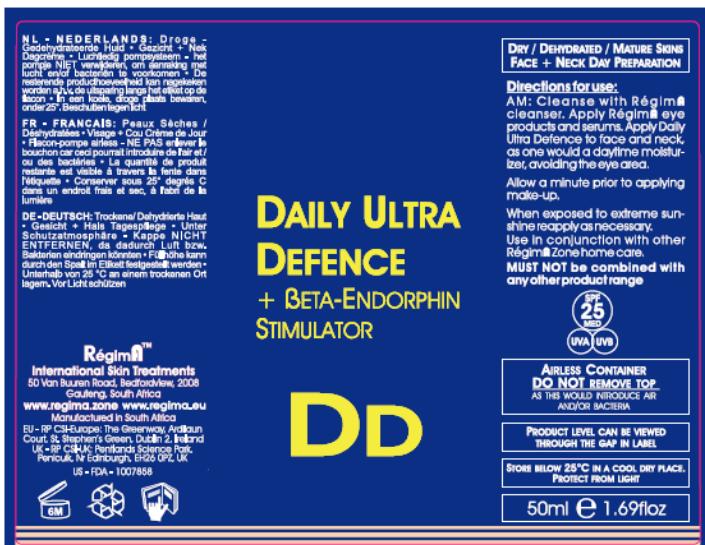
**Product Name:** Zone Daily Ultra Defence +  $\beta$ eta-Endorphin Stimulator

Product type	Moisturiser with sun protector
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	RDS002
Normal use	Leave-on face cream

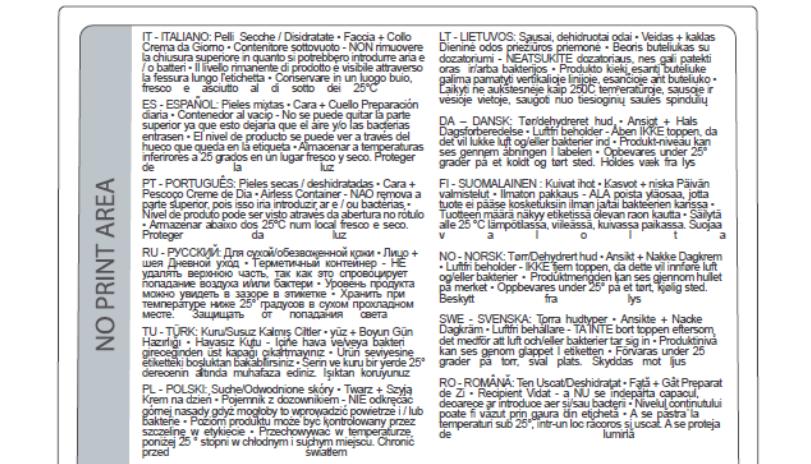
**Pictures of the Item: On following page**

## Container label

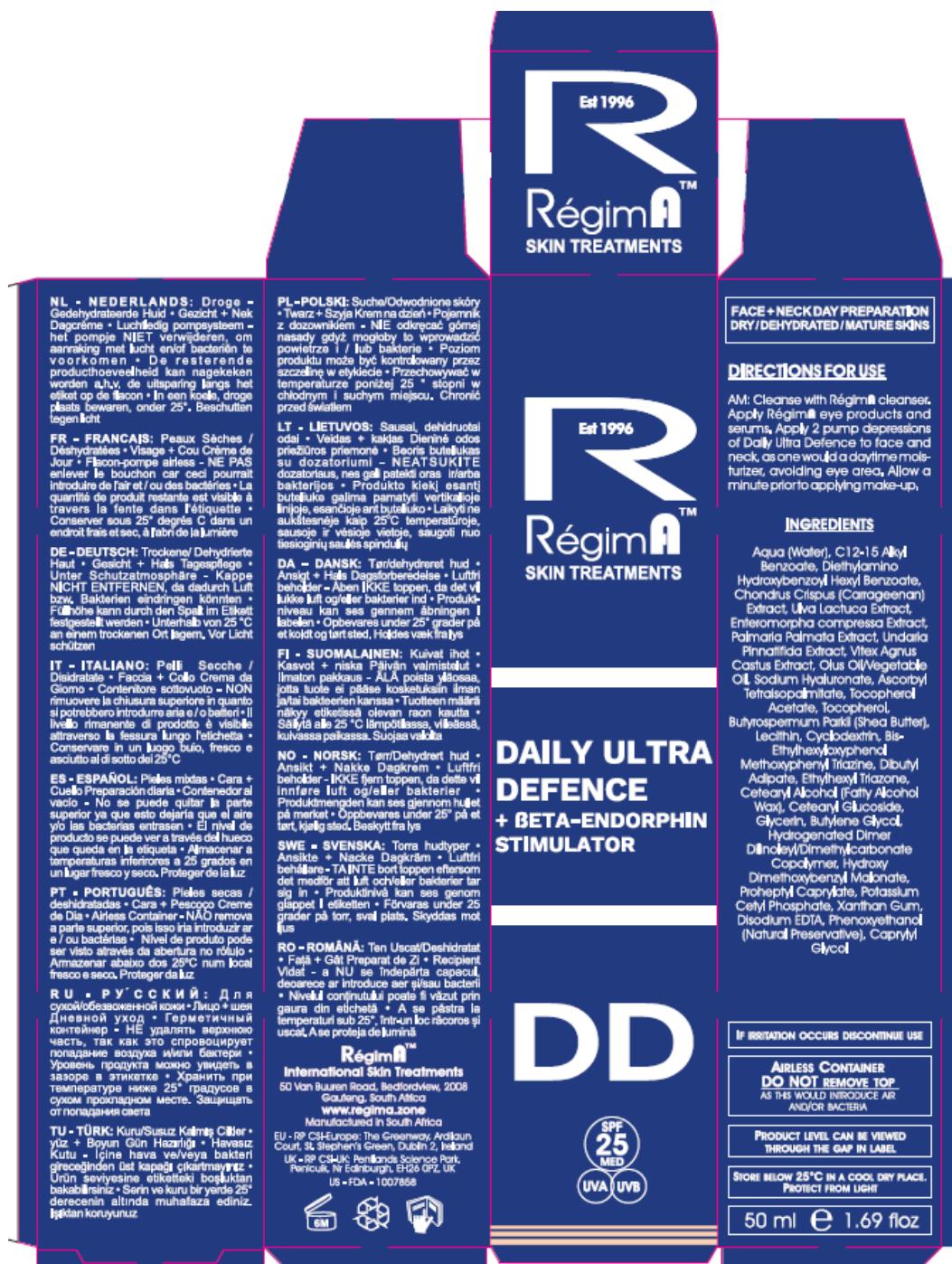
### Top layer



### 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 improve the appearance of dry and sun damaged skins whilst helping 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 Daily Ultra Defence + $\beta$ -Endorphin Stimulator base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	C12-15 Alkyl Benzoate	8.00	8.00	68411-27-8	270-112-4	Emollient UV filter	BASF (Chemgrit)	Cetiol AB
2	Diethylamino Hydroxybenzoyl Hexyl Benzoate	8.00	8.00	302776-68-7	443-860-6	Emollient UV filter	BASF (Chemgrit)	UNIVUL A PLUS GRANULAR
3	Butylene Glycol	3.95	8.00	107-88-0	203-529-7	Skin Conditioning/ Skin Protecting	Greentech (Natchem)	PHYTELENE COMPLEXE EGX 773 (BG)
	Aqua (Water)	3.95		7732-18-5	231-791-2			
	Chondrus Crispus (Carrageenan) Extract	0.02808		244023-79-8	306-561-0			
	Ulva Lactuca Extract	0.02064		97281-59-9	#			
	Enteromorpha compressa Extract	0.01704		#	#			
	Palmaria Palmata Extract	0.01704		223751-74-4	#			
	Undaria Pinnatifida Extract	0.01320		#	#			
4	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	6.00	6.00	187393-00-6	425-950-7	UV Absorber/UV Filter	BASF (Chemgrit)	Tinosorb S
5	Dibutyl Adipate	5.00	5.00	105-99-7	203-350-4	Emollient/Skin Conditioning	BASF (Chemgrit)	Cetiol B
6	Ethylhexyl Triazole	5.00	5.00	88122-99-0	402-070-1	UV Absorber/ UV Filter	BASF (Chemgrit)	Univol T 150
7	Butyrospermum Parkii (Shea Butter)	5.00	5.00	67701-30-8	266-948-4	Skin Conditioning	BASF (Chemgrit)	Cetiol SB 45
8	Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate	4.00	4.00	872182-46-2	471-510-2	Antioxidant/ Skin Conditioning	Merck	RonaCare AP

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
9	Propylheptyl Caprylate	3.00	3.00	868839-23-0	#	Emollient	BASF (Chemgrit)	Cetiol Sensoft
10	Cetearyl Alcohol	3.00	3.00	67762-27-0	267-008-6	Emollient/ Emulsifying/ Emulsion Stabilising	P.T. Musim Mas	MASCOL 68/30
11	Aqua (Water)	0.03	3.00	7732-18-5	231-791-2	Emollient/ Viscosity Controlling/ Surfactant	Seppic (Sharon Bolel Chemical Marketing)	Montanoc 68
	Glucose	0.03		50-99-7	200-075-1			
	Cetearyl Alcohol	2.37		868839-23-0	868839-23-0			
	Cetearyl Glucoside	0.57		868839-23-0	868839-23-0			
12	Potassium Cetyl Phosphate	2.50	2.50	19035-79-1	#	Emulsifying/ Surfactant	DSM Nutritional Products (Chempure)	AMPHISOL K
13	Tocopheryl Acetate	2.00	2.00	7695-91-2	231-710-0	Antioxidant/ Skin Conditioning	DSM Nutritional Products (Chempure)	dl- $\alpha$ -Tocopheryl Acetate
14	Lecithin	0.06	2.00	8002-43-5	232-307-2	Solvent/ Astringent/ Skin Conditioning	Mibelle (Carst & Walker)	Happybelle-PE
	Vitex Agnus Castus Extract	0.26		91722-47-3				
	Glycerin	0.58		56-81-5	200-289-5			
	Ascorbyl Tetraisopalmitate	0.01		183476-82-6				
	Tocopherol	0.01		59-02-9	200-412-2			
	Vegetable Oil	0.02		68956-68-3	273-313-5			
	Cyclodextrin	0.01		7585-39-9	231-493-2			
	Alcohol	0.34		64-17-5	200-578-6			
	Aqua (Water)	0.72		7732-18-5	231-791-2			
15	Butylene Glycol	2.00	2.00	107-88-0	203-529-7	Humectant/ Skin Conditioning	Various	1,3-Butylene

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
								Glycol
16	Hydrogenated Dimer Dilinoleyl/Dimethylcarbonate Copolymer	2.00	2.00	436803-57-5	#	Emulsion Stabilising/ Skin Protecting	BASF (Chemgrit)	Cosmedia DC
17	Phenoxyethanol	0.60	1.20	122-99-6	204-589-7	Preservative/ Emollient	Thor (Actichem)	Microcare PHG
	Caprylyl Glycol	0.60		1117-86-8	214-254-7			
18	Aqua (Water)	0.80	1.00	7732-18-5	231-791-2	Buffering	Various	Caustic soda flakes
	Sodium Hydroxide	0.20		1310-73-2	2151855			
19	Xanthan Gum	0.35	0.35	11138-66-2	234-394-2	Binding/ Emulsifying	Jungbunzlauer	Xanthan Gum
20	Sodium Hyaluronate	0.20	0.200	9067-32-7	#	Humectant/ Skin Conditioning	Contipro	Hyaluronic acid
21	Disodium EDTA	0.20	0.20	139-33-3	205-358-3	Chelating/ Viscosity Controlling	BASF	Trilon BD
22	Aqua (Water)	28.55	28.550	7732-18-5	231-791-2	Solvent	In-House	Water

# not assigned

Ingredient order for the label: Aqua (Water), C12-15 Alkyl Benzoate, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Butylene Glycol, Cetearyl Alcohol, Butyrospermum Parkii (Shea Butter), Dibutyl Adipate, Ethylhexyl Triazone, Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate, Propylheptyl Caprylate, Potassium Cetyl Phosphate, Hydrogenated Dimer Dilinoleyl/Dimethylcarbonate Copolymer, Tocopheryl Acetate, Caprylyl Glycol, Phenoxyethanol, Glycerin, Cetearyl Glucoside, Xanthan Gum, Alcohol , Vitex Agnus Castus Extract, Disodium EDTA, Sodium Hyaluronate, Sodium Hydroxide, Lecithin, Glucose, Chondrus Crispus (Carrageenan) Extract, Ulva Lactuca Extract, Vegetable Oil, Enteromorpha compressa Extract, Palmaria Palmata Extract, Undaria Pinnatifida Extract, Tocopherol, Ascorbyl Tetraisopalmitate, Cyclodextrin

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 Daily Ultra Defence +  $\beta$ -Endorphin Stimulator 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 ...)	O/w mixture
3 organoleptic properties (colour, odour, whenever relevant)	Yellow, characteristic odour
4 pH (at 25°C)	5.25
5 viscosity (at 25°C)	75000 cPs
6 thermal stability (glass bottle)	Stable at 50°C for 12 weeks
7 Specific gravity	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 12 weeks. The viscosity increased at elevated temperatures (40°C and 50°C) from week 8 onwards from 75000 to 95000 and 94000, respectively.

### **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). 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 Daily Ultra Defence +  $\beta$ -Endorphin Stimulator is a product designed to maintain equilibrium of moisturisation, whilst providing protection 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, avoiding the eye area.

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

Site of application	Face and neck (avoiding the eye area)
Surface area of application (cm <sup>2</sup> )	565 cm <sup>2</sup>
Volume of product applied (ml)	0.5 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)	0.5ml exposure daily Estimated exposure based on 60 kg adult =8.34 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	34.05	8.34	1	2.8398
C12-15 Alkyl Benzoate 68411-27-8	8.00	8.34	1	0.6672
Diethylamino Hydroxybenzoyl Hexyl Benzoate 302776-68-7	8.00	8.34	1	0.6672
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine 187393-00-6	6.00	8.34	1	0.5004
Butylene Glycol 107-88-0	5.95	8.34	1	0.4962
Cetearyl Alcohol 67762-27-0	5.37	8.34	1	0.4479
Butyrospermum Parkii (Shea Butter) 67701-30-8	5.00	8.34	1	0.4170
Dibutyl Adipate 105-99-7	5.00	8.34	1	0.4170
Ethylhexyl Triazone 88122-99-0	5.00	8.34	1	0.4170
Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate 872182-46-2	4.00	8.34	1	0.3336
Propylheptyl Caprylate 868839-23-0	3.00	8.34	1	0.2502
Potassium Cetyl Phosphate 19035-79-1	2.50	8.34	1	0.2085
Hydrogenated Dimer Dilinoleyl/Dimethylcarbonate Copolymer 436803-57-5	2.00	8.34	1	0.1668
Tocopheryl Acetate 7695-91-2	2.00	8.34	1	0.1668
Caprylyl Glycol 1117-86-8	0.60	8.34	1	0.0500

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)
Phenoxyethanol 122-99-6	0.60	8.34	1	0.0500
Glycerin 56-81-5	0.58	8.34	1	0.0484
Cetearyl Glucoside 67762-27-0	0.57	8.34	1	0.0475
Xanthan Gum 11138-66-2	0.35	8.34	1	0.0292
Alcohol 64-17-5	0.34	8.34	1	0.0284
Vitex Agnus Castus Extract 91722-47-3	0.26	8.34	1	0.0214
Disodium EDTA 139-33-3	0.20	8.34	1	0.0167
Sodium Hyaluronate 9067-32-7	0.20	8.34	1	0.0167
Sodium Hydroxide 1310-73-2	0.20	8.34	1	0.0167
Lecithin 8002-43-5	0.06	8.34	1	0.0052
Glucose 50-99-7	0.03	8.34	1	0.0025
Chondrus Crispus (Carrageenan) Extract 244023-79-8	0.02808	8.34	1	0.0023
Ulva Lactuca Extract 97281-59-9	0.02064	8.34	1	0.0017
Vegetable Oil 68956-68-3	0.02	8.34	1	0.0017
Enteromorpha compressa Extract ##	0.01704	8.34	1	0.0014
Palmaria Palmata Extract 223751-74-4	0.01704	8.34	1	0.0014
Undaria Pinnatifida Extract ##	0.01320	8.34	1	0.0011
Tocopherol 59-02-9	0.01	8.34	1	0.0008
Ascorbyl Tetraisopalmitate 183476-82-6	0.01	8.34	1	0.0004
Cyclodextrin 7585-39-9	0.01	8.34	1	0.0004

# 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.

## no CAS available

## A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Haz ard ID and list <sup>a</sup>	Refere nce for hazard ID	Irrit ant to eyes	Irrit ant to skin	Sensit iser	Hum an data	NOA EL (mg/ kg bw/d ay)	SE D <sup>b</sup>	Mo S <sup>c</sup>	comm ent
C12-15 Alkyl Benzoate 68411-27-8	A	Safe 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- Ethylhexyloxyphen ol 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								
Butylene Glycol 107-88-0	A	Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006								
Cetearyl Alcohol 67762-27-0	A	2014 CIR Compendium, safe at use up to 25% JACT 7(3):359-413, 1988 confirmed 12/05								
Butyrospermum Parkii (Shea Butter) 67701-30-8	A	Safe when used up to 60% , Final report 03/11 CIR Compendium, 2014								
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								
Ethylhexyl Triazone 88122-99-0	A	Maximum concentration in ready for use concentration 5%, Annex VI of Regulation (EC) 1223/2009								
Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate 872182-46-2	## <sup>1</sup>	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." 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.								
Potassium Cetyl Phosphate 19035-79-1	A	Safe for use when formulated to be non-irritating, Safety Assessment of Alkyl Phosphates as Used in Cosmetics, Final Report 09/2014, Cosmetic Ingredient Review								
Hydrogenated Dimer	## <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								

Ingredient (INCI name & CAS number)	Haz ard ID and list <sup>a</sup>	Refere nce for hazard ID	Irrit ant to eyes	Irrit ant to skin	Sensit iser	Hum an data	NOA EL (mg/ kg bw/d ay)	SE D <sup>b</sup>	Mo S <sup>c</sup>	comm ent
Dilinoleyl/Dimethyl carbonate Copolymer 436803-57-5										
Dilinoleyl/Dimethyl carbonate Copolymer 436803-57-5										
Dilinoleyl/Dimethyl carbonate Copolymer 436803-57-5										
Dilinoleyl/Dimethyl carbonate Copolymer 436803-57-5										
Dilinoleyl/Dimethyl carbonate Copolymer 436803-57-5										
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								
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								
Phenoxyethanol 122-99-6	B	Safe for use when included up to 1%, CosIng Annex V/29								
Glycerin 56-81-5	A	GRAS#, FDA approved food additive, FDA approved over the counter (OTC) for skin								
Cetearyl Glucoside 67762-27-0	A	2014 CIR Compendium, safe for use 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								
Alcohol 64-17-5	A	2014 CIR Compendium, safe for use up to 99% (when denatured). IJT 27 (S1):1-43, 2008								
Vitex Agnus Castus Extract 91722-47-3	A	Well tolerated at the recommended dosage (40-240mg) 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 40mg/kg in a 26 week chronic study, therefore the MoS is 40mg/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 after treatment with 370mg/kg bw/day of the tree for 12 weeks; The Essential Guide to Herbal Safety, Simon Mills and Kerry Bone, pages 333-336								
Disodium EDTA 139-33-3	A	2014 CIR Compendium safe up to 1%, IJT 21(S2):95-142, 2002								
Sodium Hyaluronate 9067-32-7	A	Safe when used at up to 2%, IJT 28 (1): 5-67, 2009								
Sodium Hydroxide 1310-73-2	B	Safe for restricted use according to CosIng Annex III/15a								

Ingredient (INCI name & CAS number)	Haz ard ID and list <sup>a</sup>	Refere nce for hazard ID	Irrit ant to eyes	Irrit ant to skin	Sensit iser	Hum an data	NOA EL (mg/ kg bw/d ay)	SE D <sup>b</sup>	Mo S <sup>c</sup>	comm ent
Lecithin 8002-43-5	A									
Glucose 50-99-7	A									
Vegetable Oil 68956-68-3	A									
Chondrus Crispus (Carrageenan) Extract 244023-79-8	##									
Ulva Lactuca Extract 97281-59-9	## <sup>1</sup>									
Enteromorpha compressa Extract ##										
Palmaria Palmata Extract 223751-74-4										
Undaria Pinnatifida Extract ##										
Tocopherol 59-02-9	A									
Ascorbyl Tetraisopalmitate 183476-82-6	A									
Cyclodextrin 7585-39-9	A									

Ingredient (INCI name & CAS number)	Haz ard ID and list <sup>a</sup>	Refere nce for hazard ID	Irrit ant to eyes	Irrit ant to skin	Sensit iser	Hum an data	NOA EL (mg/ kg bw/d ay)	SE D <sup>b</sup>	Mo S <sup>c</sup>	comm ent	
		a repeated insult occlusive patch test in human volunteers; Background review for cyclodextrins used as excipients, EMA/CHMP/333892/2013, GRAS									

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitizer	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Propylheptyl Caprylate 868839-23-0	-	-	Sligh tly irritat ing to rabbit eyes	Mod. irritatin g- however ingredient was applied neat (amount not specified) on 3 ♀ rabbits after a 4h semi-occlusive patch. Dermal application of 2000 mg/kg bw (applied semi-occlusive and neat) had no reported irritation (Wistar rats)	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 Cosmetics, 04/2013, Cosmetic Ingredient Review.

<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.

##1 other or read-across to information on components

### **Fragrances:**

Zone Daily Ultra Defence + βeta-Endorphin Stimulator 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 Daily Ultra Defence + βeta-Endorphin Stimulator was released in 2015. Over the period September 2015 to July 2016, 8761 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 Daily Ultra Defence +  $\beta$ -Endorphin Stimulator will cause damage to human health when used as directed.

It is therefore concluded that Zone Daily Ultra Defence +  $\beta$ -Endorphin Stimulator can be placed on the market in the EU as a daytime moisturizer with sun protection.

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

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their moisturising and sun protecting 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.

A handwritten signature in black ink, appearing to read "Shirley Hudson". It is written in a cursive style with a long horizontal line extending from the end of the "n" in "Hudson".

## **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**

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.