

# 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**

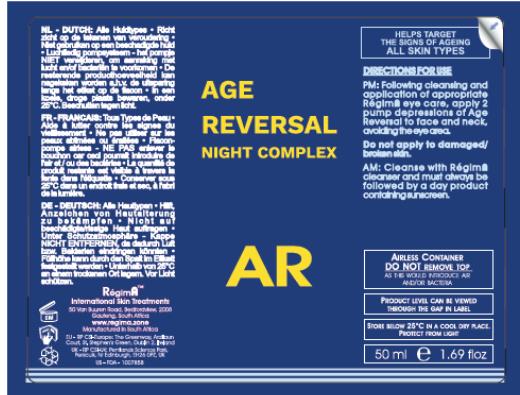
**Product Name: Zone Age Reversal Night Complex**

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

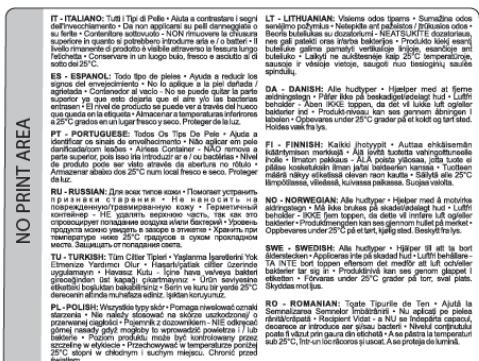
**Pictures of the Item: On following page**

## Container label

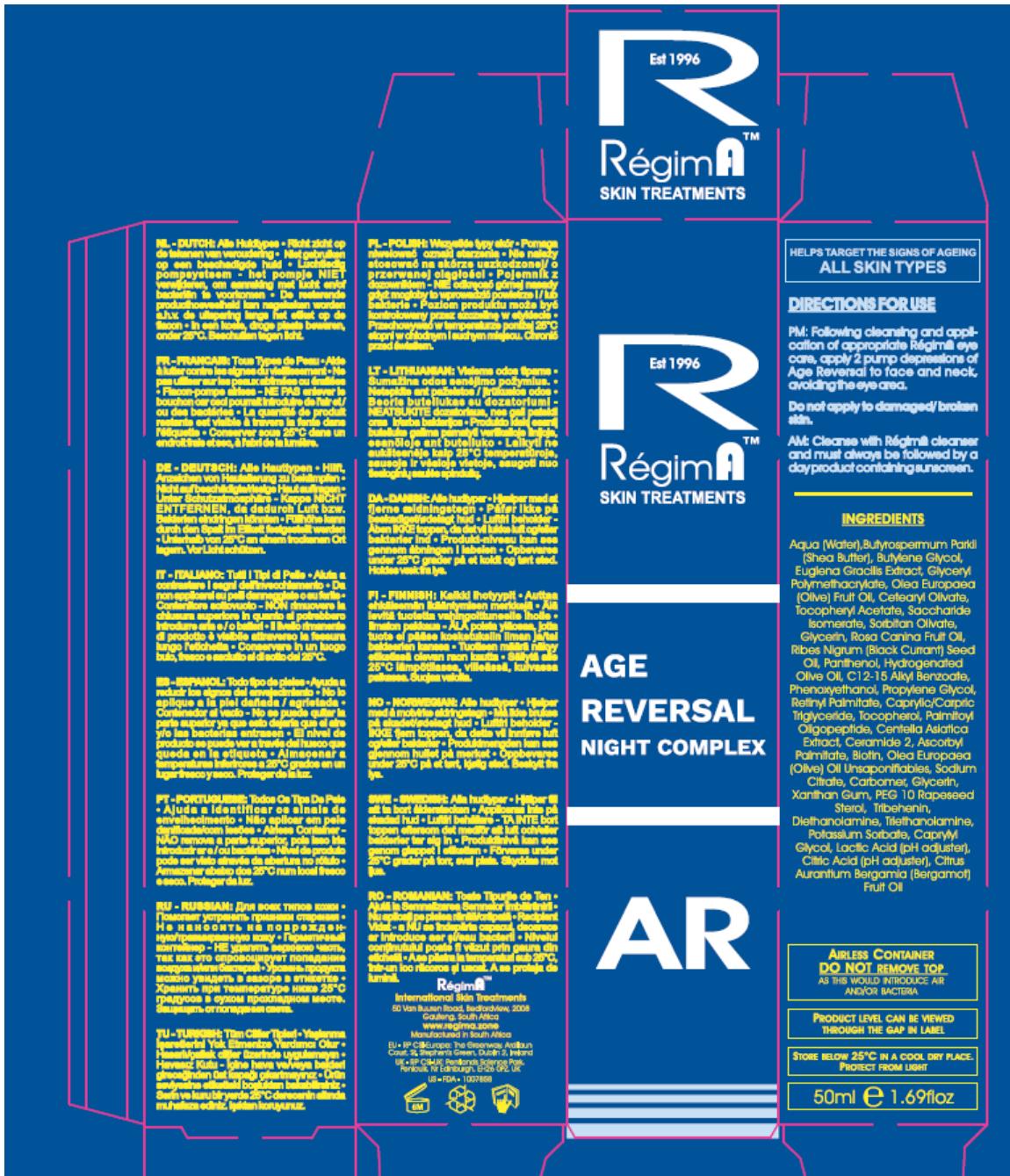
Top layer



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 left side of the box under the signature.

## **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	0.01	3.01
Citronellol	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-53-0	A	A	A
Evernia 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.

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## **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.