

PRODUCT INFORMATION FILE*

RegimA

Zone Derma Deep Rich Creamy Cleanser

Prepared: January 2017
(Label and packaging update August 2021)

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

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INTRODUCTION

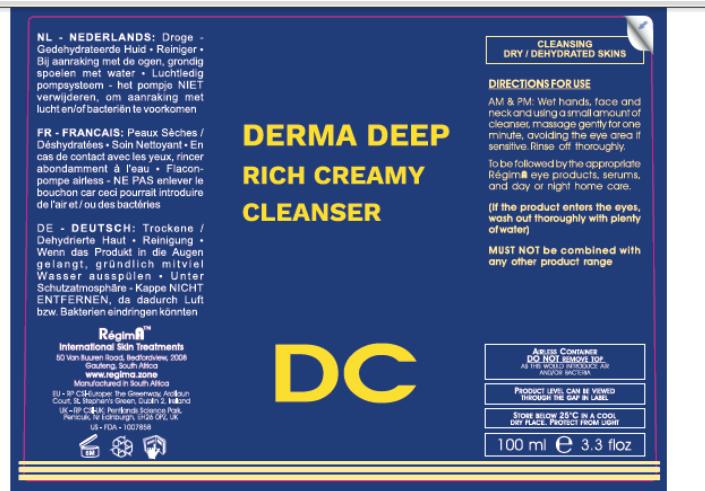
PRODUCT DESCRIPTION

Product Name: Zone Derma Deep Rich Creamy Cleanser

Product type	Rich moisturizing creamy cleanser to deeply hydrate and thoroughly cleanse the skin
Form	Thick liquid
Colour	Off white
Pack size	100 ml
Pack type	Airless container
Dispenser type	Pump
Part of a set	No
Manufacturer code	RCC 005
Normal use	AM & PM: Wet hands, face and neck and using one pump depression of cleanser, massage gently for one minute, avoiding the eye area if sensitive. Rinse off thoroughly. To be followed by the appropriate RegimA eye products, serums and day or night home care. (If the product enters the eyes, wash out thoroughly with plenty of water).

Pictures of the Item: On following page

Container label



Base layer

NO PRINT AREA

IT - ITALIANO: Pelli Secche / Desidratate • Detergente • Se il prodotto entra negli occhi, risciacquare accuratamente con abbondante acqua • Contenitore sottovuoto • NON rimuovere la chiusura superiore in quanto si potrebbero introdurre aria e/o batteri

ES - ESPANOL: Pieles secas / deshidratadas • Limpieza • Si el producto entra en los ojos, lavelos a fondo con agua abundante • Contenedor al vacío • NÃO remova a parte superior, pois isso iria introduzir ar e/ou bactérias

PT - PORTUGUÉS: Peles Secas/Desidratadas • Gels de Limpeza • Se o produto entrar para os olhos, lavar com água abundante • Áltress Container • NÃO remove a parte superior, pois isso iria introduzir ar e/ou bactérias

RU - РУССКИЙ: Для сухой/обезвоженной кожи • Очищающее • При попадании продукта в глаза тщательно промойте глаза большим количеством воды • Герметичный контейнер • НЕ удалять верхнюю часть, так как это спровоцирует попадание воздуха и/или бактерий

TU - TÜRK: Kuru/Susuz Kalıcıller • Temizleyici • Gözde teması halinde bu su ile yıkayın • Havazız Kutu • İçine havza ve/veya bakteri gireceğinden ötürü kapaklı bırakmayın

PL - POLSKI: Sucha/Odwodniona skóra • Oczyszczanie • jeśli produkt dostanie się do oczu, należy go dokładnie przemyć przy użyciu dużej ilości wody • Pojemnik z dozownikiem • NIE odrywać górną nasadę gązki/mogilki do wprowadzić powietrze i/lub bakterie

LT - LIETUVOS: Sausai, dehidruotai odai • Valiklis • Krupšalių nuplukite. Patekus į akis, prauskite plaukti vandeniu. • Beoris buteliukas su dozatoriumi • NEATSUKITE dozatoriaus, nes galį patekti oras ir/arba bakterijos

DA - DANSK: Terdehydreret hud • Rensende • Hvis produktet kommer i øjnene, skal der vaskes efter med masser af vand • Luftfri beholdør • Åben IKKE toppen, da det vil lukke luft og/eller bakterier ind

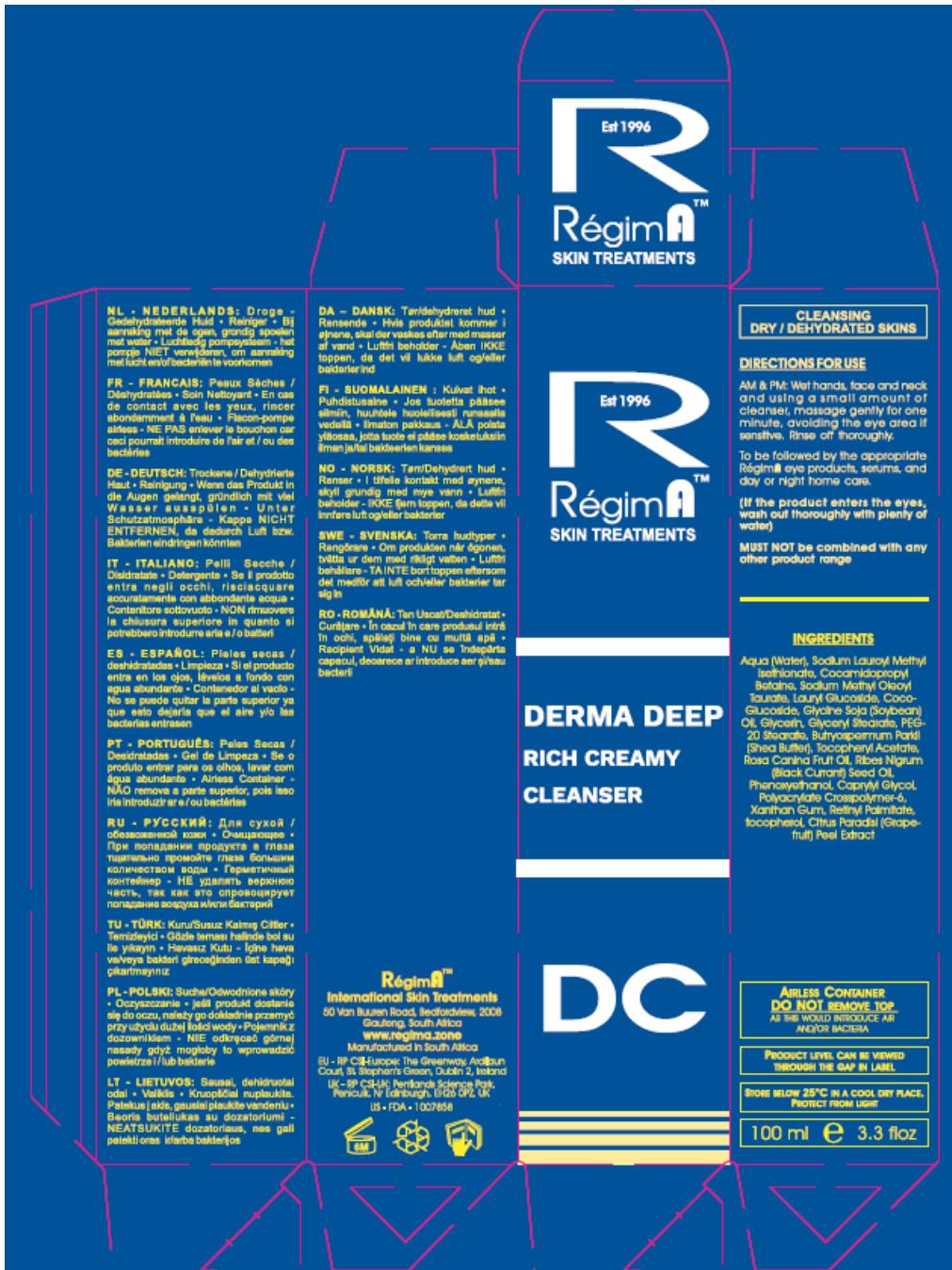
FI - SUOMALAINEN: Kuljet ihon • Puhdistusaine • Jos tuoteita pääsee silmiin, huuhkilee huolellisesti runsaalla vedällä • Ilmaton pakkauks • ÄLÄ poista ylösosa, jotta kute vedällä kesketuskilin ilman ja/tai bakteerien kanssa

RU - NORSK: Terdehydrert hud • Renser • I tilfell kontakt med øynene, skyll grundig med mye vann • Luftri beholdør • IKKE fjern toppen, da dette vil innføre luft og/eller bakterier

SWE - SVENSKA: Torkt/hudtyper • Rengörare • Om produkten når ögonen, tvätta ur dem med riktigt vatten • Luftfri behållare • TA INTE bort toppen eftersom det medfört att luft och/villera bakterier tar sig in

RO - ROMÂNĂ: Ten uscat/Deshidratat • Curățare • În cazul în care produsul intră în ochi, spălați bine cu multă apă • Recipient vidat - a nu se îndepărta capacul, deoarece ar introduce aer și/sau bacterii

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 deeply hydrate whilst thoroughly cleansing.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Zone Derma Deep Rich Creamy Cleanser Base Formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Aqua (water)	10.8	20	7732-18-5	231-791-2 (I)	Cleansing/ Surfactant/ Viscosity/ Controlling/ Masking/ Preservative	Innospec (Akulu Marchon)	Iselux® Ultra Mild
	Sodium Lauroyl Methyl Isethionate	3		156572-81-5/ 928663-45-0	700-150-3			
	Cocamidopropyl Betaine	2.2		61789-40-0	263-058-8/ 931-296-8			
	Sodium Methyl Oleoyl Taurate	1.8		137-20-2/ 7308-16-9 61791-41-1	205-285-7/ 230-762-1			
	Lauryl Glucoside	1		110615-47-9	600-975-8			
	Coco-Glucoside	1		68515-73-1 110615-47-9	600-975-8 500-220-1			
	Sodium Benzoate	0.2		532-32-1	208-534-8			
2	Glycine Soja Oil	8	8	800-22-7	232-274-4	Emollient/ Perfuming/ Skin conditioning	Textron Tecnica (CJP)	Glycine Soja Oil
3	Glycerin	5	5	56-81-5	200-289-5	Humectant/ Perfuming/ Skin Protecting/ Viscosity Controlling	Various	Glycerine BP
4	Glyceryl Stearate	2	4	31566-31-1	250-705-4/ 286-490-9	Emollient/ Emulsifying/ Surfactant	Croda Chemicals	Arlacel™ 165FP-PA- (RB)
	PEG-100 Stearate	2		9004-99-3	#			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
5	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			
6	Butyrospermum Parkii Butter	1	1	194043-92-0/ 91080-23-8/ 67701-30-8	293-515-7/ 266-948-4	Skin Conditioning/ Viscosity Controlling	BASF (Chemgrits)	Cetiol SB 45
7	Tocopheryl Acetate	1	1	7695-91-2/ 58-95-7	231-710-0/ 200-405-4	Antioxidant/ Skin Conditioning	DSM Nutritional Products	DL-alpha- Tocopheryl Acetate
8	Rosa Canina Fruit Oil	1	1	84696-49-7/ 84603-93-0	283-652-0	Emollient/ Skin conditioning	Seatons (Croda)	Rosehip Oil
9	Ribes Nigrum Seed Oil	1	1	68606-81-15/ 97676-19-2	271-749-0	Emollient	Momentive (Savannah Fine Chemicals)	Blackcurran t Oil
10	Polyacrylate crosspolymer-6	0.48	0.5	#	#	Emulsion Stabilising/ Viscosity Controlling/ Perfuming	Sepic (CJP)	SepiMax ZEN
	T-Butyl Alcohol	0.02		75-65-0	200-889-7			
11	Xanthan Gum	0.5	0.5	11138-66-2	234-394-2	Binding/ Emulsifying/ Emulsion	CP Kelco (Tranarc)	Keltrol CG- T

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
						Stabilising/ Skin Conditioning/ Viscosity Controlling		
12	Retinyl Palmitate	0.2775	0.5	79-81-2	201-228-5	Antioxidant/ Masking/ Skin Conditioning/ Perfuming	DSM Nutritional Products	Vitamin A Palmitate/M 1.0 MIU/g (stabilised with tocopherol)
	Tocopherol	0.005		54-28- 4(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	200-201-5/ 240-747-1/ 233-466-0/ 215-798-8/ 218-197-9/ 200-412-2			
	Caprylic/capric Triglyceride	0.2175		73398-61-5/ 65381-09-1	277-452-2/ 265-724-3			
13	Citrus Paradisi Peel Oil	0.5	0.5	8016-20-4	#	Masking/ Perfuming	Scatters Oils	Grapefruit Star Ruby Oil
14	Tocopherol	0.2	0.2	54-28- 4(gamma)/ 16698-35- 4(beta)/ 10191-41-	200-201-5/ 240-747-1/ 233-466-0/ 215-798-8/ 218-197-9/	Antioxidant/ Masking/ Skin conditioning	DSM Nutritional Products	DL-Alpha- Tocopherol

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
				0(DL)/ 119-13-1/ 1406-18-4/ 1406-66-2/ 2074-53- 5(DL)/ 59-02-9(D)/ 7616-22-0	200-412-2			

not assigned

Ingredient order for the label: Water, Glycine Soja Oil, Glycerine, Sodium Lauroyl Methyl Isetionate, Cocamidopropyl Betaine, Glyceryl Stearate, PEG-100 Stearate, Sodium Methyl Oleoyl Taurate, Lauryl Glucoside, Coco-Glucoside, Butrospermum Parkii butter, Tocopheryl Acetate, Rosa Canina Fruit Oil, Ribes Nigrum Seed Oil, Phenoxyethanol, Caprylyl Glycol, Xanthum Gum, Citrus Paradisi Peel Oil, Polyacrylate crosspolymer-6, Limonene, Retinyl Palmitate, Tocopherol, Caprylic/capric Triglyceride, Sodium Benzoate, T-Butyl Alcohol.

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 >0.01% in a wash off product.

Fragrance allergens

<i>INCI (EU) Name</i>	<i>CAS number</i>	<i>EC number</i>	<i>Concentration % w/w</i>	<i>IFRA Standard</i>	<i>Comment</i>
Alpha-Pinenes	80-56-8	201-291-9	0.002105*		Peroxide value less than 10 mmoles/L
L- Beta Pinene	127-91-3	204-872-5	0.000265*		Peroxide value less than 10 mmoles/L
Limonene	5989-27-5	227-813-5	0.475	d-, l- and dl-limonene and natural products containing substantial amounts of it, should only be used when the level of peroxides is kept to the lowest practical level, for instance by adding antioxidants at the time of production. Such products should have a peroxide value of less than 20 millimoles peroxides per liter, determined according to the FMA method.	Entire product has less than 20 mmoles/L. The product also contains antioxidants tocopherol and tocopheryl acetate and the preservative phenoxyethanol.
Linalool	78-70-6	201-134-4	0.0025*		
Citral	5392-40-5	226-394-6	0.001*		
Caryophyllene	87-44-5	201-746-1	0.001235*		
Citronellol	106-22-9	203-375-0	0.0000447375*		* Indicated as a trace amount in MSDS
Geraniol	106-24-1	203-377-1	0.0000447375*		* Indicated as a trace amount in MSDS

* Presented for completeness but not required to be listed as less than 0.01%

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

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

Physical and Chemical Characterization of the product

1	Physical state (at 25°C)	Thick liquid
2	Type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Emulsion
3	Organoleptic properties (colour, odour, whenever relevant)	Off white, characteristic odour
4	pH	6.50
5	Viscosity	4900 cPs
6	Thermal stability (glass bottle)	12 weeks at 40°C
7	Specific gravity	1.013 g/ml

Stability of the product

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

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass jars has confirmed stability at 40°C for 12 weeks. The creamy cleanser was slightly darker in samples stored at 50°C for 12 weeks, at which time an 8.6% increase in viscosity was also noted. The product appeared to separate at week 8 at 50°C.

A.3 Microbiological Quality

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

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

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

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

The WSZ100 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 Derma Deep Rich Creamy Cleanser is a rich moisturizing creamy cleanser containing rosehip and blackcurrant fruit oils, rich in vitamins, anti-oxidants and essential fatty acids that deeply hydrate the skin whilst thoroughly cleansing. It is a wash off product that in normal circumstances will be used twice daily on the face, avoiding the eye area if sensitive.

A.6 Exposure to the Cosmetic Product

Site of application	Face and neck
Surface area of application (cm ²)	565 (face) and 320 (neck)
Volume of product applied (ml)	0.25ml (one pump depression)
Frequency of application/use per day	Twice daily (am and pm)
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 = 8.33 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 [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Glycine Soja Oil 800-22-7	8	8.33	1	0.67
Glycerin 56-81-5	5	8.33	1	0.42
Sodium Lauroyl Methyl Isethionate 156572-81-5	3	8.33	1	0.25
Cocamidopropyl Betaine 61789-40-0	2.2	8.33	1	0.18
Glyceryl Stearate 31566-31-1	2	8.33	1	0.17
PEG-100 Stearate 9004-99-3	2	8.33	1	0.17
Sodium Methyl Oleoyl Taurate 137-20-2	1.8	8.33	1	0.15
Lauryl Glucoside 110615-47-9	1	8.33	1	0.083
Coco-glucoside 68515-73-1	1	8.33	1	0.083
Butyrospermum Parkii Butter 194043-92-0	1	8.33	1	0.083
Tocopheryl Acetate 7695-91-2	1	8.33	1	0.083
Rosa Canina Fruit Oil 84696-49-7	1	8.33	1	0.083
Ribes Nigrum Seed Oil 68606-81-15	1	8.33	1	0.083
Phenoxyethanol 122-99-6	0.975	8.33	1	0.081
Caprylyl Glycol 1117-86-8	0.525	8.33	1	0.044
Xanthan Gum 11138-66-2	0.5	8.33	1	0.042

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Citrus Paradisi Peel Oil 8016-20-4	0.5	8.33	1	0.042
Polyacrylate crosspolymer- 6 *	0.48	8.33	1	0.040
Retinyl Palmitate 79-81-2	0.278	8.33	1	0.023
Caprylic/capric triglyceride 73398-61-5	0.2175	8.33	1	0.018
Tocopherol 10191-41-0	0.205	8.33	1	0.017
Sodium Benzoate 532-32-1	0.2	8.33	1	0.017
T-Butyl Alcohol 75-65-0	0.02	8.33	1	0.0017

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.

* CAS no. not assigned

A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	Comment
Glycine Soja Oil 800-22-7	A	2014 CIR Compendium, safe up to 95%, Safety Assessment of Plant derived fatty acid oils, Final Report, CIR, March, 2011.								
Glycerin 56-81-5	A	Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin, Final Report 01/2015, available from CIR.								
Sodium Lauroyl Methyl Isethionate 156572-81-5	A	Safe for use in cosmetics when formulated to be non-irritating. Final report 09/2013 available from CIR. In addition, read across to sodium cocoyl isethionate (due to shared core chemical structure and functions) allows for safe use at up to 50% for rinse off products, Final Report 10/2013, available from CIR.								
Cocamidopropyl Betaine 61789-40-0	A	2014 CIR Compendium, safe for use when formulated to be non-sensitising (based on a qualitative risk assessment), no irritation or sensitization was observed when clinically tested at 3%, JACT 10(1):33-52, 1991 & safe for use at 2.4%, SIDS Initial Assessment Profile, SIAM 23, 2006. In addition, the CIR Expert Panel concluded that as cocamidopropyl betaine has a large molecular weight structure and is water soluble, therefore it would not be readily absorbed into the skin.								
Glyceryl Stearate 31566-31-1	A	2014 CIR Compendium, safe up to 50%; JACT 1(4), 169-192, 1982.								
PEG-100 Stearate 9004-99-3	A	2014 CIR Compendium, safe up to 6% IJT 24(S1):1-102, 2005.								
Sodium Methyl Oleoyl Taurate 137-20-2	C	-	Slight ly irritati ng	Non- irritating	Non- sensitizin g	Non- genotoxi c, 1 case of SUE	>1000 mg/kg/d	0.1666	6002.4	NOAEL based on reproduction /

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	Comment
						when % of hair dye concentr ation applied & reaction observed				development al toxicity effects in male and female rats.
Lauryl Glucoside 110615-47-9	A	2014 CIR Compendium, safe for use in cosmetics when formulated to be non-irritating IJT 32 (S3): 22-48, 2013. No irritation or sensitization when 5% lauryl glucoside applied dermally, species unspecified.								
Coco-Glucoside 68515-73-1	A	2014 CIR Compendium, safe in cosmetics when formulated to be non-irritating IJT 32 (S3): 22-48, 2013. No irritation or sensitization when <3% caprylyl/capryl glucoside applied dermally to rabbits, strain unspecified.								
Butyrospermum Parkii Butter 194043-92-0	A	2014 CIR Compendium, safe up to 60%, Final report 03/11.								
Tocopheryl Acetate 7695-91-2	A	2014 CIR compendium, safe up to 36% (100% in Vitamin E oil) IJT 21(S3):51-116, 2002.								
Rosa Canina Fruit Oil 84696-49-7	A	2014 CIR Compendium, safe up to 19%, Final report 03/2013 (CIR).								
Ribes Nigrum Seed Oil 68606-81-15	A	2014 CIR Compendium, safe up to 0.3% ² , Final report 03/2013 (CIR) current formulation has 2%, Food item GRAS#.								

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	Comment
Phenoxyethanol 122-99-6	B									
Caprylyl Glycol 1117-86-8	A									
Xanthan Gum 11138-66-2	A									
Citrus Paradisi Peel Oil 8016-20-4	B									
Polyacrylate crosspolymer-6 *	C	-	Slightly irritatin g	Non- irritant	Non- sensitizing	Non- sensitizin g and non- irritating in humans at ~5%	Not available	Not availabl e	Not availabl e	Not genotoxic (negative bacterial revere mutation). Based on assumed low hazard (meets the NICNAS polymer of low concern criteria) and assessed use pattern (up to 5% in cosmetics),

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	Comment
										not considered to be an unreasonable health risk
Retinyl Palmitate 79-81-2	A	2014 CIR Compendium, safe up to 5%; JACT, 6(3), 279-320, 1987; confirmed 06/06.								
Caprylic/capric Triglyceride 73398-61-5	A	2014 CIR Compendium, safe up to 84% JEPT 4 (4): 105-20, 1980 confirmed 06/01 IJT 22 (S1): 1-35, 2003.								
Tocopherol 10191-41-0	A	2014 CIR Compendium, safe up to 1%; IJT 21(S3):51-116, 2002; Final report 03/2014.								
Sodium Benzoate 532-32-1	A	2014 CIR Compendium, safe up to 1%, IJT 20(S3):23-50, 2001.								
T-Butyl Alcohol 75-65-0	A	2014 CIR Compendium, safe for use up to 0.5% IJT 24(2):1-20, 2005, (Amended) JACT 8(4):627-41, 1989 (Original Report).								

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

^b all possible routes of exposure should be considered.

^c A MoS of greater than 100 is considered to represent safe use.

Food item, hazard and exposure data not required.

*CAS no. not assigned.

Fragrances:

Zone Derma Deep Rich Creamy Cleanser contains a fragrance. Certificates of allergen composition for the plant extracts used have been presented in Appendix 3. While limonene (0.4755) is present above the wash off limit of 0.01%, it is not likely to induce sensitization when used as intended. In addition, the IFRA standards states that “d-, l- and dl-limonene and natural products containing substantial amounts of it, should only be used when the level of peroxides is kept to the lowest practical level, for instance by adding antioxidants at the time of production. Such products should have a peroxide value of less than 20 millimoles peroxides per liter, determined according to the FMA method”. Zone Derma Deep Rich Creamy Cleanser has less than 20 mmoles peroxides/L. The product also contains antioxidants tocopherol and tocopheryl acetate and the preservative phenoxyethanol.

A.9 Undesirable Effects and Serious Undesirable Effects

No undesirable effects are anticipated based on the product being used as directed on the face avoiding the eye area if sensitive, twice daily.

A.10 Information on the Cosmetic Product

Zone Derma Deep Rich Creamy Cleanser was released in 2017. Over the period September 2017 to November 2017 489 units have been sold and there have been no adverse reactions reported to RégimA.

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 Derma Deep Rich Creamy Cleanser will cause damage to human health when used as directed.

It is therefore concluded that Zone Derma Deep Rich Creamy Cleanser can be placed on the market in the EU as a salon take home product to richly moisturize and to deeply hydrate and thoroughly cleanse the skin.

Review of human data on the product

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

B.2 Label Warnings and Instructions for Use

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

AM & PM: Wet hands, face and neck and using one pump depression of cleanser, massage gently for one minute, avoiding the eye area if sensitive. Rinse off thoroughly. To be followed by the appropriate RegimA eye products, serums and day or night home care.

Warnings:

‘If the product enters the eyes, wash thoroughly with plenty of water’

‘Discontinue use if irritation occurs’

‘Must not be used in combination with any other product range’

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

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

B.3 Reasoning

This product contains many ingredients with a positive reputation for their skin cleansing properties and with. There are no reasons to anticipate tolerance problems with use twice daily (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, MSB

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 cleanser.

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, 9th Revision, 29 September 2015 (SCCS/1564/15)
European Commission database on cosmetic ingredients (CosIng)
<http://ec.europa.eu/consumers/cosmetics/cosing/>
Cosmetic ingredient review <http://www.cir-safety.org/>
OECD, SIDS <http://www.oecd.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

POSTAL ADDRESS: PO BOX 9523 Edenglen 1613

PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA

Animal Testing Compliance Statement

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

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

Appendix 1: Safety Data Sheets or Ingredient Specifications

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

Appendix 2: Microbial Challenge Test

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

Appendix 3: Certificates of Allergen Content

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

Appendix 4: Miscellaneous

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

PRODUCT INFORMATION FILE*

RégimA

Derma Zest Cleansing +
Toning Gel

Prepared: 16 December, 2014
(Product label & 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:

Product type	Face wash and toner
Form	Semi-viscous surfactant based mixture
Colour	Dark Orange
Pack size	10, 100 & 300 ml
Pack type	HDPE and Polypropylene/polyethylene based dispenser pump
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	NFW007
Normal use	Rinse-off cleansing product

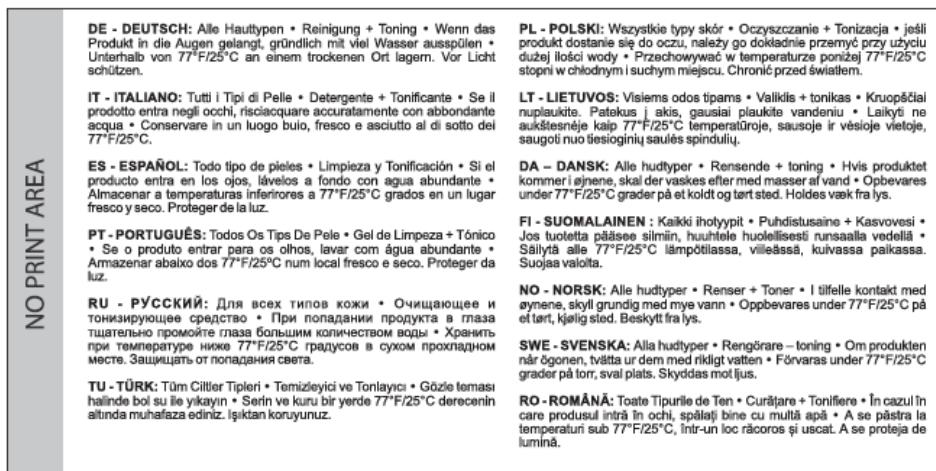
Pictures of the Item:

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 makes no direct or implied claims.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Derma Zest Cleansing + Toning Gel base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixtur e % w/w Wt(g/k g)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Sodium Coceth Sulfate	5	25 / 250.00	#	#	Surfactant emulsifying foaming	Seppic (CJP)	Oronal LCG
	PEG-40 Glyceryl Cocoate	10		#	#			
	Caprylyl Glycol	0.25		CAS: 1117-86-8	EC: 214-254-7			
	Aqua	9.75		CAS: 7732-18-5	EC: 231-791-2			
2	Propylene Glycol	5	10 / 100.00	CAS: 57-55-6	EC: 200-338-0	Surfactant Viscosity controlling	Evonik (Protea Chemicals)	Antil 141
	PEG-55 Propylene Glycol Oleate	5		CAS: 86481-08-5	#			
3	Cocamidopropyl Betaine	2.4	8/ 80.00	CAS: 61789-40-0	EC: 263-058-8 /931-296-8	Surfactant foam boosting viscosity controlling	Akulu Marchon	Empigen BSF-A/AF
	Aqua	5.6		CAS: 7732-18-5	EC: 231-791-2			
4	Disodium Ricinoleamido MEA-Sulfosuccinate	2	5/ 50.00 -	CAS: 67893-42-9	EC: 267-617-7	Surfactant	Evonik (Protea Chemicals)	Rewoderm1333
	Aqua	3		CAS: 7732-18-5	EC: 231-791-2			
5	Sodium Lauroyl Oat Amino acids	5	5/ 50.00	CAS: 222400-43-3	#	Conditioning Surfactant	Seppic (CJP)	Proteol OAT
6	Glycerin	3	3/ 30.00	CAS: 56-81-5	EC: 200-289-5	Humectant	CJ Petrow	Glycerine BP
7	Coco-Glucoside	0.96	3/ 30.00	CAS: 141464-42-8	#	Conditioning Surfactant	Cognis	LAMESOFT PO65
	Glyceryl Oleate	0.78		CAS 25496-72-4 / 111-03-5	EC: 247-038-6			
	Aqua	1.08		CAS: 7732-18-5	EC: 231-791-2			
	Citric acid	0.15		CAS 77-92-9				
8	Betaine	2	2/ 20.00	CAS: 107-43-7	EC: 203-490-6	Conditioning Viscosity controlling humectant	Arch Chemicals	Betafin BP20
9	Panthenol	2	2/ 20.00	CAS: 81-13-0	EC: 201-327-3	Humectant Antistatic conditioning	DSM Nutritional Products	D-Panthenol

No	Raw Ingredient (INCI Name)	% (w/w)	Mixtura e % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
10	Lavandula Angustifolia FlowerExtract	0.02	2/ 20.00	CAS: 90063-37-9	EC: 289-995-2	Cleansing Deodorant Masking Refreshing tonic	Greentech SA (Natchem)	Lavender HG extract
	Propylene Glycol	0.99		CAS: 57-55-6	EC: 200-338-0			
	Aqua	0.99		CAS: 7732-18-5	EC: 231-791-2			
11	Pelargonium Graveolens Extract	0.02	2/ 20.00	CAS: 90082-51-2	EC: 290-140-0	Masking conditioning	Greentech SA (Natchem)	Geranium HG (BG) extract
	Butylene glycol	0.99		CAS : 107-88-0	EC: 203-529-7			
	Aqua	0.99		CAS: 7732-18-5	EC: 231-791-2			
12	Centella Asiatica Leaf Extract	0.024	2/ 20.00	CAS: 84696-21-9	EC: 283-640-5	conditioning	Greentech SA (Natchem)	Centella EG
	Propylene Glycol	1.05		CAS: 57-55-6	EC: 200-338-0			
	Aqua	0.926		CAS: 7732-18-5	EC: 231-791-2			
13	Phenoxyethanol	0.975	1.5/ 15.00	CAS: 122-99-6	EC: 204-589-7	Preservative	Actichem	Microcare PHG
	Caprylyl Glycol	0.525		CAS: 1117-86-8	EC: 214-254-7			
14	PEG-40 Hydrogenated Castor Oil	1.5	1/5 15.00	CAS: 61788-85-0	#	Emulsifying surfactant	BASF	Eumulgin CO40
15	Rosmarinus Officinalis (Rosemary) Leaf Extract	0.05	1/ 10.00	CAS: 84604-14-8	EC: 283-291-9	Antimicrobial Masking conditioning	Greentech SA (Natchem)	Rosemary glycolic extract
	Propylene Glycol	0.85		CAS: 57-55-6	EC: 200-338-0			
	Aqua	0.10		CAS: 7732-18-5	EC: 231-791-2			
16	Achillea Millefolium Extract	0.01	1/ 10.00	CAS: 84082-83-7	EC: 282-030-6	Cleansing Masking Refreshing Conditioning Soothing tonic	Greentech SA (Natchem)	Yarrow Phytelene EG
	Propylene Glycol	0.525		CAS: 57-55-6	EC: 200-338-0			
	Aqua	0.465		CAS: 7732-18-5	EC: 231-791-2			
17	Sodium Hydroxide	0.1	0.5/ 5.00	CAS: 1310-73-2	EC: 215-185-5	Buffering	Various	Sodium hydroxide solution
	Aqua	0.4		CAS: 7732-18-5	EC: 231-791-2			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixturae % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
18	Citrus Paradisi Peel Extract	0.5	0.5/ 5.00	CAS: 8016-20-4	#	Olfactory Profile Perfuming conditioning	Scatters	Grapefruit Star Ruby Oil
19	Citrus Reticulata, X C. Sinesis Peel Extract	0.3	3/ 3.00	CAS:93686-22-7	EC:297-672-2	Perfuming	SBCM	Bergamot Oil
20	Bisabolol	0.1	0.1/ 1.00	CAS: 515-69-5	EC: 208-205-9 / 245-423-3	Masking perfuming	Symrise	DragoSantol 100 - MSDS.pdf
21	Aqua	24.6	24.6/ 246.00	CAS: 7732-18-5	EC: 231-791-2	Solvent	In-House	
		100	1000					

not assigned

Ingredient order for the label:

Aqua, PEG-40 Glyceryl Cocoate, Propylene Glycol, PEG-55 Propylene, Glycol Oleate, Sodium Coceth Sulfate, Sodium Lauroyl Oat Amino acids, Glycerin, Cocamidopropyl Betaine, Betaine, Disodium Ricinoleamido MEA-Sulfosuccinate, Panthenol, PEG-40 Hydrogenated Castor Oil, Centella Asiatica Leaf Extract, Bisabolol, Citrus Paradisi Peel Extract, Citrus Reticulata, X C. Sinesis Peel Extract, Achillea Millefolium Extract, Pelargonium Graveolens Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Lavandula Angustifolia Flower Extract, Coco-Glucoside, Glyceryl Oleate, Caprylyl Glycol, Butylene glycol, Phenoxyethanol, Citric acid, Sodium Hydroxide, Limonene, Linalool

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 >0.01% in a wash-off product.

Fragrance allergens

<i>INCI (EU) Name</i>	<i>CAS number</i>	<i>EC number</i>	<i>Concentration % w/w</i>
Limonene	CAS: 5989-27-5	EC: 227-813-5	0.557
Linalool	CAS: 78-70-6	EC: 201-134-4	0.034
Alpha-Pinenes	CAS: 80-56-8	EC: 201-291-9	0.002*
Citral	CAS: 5392-40-5	EC: 226-394-6	0.009*
Citronellol	CAS: 106-22-9	EC: 203-375-0	0.000014*
Courmarin	CAS 91-64-5	202-086-7	0.0024*

* Presented for completeness but not required to be listed as less than 0.01%

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

Physical and chemical characteristics of the ingredients have been listed in the safety data sheets which are presented in the report appendices as shown in the base formula table.

Physical and Chemical Characterization of the product

1 Physical state	Gel
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Semi-viscous surfactant based mixture with various conditioners and emollients
3 organoleptic properties (colour, odour, whenever relevant)	Dark orange with a characteristic odour
4 pH (at °C)	ca. 5
5 viscosity (at °C) for liquid forms	ca. 2460 cPs at 25°C
6 thermal stability (glass bottle)	Stable at 50°C for 12 weeks
7 Specific gravity	ca. 1.05 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 retain sample of the product has been stored in the packaging for up to 8 months with no evidence of product spoilage and a stability test of the product in glass bottles has confirmed stability at 50°C for 12 weeks.

A.3 Microbiological Quality

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

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

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

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

RégimA Skin Treatments

CK92/05371/23
VAT No. 4590131043

Tel: 011 615 2869 or 011 622 7827
Fax: 011 616 8008
Cell: 0836537020
e-mail: jax@regima.com

POSTAL ADDRESS: PO BOX 9523 Edenglen 1613

PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA

In-House Packaging Suitability Testing – Statement of Effect

This letter is to serve as testimony as to the suitability of the PISA 100ml, 300ml and 500ml HDPE bottles – Pearl Blue – for the containment of the “RégimA Derma Zest Cleansing + Toning” product therein.

The acquired packaging has been tested for product suitability with the Derma Zest product. Examples of the packaging were filled with a finalized retention sample batch of the Derma Zest product in February 2014, and to date have remained stable in this packaging, with no evidence of product spoilage. This would serve as some evidence as to the suitability of this packaging for the Derma Zest product in question, and will be the basis for continued stability testing of the product in these bottles.

A.5 Normal and reasonably foreseeable use

Derma Zest Cleansing +Toner Gel is a face wash that will be used in normal circumstances once or twice daily on the face and neck. It is a rinse-off product intended for adult use.

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

AM & PM: Wet hands, face and neck and using one pump depression of cleanser, massage gently for a minute, avoiding the eye area if sensitive. Rinse off thoroughly.

A.6 Exposure to the Cosmetic Product

Site of application	Face and neck
Surface area of application (cm ²)	565 cm ² (note there are no default values for the neck)
Volume of product applied (ml)	1.2 ml at each application, maximum daily volume = 2.4 ml
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)	2.4 x 0.01 retention factor = 0.024 ml exposure daily Estimated exposure based on 60 kg adult = 0.0004 mg/kg bw /day
Dermal absorption information other	Unknown but likely to be negligible.

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 [#]	Daily ingredient exposure or SED (mg/kg bw/day)
PEG-40 Glyceryl Cocoate	10	0.0004	1	4.00E-05
propylene glycol total	8.42	0.0004	1	3.37E-05
PEG-55 Propylene Glycol Oleate	5	0.0004	1	2.00E-05
Sodium Coceth Sulfate	5	0.0004	1	2.00E-05
Sodium Lauroyl Oat Amino acids	5	0.0004	1	2.00E-05
Glycerin	3	0.0004	1	1.20E-05
Cocamidopropyl Betaine	2.4	0.0004	1	9.60E-06
Betaine	2	0.0004	1	8.00E-06
Disodium Ricinoleamido MEA-Sulfosuccinate	2	0.0004	1	8.00E-06
Panthenol	2	0.0004	1	8.00E-06
PEG-40 Hydrogenated Castor Oil	1.5	0.0004	1	6.00E-06
Butylene glycol	0.99	0.0004	1	3.96E-06

Phenoxyethanol	0.98	0.0004	1	3.90E-06
Coco-Glucoside	0.96	0.0004	1	3.84E-06
Glyceryl Oleate	0.78	0.0004	1	3.12E-06
Capryl glycol total	0.78	0.0004	1	3.10E-06
Citrus Paradisi Peel Extract	0.5	0.0004	1	2.00E-06
Citrus Reticulata, X C. Sinesis Peel Extract	0.3	0.0004	1	1.20E-06
Citric acid	0.15	0.0004	1	6.00E-07
Bisabolol	0.1	0.0004	1	4.00E-07
Sodium Hydroxide	0.1	0.0004	1	4.00E-07
Rosmarinus Officinalis (Rosemary) Leaf Extract	0.05	0.0004	1	2.00E-07
Centella Asiatica Leaf Extract	0.024	0.0004	1	9.60E-08
Pelargonium Graveolens Extract	0.024	0.0004	1	9.60E-08
Lavandula Angustifolia FlowerExtract	0.02	0.0004	1	8.00E-08
Achillea Millefolium Extract	0.01	0.0004	1	4.00E-08

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 ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Propylene glycol, CAS: 57-55-6	A	Safe (when formulated to be non-irritating), Safety assessment of propylene glycol tripropylene glycol and PPGs as Used in Cosmetics, Fiume, M. et al., International Journal of Toxicology 31(S 2), 2012								
Sodium coceth sulfate CAS: #	A	Safe up to 29%, International Journal of Toxicology 29 (S2), 115-132,2010								
PEG-40 Glyceryl cocoate CAS:	A	Safe as used in rinse-off products; International Journal of Toxicology 19 (S1), 51-59, 1999								
PEG-55 Propylene Glycol Oleate CAS: 86481-08-5	A	Safe up to 10% , International Journal of Toxicology 20(S4), 13-26, 2001								
Cocamidopropyl betaine CAS: 61789-40-0	A	Safe for use when formulated to be non-sensitising (based on a qualitative risk assessment), JACT 10(1):33-52, 1991 & Safe for use at 2.4%, SIDS Initial Assessment Profile, SIAM 23, 2006								
Glycerol oleate CAS: 25496-72-4	A	Safe up to 5%, JACT 5(5): 391-413								
Glycerin CAS: 56-81-5	A	Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin								
Coco-glucoside CAS: 141464-42-8	A	Derived from coconut/palm kernel, sunflower oil, glucose, glycerine; Safe; Plant derived fatty acid oils used in cosmetics, Cosmetic Ingredient Review, 2011								
Betaine CAS: 107-43-7	A	Safe (when formulated to be non-irritating), Safety Assessment of Alkyl Betaines as used in Cosmetics, Cosmetic Ingredient Review, 2014								
Panthenol CAS: 81-13-0	A	Safe up to 25%, JAQCT 6(1): 139-62, 2006								
Lavandula Angustifolia Flower Extract CAS: 90063-37-9	A	MedlinePlus: Lavender http://www.nlm.nih.gov/medlineplus/druginfo/natural/838.html								
Phenoxyethanol CAS: 122-99-6	B	Safe for use when included up to 1%, CosIng Annex V/29								
Caprylyl glycol CAS: 1117-86-8	A	Safe when used up to 5%, Safety assessment of 1,2-gltcols as used in cosmetics, International Journal of Toxicology 31 (S2), 1475-1685, 2012								
PEG 40 hydrogenated castor oil CAS: 61788-85-0	A	Safe (when formulated to be non-irritating), Amended safety assessment of PEGylated oils as used in cosmetics, CIR 2012								
Sodium hydroxide CAS: 1310-73-2	B	Safe for restricted use according to CosIng Annex III/15a								
Citrus Paradisi Peel Extract	B	Safe when allergen components are used (see A1 Fragrance Allergen table) up to the levels allowed, allergen components include Citral, Limonene, Linalool.								

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
CAS: 8016-20-4										
Citrus Reticulata, X C. Sinesis Peel Extract CAS: 93686-22-7	B		Safe when allergen components are used (see A1 Fragrance Allergen table), allergen components include Citral, Limonene, Linalool.							
Bisabolol CAS: 515-69-5	A		Safe when used up to 1%; International Journal of Toxicology 18(S3); 33-40. 1999							
Butylene glycol CAS:107-88-0	A		Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006							
Citric Acid CAS:77-92-9	A		Safe up to 39%, International Journal of Toxicology 33(S2), 16-46, 2014							
Sodium Lauroyl Oat Amino acids CAS: 222400-43-3	A		Safe (when formulated to be non-irritating), Safety Assessment of Amino Acid Alkyl Amides as Used in Cosmetics, CIR 2014							
Achillea Millefolium Extract CAS: 84082-83-7	A		Safe at inclusion concentration dermal use confirmed, Final Report on the Safety Assessment of Yarrow (Achillea Millefolium) Extract, CIR, 2001							
Disodium Ricinoleamido MEA- Sulfosuccinate CAS:67893-42-9	-	-	Non-irritant	Non-irritant	Not sensitising	No mutagenic effects	500	8.0 x10 ⁻⁶	1.6 x10 ⁻⁸	
Centella asiatica leaf extract CAS:84696-21-9	-	-	Non-irritant	Non-irritant	Safe at 0.024% inclusion rate	Not genotoxic	10	9.60x10 ⁻⁶	1.04x10 ⁶	NOAEL based on reproduction toxicity effects in male rats
Rosmarinus officinalis (Rosemary) leaf extract CAS: 84604-14-8	-	-	Non-irritant	Non-irritant	Not listed as a sensitiser	#	#	#	#	GRAS (FDA food additive database)
Pelargonium Graveolens Extract CAS: 90082-51-2	-	-	Non-irritant	Non-irritant	Not listed as a sensitiser	#	#	#	#	GRAS (FDA food additive database)

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

^b all possible routes of exposure should be considered

^c A MoS of greater than 100 is considered to represent safe use

Food item, hazard and exposure data not required.

Fragrances:

Certificates of allergen composition for the plant extracts used in the cleansing & toning gel formulation have been presented in Appendix 3.

Based on the very low concentrations used in this product (Limonene 0.557%, Linalool 0.034%) it is not likely to induce sensitization when used as intended.

A.9 Undesirable Effects and Serious Undesirable Effects

No undesirable effects are anticipated based on the product being used as directed for a face wash once or twice daily.

A.10 Information on the Cosmetic Product

Derma Zest Cleansing + Toning Gel was released in 2014 as a slightly modified version of a previous formulation cleanser that has been on the market for almost 20 years. This similar product had a clear record of easy tolerance with no undesirable effects reported to RégimA Skin Treatments.

In conclusion neither product version has received any negative feedback with regards to its usage by the public during its lifetime, and it is not expected that Derma Zest Cleansing + Toning Gel will cause any tolerance problems judging by the previous version's 20 year performance on the market.

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
- formulation, history of 1 year of safe use and 20 years of safe use for a very similar product whilst being on the market in South Africa

it is not expected that Derma Zest Cleansing + Toning Gel will cause damage to human health. A recommendation that the product is not used in combination with other products has been listed on the product label to mitigate against the potential for irritancy or allergic reaction.

It is therefore concluded that Derma Zest Cleansing + Toning Gel can be placed on the market in the EU as a rinse-off facial cleansing 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

Warnings – MUST NOT be combined with any other product range'

Directions for use are given on the product insert.



CSI - RégimA Zone
Product Insert - V2 - :

AM & PM: Wet hands, face and neck and using one pump depression of cleanser, massage gently for a minute, avoiding the eye area if sensitive. Rinse off thoroughly. To be followed by the appropriate RégimA eye products, serums, and day or night home care.

B.3 Reasoning

This product is a fairly typical facial wash that contains many ingredients common to many cosmetic formulations. Past experience with these products is that there are very few if any adverse effects or problems reported.

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

This product is intended for external use in adults only.

B.4 Assessors Credentials and Approval of Part B

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

CBiol, MBS

Member of the British Toxicology Society

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

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



List of References

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

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

METHOD OF MANUFACTURE / GMP CERTIFICATION



PROOF OF EFFECT CLAIMED

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

ANIMAL TESTING STATEMENT

To the best of our knowledge, the manufacturer and his suppliers have not carried out or commissioned any animal testing for the purpose of developing new cosmetic products. The statement below from is a confirmation of the company policy:

RégimA Skin Treatments

CK92/05371/23
VAT No. 4590131043

Tel: 011 615 2869 or 011 622 7827
Fax: 011 616 8008
Cell: 0836537020
e-mail: jax@regima.com

POSTAL ADDRESS: PO BOX 9523 Edenglen 1613

PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA

Animal Testing Compliance Statement

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

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

Appendix 1: Safety Data Sheets or Ingredient Specifications

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

Appendix 2: Microbial Challenge Test



Derma Zest stability
certificate.pdf

Appendix 3: Certificates of Allergen Content

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

PRODUCT INFORMATION FILE*

RegimA

Zone Epi-Genes Xpress

Prepared: October 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 Epi-Genes Xpress

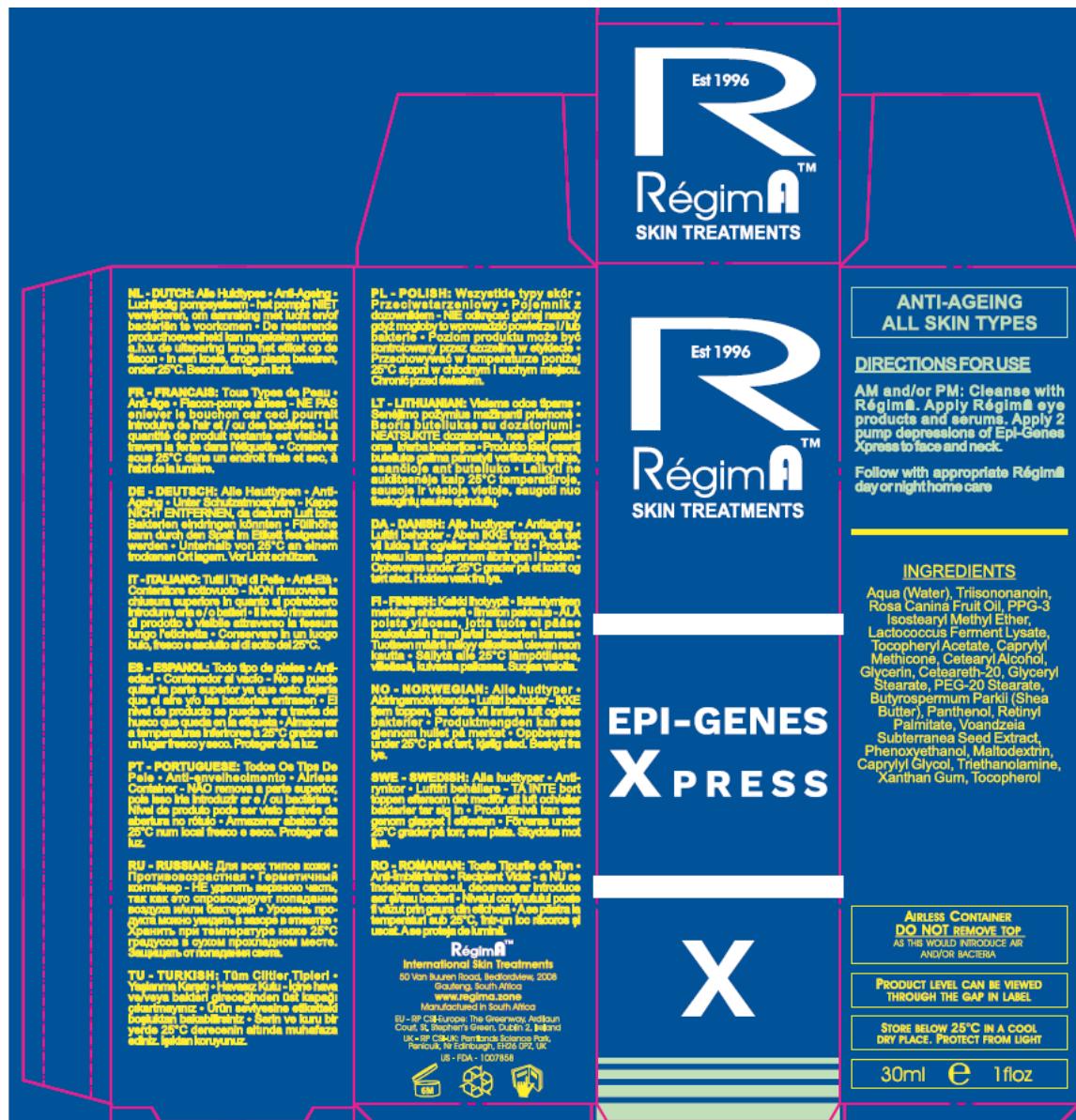
Product type	Cream to help stimulate epidermal renewal and skin appears smoother, thicker and more youthful.
Form	Cream
Colour	Off white
Pack size	30 mL
Pack type	WSZ Airless Bottle
Dispenser type	WSZ Airless bottle
Part of a set	No
Manufacturer code	EPG 001
Normal use	Yes

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:

The carton and product label state that the product helps target the signs of ageing whilst the product insert claims to stimulate epidermal renewal and skin appears smoother, thicker and more youthful.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Zone Epi- Genes Xpress base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Triisononanooin	7	7	56554-53-1 206354-95-2	260-257-1	Skin Conditioning/ Viscosity Controlling	Industria Quimca Lasem (Savannah Fine Chemicals)	Waglinol 3/929
2	Cetearyl Alcohol	3.5	5	67762-27-0 8005-44-5	267-008-6	Emollient/ Emulsifying	Croda Chemicals	Cosmowax D
	Ceteareth- 20	1.5		68439-49-6	#			
3	Aqua (Water)	5	5	7732-18-5	231-791-2	Solvent	In-House	Deionised Water
4	Rosa Canina Fruit Oil	5	5	84603-93-0	283-652-0	Emollient	Seatons (Croda)	Rose Hips Oil
5	Glyceryl Stearate	2	4	31566-31-1	250-705-4 286-490-9	Emulsifying	Croda Chemicals	Arlacel 165
	PEG-100 Stearate	2		9004-99-3	#			
6	PPG-3 Isostearyl Methyl Ether	3.999	4	1429060-56-9	#	Emollient/ Emulsifying/ Antioxidant	Croda Chemicals	Arlamol LST
	Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate	0.001		6683-19-8	229-722-6			
7	Lactococcus Ferment Lysate	2.9505	3	#	#	Skin Conditioning/ Anticorrosive/ Viscosity Controlling	CLR (IMCD)	ProRenew Complex CLR
	Sodium Benzoate	0.0105		532-32-1	208-534-8			
	Sodium Chloride	0.009		7647-14-5	231-598-3			
	Lactic Acid	0.03		50-21-5	200-018-0			
8	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
9	Caprylyl Methicone	3	3	17955-88-3	241-881-3	Skin Conditioning	Momentive (Savannah Fine Chemicals)	Silsoft 034

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	Skin Conditioning/ Viscosity Controlling	Various	Glycerine
11	Butyrospermum Parkii Butter	2	2	194043-92-0 - 91080-23-8	293-515-7	Skin Conditioning/ Viscosity Controlling	BASF (Chemgrits)	Cetiol SB 45
12	Phenoxyethanol	0.975	1.5	122-99-6	204-589-7	Preservative/ Emollient/ Skin Conditioning	Acti-Chem	Microcare PHG
	Caprylyl Glycol	0.525		1117-86-8	214-254-7			
13	Panthenol	0.75	1	81-13-0/ 16485-10-2	201-327-3/ 240-540-6	Skin Conditioning/ Humectant	DSM Nutritional Products	D-Panthenol 75L
	Pantolactone	0.01		599-04-2	209-963-3			
	Aqua (Water)	0.24		7732-18-5	231-791-2			
14	Maltodextrin	0.4	0.5	9050-36-6	232-940-4	Binding/ Emulsion Stabilising/ Skin Conditioning	BASF (Botanicchem)	Epigenist™
	Voandzeia Subterranea Seed Extract	0.1		#	#			
15	Triethanolamine	0.4975	0.5	102-71-6	203-049-8	Buffering/ Emulsifying/ Surfactant	Various	TEA 99%
	Diethanolamine	0.0025		111-42-2	203-868-0			
16	Retinyl palmitate	0.2775	0.5	79-81-2	201-228-5	Skin conditioning	DSM	Vitamin A Palmitate 1.0 MIU/g (stabilized with tocopherol)
	Caprylic/Capric Triglyceride	0.005		73398-61-5	277-452-2			
	Tocopherol	0.2175		10191-41-0	240-747-1			
17	Xanthan Gum	0.3	0.3	11138-66-2	234-394-2	Binding/ Emulsifying/ Skin Conditioning/ Viscosity Controlling	CP Kelco (Tranarc)	Keltrol TF
18	Tocopheryl Acetate	0.2	0.2	7695-91-2 58-95-7	231-710-0 200-405-4	Antioxidant/ Skin Conditioning	DSM Nutritional	DL-Alpha-Tocopherol

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
							Products	
19	Aqua (Water)	52.5	52.5	7732-18-5	231-791-2	Solvent	In-House	

not assigned

Ingredient order for the label: Aqua (Water), Triisononanoin, Rosa Canina Fruit Oil, PPG-3 Isostearyl Methyl Ether, Cetearyl Alcohol, Tocopheryl Acetate, Caprylyl Methicone, Lactococcus Ferment Lysate, Butyrospermum Parkii Butter, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Ceteareth- 20, Phenoxyethanol, Panthenol, Caprylyl Glycol, Triethanolamine, Maltodextrin, Xanthan Gum, Retinyl palmitate, Tocopherol, Voandzeia Subterranea Seed Extract, Lactic Acid, Sodium Benzoate, Pantolactone, Sodium Chloride, Caprylic/Capric Triglyceride, Diethanolamine, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate.

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 Epi- Genes Xpress 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 emulsion
3 organoleptic properties (colour, odour, whenever relevant)	Off white, characteristic odour
4 pH (at 25°C)	5.94
5 viscosity (at 25°C)	58720 cPs
6 thermal stability (glass bottle)	50 °C for 8 weeks
7 Specific gravity	0.946 g/ml

Stability of the product

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

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass bottles has confirmed stability at 50°C for 8 weeks. The emulsion broke down and began to separate in samples stored at 50°C for 12 weeks.

A.3 Microbiological Quality

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

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

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

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

The WSZ airless pump bottle body is made from acrylonitrile-styrene resin (SAN) with a polyethylene liner. The pump is polypropylene. The components of the packaging material and suitability of use criteria are included in a certificate in Appendix 4. This is maintained electronically with the PIF by the Responsible Person and is available on request.

A.5 Normal and reasonably foreseeable use

Zone Epi- Genes Xpress is a product designed to help maintain a good bacterial balance on the skin whilst stimulating epidermal renewal and to make the skin appear smoother, thicker and more youthful. It is a leave-on product that in normal circumstances will be used up to 2 times daily on the face and neck.

A.6 Exposure to the Cosmetic Product

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

A.7 Exposure to the Substances

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

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Triisononanoic acid 56554-53-1	7	16.67	1	1.17
Rosa Canina Fruit Oil 84603-93-0	5	16.67	1	0.83
Cetearyl Alcohol 67762-27-0	3.5	16.67	1	0.58
Tocopheryl Acetate 7695-91-2	3.2	16.67	1	0.53
Caprylyl Methicone 17955-88-3	3	16.67	1	0.50
Lactococcus Ferment Lysate #	2.9505	16.67	1	0.49
PPG-3 Isostearyl Methyl Ether 1429060-56-9	3.999	16.67	1	0.67
Butyrospermum Parkii Butter 194043-92-0 - 91080-23-8	2	16.67	1	0.33
Glycerin 56-81-5	2	16.67	1	0.33
Glyceryl Stearate 31566-31-1	2	16.67	1	0.33
PEG-100 Stearate 9004-99-3	2	16.67	1	0.33
Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate 6683-19-8	0.001	16.67	1	0.0002
Ceteareth- 20 68439-49-6	1.5	16.67	1	0.25
Phenoxyethanol 122-99-6	0.975	16.67	1	0.16
Panthenol 81-13-0	0.75	16.67	1	0.13
Caprylyl Glycol 1117-86-8	0.525	16.67	1	0.09
Triethanolamine 102-71-6	0.4975	16.67	1	0.08

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Maltodextrin 9050-36-6	0.4	16.67	1	0.07
Xanthan Gum 11138-66-2	0.3	16.67	1	0.05
Retinyl palmitate 79-81-2	0.2775	16.67	1	0.05
Tocopherol 10191-41-0	0.2175	16.67	1	0.04
Voandzeia Subterranea Seed Extract #	0.1	16.67	1	0.0167
Lactic Acid 50-21-5	0.03	16.67	1	0.0050
Sodium Benzoate 532-32-1	0.0105	16.67	1	0.0018
Pantolactone 599-04-2	0.01	16.67	1	0.0017
Sodium Chloride 7647-14-5	0.009	16.67	1	0.0015
Caprylic/Capric Triglyceride 73398-61-5	0.005	16.67	1	0.0008
Diethanolamine 111-42-2	0.0025	16.67	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.

A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Trisononanoin 56554-53-1	A	2014 CIR Compendium, safe for use in cosmetics with no restrictions for rinse-off or leave-on products. Low dermal absorption but may enhance the penetration of other chemicals. This has been taken into consideration and it has been determined that enhanced absorption of any of the other ingredients in this product would not significantly change the safety assessment of the product.								
Rosa Canina Fruit Oil 84603-93-0	A	2014 CIR Compendium, safe up to 19%, Final report 03/2013 (CIR)								
Cetearyl Alcohol 67762-27-0	A	2014 CIR compendium, safe at use up to 25% JACT 7(3):359-413, 1988 confirmed 12/05								
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 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.								
Lactococcus Ferment Lysate #	#	Lactococcus is a well-established genus of micro-organism used to produce commonly consumed foods e.g cheese. Intentionally used in food, bacteria removed (ferment lysate). GRAS.								
PPG-3 Isostearyl Methyl Ether 1429060-56-9	## ¹	Read across to PPG ethers: 2014 CIR Compendium, safe as used when PPG \geq 3, when formulated to be non-irritating, Final Report on Safety Assessment of Alkyl PEG/PPG ethers as Used in Cosmetics, 10/2014=3, CIR Compendium, 2014.								
Butyrospermum Parkii Butter 194043-92-0 - 91080-23-8	A	Safe when used up to 60% , Final report 03/11 CIR Compendium, 2014								
Glycerin 56-81-5	#	GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin								
Glyceryl Stearate 31566-31-1	A	Safe up to 50%; JACT 1(4), 169-192, 1982								
PEG-100 Stearate 9004-99-3	A	2014 CIR Compendium, safe for use up to 6%; International Journal of Toxicology 24 (S1): 1-102, 2005								
Pentaerythrityl Tetra-Di-T- Butyl	A	2014 CIR Compendium, safe for use up to 0.8%, Final Report 03/2014								

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Hydroxyhydrocinnamate 6683-19-8										
Ceteareth- 20 68439-49-6	B	Safe when formulated to be non-irritating; 2014 CIR Compendium, Final Report 12/10 (CIR); International Journal of Toxicology 18(S3), 41-49, 1999 and International Journal of Toxicology 31 (S2), 169-244, 2012								
Phenoxyethanol 122-99-6	A	2014 CIR Compendium safe up to 1%, JACT 9(2):259-77, 1990								
Panthenol 81-13-0	A	Safe up to 25%, JAQCT 6(1): 139-62, 2006								
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								
Triethanolamine 102-71-6	A	Cosing Annex III/62, limit of inclusion 2.5%, not to contain more than 0.5% secondary amine. Not to be used with nitrosating systems or use inhibitors. Formulation contains an inhibitor – tocopherol.								
Maltodextrin 9050-36-6	A	Polysaccharide, food additive, GRAS by the FDA.								
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								
Retinyl palmitate 79-81-2	A	Safe up to 5%; JACT, 6(3), 279-320, 1987; confirmed 06/06								
Tocopherol 10191-41-0	A	Safe when used up to 1%; IJT 21(S3):51-116, 2002; Final report 03/2014 CIR Compendium, 2014								
Voandzeia Subterranea Seed Extract #	#	Food item, seeds are used for food and beverages due to high protein content. Used medicinally for digestive system applications. No toxicity expected when applied dermally. http://ecocrop.fao.org/ecocrop/srv/en/dataSheet?id=10830								
Lactic Acid 50-21-5	B	2014 CIR compendium, αHAs included at 0.03% - 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 Safe use in this product is supported by human usage information (see section A.10 and B.1)								
Sodium Benzoate 532-32-1	A	2014 CIR Compendium, safe for use up to 1%, IJT 20(S3):23-50, 2001								
Pantolactone 599-04-2	-	Toxtree v.2.6.13	Unknown	No alerts	No alerts	No data	Toxic hazard,	0.037	-	No data

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
							low (Class I by Cramer rules, with extension)			
Sodium Chloride 7647-14-5	#									
Caprylic/Capric Triglyceride 73398-61-5	A									
Diethanolamine 111-42-2	A									

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

^b all possible routes of exposure should be considered

^c A MoS of greater than 100 is considered to represent safe use

Food item, hazard and exposure data not required.

##¹ other; read-across to information on related substances

Fragrances:

Zone Epi-Genes Xpress 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 Epi-Genes Xpress was released in 2016. Over the period June 2016 to August 2016 1160 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 Epi-Genes Xpress will cause damage to human health when used as directed.

It is therefore concluded that Zone Epi-Genes Xpress can be placed on the market in the EU as a product to help maintain a good bacterial balance on the skin whilst stimulating epidermal renewal and to make the skin appear smoother, thicker and more youthful.

Review of human data on the product

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

B.2 Label Warnings and Instructions for Use

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

AM and/or PM: Cleanse with RegimA. Apply RegimA eye products and serums. Apply 2 pump depressions of Epi-Genes Xpress to face and neck. Follow with appropriate RegimA day or night home care.

Based on a review of the ingredients in this formulation, no label warnings are required.

B.3 Reasoning

This product contains many ingredients with a positive reputation for properties to stimulate epidermal renewal and to make the skin appear smoother, thicker and more youthful 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 an eye cream.

List of References

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

METHOD OF MANUFACTURE / GMP CERTIFICATION



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

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 Eye Opener Serum

Prepared: August 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 Eye Opener Serum

Product type	Serum to make the signs of ageing less pronounced
Form	Lotion
Colour	Light brown
Pack size	15 mL
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	RVE003
Normal use	Leave-on eye serum

Pictures of the Item: On following page

Container label



NO PRINT AREA

IT - ITALIANO: Cura per il Contorno Occhi • Tutti i Tipi di Pelle • Da non applicarsi su pelli danneggiate o sensive • Contenitore sottovuoto - NON rimuovere la chiusura superiore in quanto si potrebbero introdurre aria e/o batteri

ES - ESPAÑOL: Cuidado de los ojos • Todo tipo de pieles • No aplicar sobre esquís dañados / roto • Contenedor al vacío - No se puede quitar la parte superior ya que esto dejaría que el aire y/o las bacterias entrasen

PT - PORTUGUÊS: Cuidados de Olhos • Todos Os Tipos De Pele • Não se aplicam a danos / skin quebrado • Airless Container - NÃO remova a parte superior, pois isso iria intoduzir ar/e ou bactérias

RU - РУССКИЙ: Уход за кожей вокруг глаз • Для всех типов кожи • Не наносить на поврежденную / сломанной лыжи • Герметичный контейнер - НЕ удалять верхнюю часть, так как это спровоцирует попадание воздуха и/или бактерий

TR - TÜRK: Göz Bakımı • Tüm Ciltler Tipleri • hasarı cilt için değildir • Havasız Kutu - İçine hava ve/veya bakteri gireceğinden üst kapağı kapatmayınız

PL - POLSKI: Pielegnacja okolicy oczu • Wszystkie typy skór • Nie należy stosować na skórze uszkodzonej • Pojemnik z dozownikiem - NIE odkręcać górnego nasady gdyż mogłoby to wprowadzić powietrze i lub bakterie

LT - LIETUVOS: Akčių priežiūra • Visiems odos tipams • Netepkite ant pažeistos / ištrukusios odos • Beis buteliukas su dozatoriumi - NEATSUKITE dozatoriaus, nes galėtų patekti oras ir/arba bakterijos

DA - DANSK: Øjen-pleje • Alle hudtyper • Prøv ikke på beskadiget/ødelagt hud • Luftfri beholder - Aben IKKE toppen, da det vil lukke luft og/eller bakterier ind

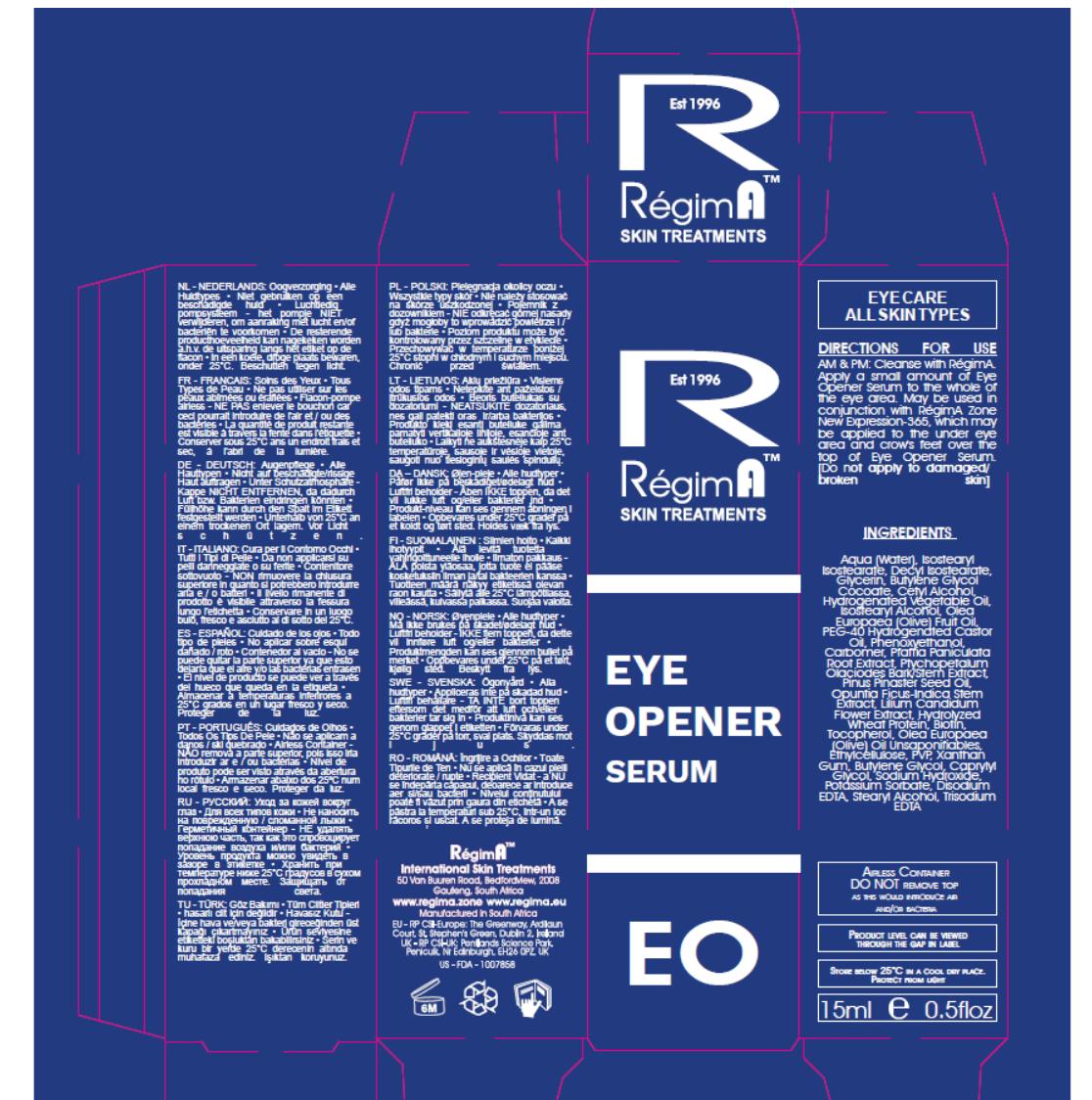
FI-SUOMALAINEN : Silmien hoito • Kaikki ihotyyppit • Älä levitä tuotetta vahingoittuneelle iholle • Ilman pakkaus - Älä poista yläosa, jotta tuote ei pääse kosketuksiin ilman ja/tai bakterien kanssa

NO - NORSK: Øyenpleie • Alle hudtyper • Må ikke brukes på skadet/ødelagt hud • Luftfri beholder - IKKE fjern toppen, da dette vil innføre luft og/eller bakterier

SWE - SVENSKA: Ögonvård • Alla hudtyper • Använd inte på skadad hud • Luftfri behållare - TA INTE bort toppen eftersom det medför att luft och/eller bakterier tar sig in

RO - ROMÂNĂ: Îngrijire a Ochilor • Toate Tipurile de Ten • Nu se aplică în cazul pielii deteriorate / rupte • Recipient Vidat - nu se îndepărta capacul, deoarece ar introduce aer și/sau bacterii

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 make the signs of ageing less pronounced.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Zone Eye Opener Serum base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Aqua (Water)	8.50605	10	7732-18-5	231-791-2	Skin Conditioning/ Skin Protecting	Sederma (Croda Chemicals)	Skin Tightener ST
	Glycerin	0.5		56-81-5	200-289-5			
	Pinus Pinaster Seed Oil	0.4		999999-99-4	310-127-6			
	Hydrolyzed Wheat Protein	0.25		94350-06-8	305-225-0			
	PVP	0.2		9003-39-8	#			
	Phenoxyethanol	0.13		122-99-6	204-589-7			
	Potassium Sorbate	0.013		24634-61-5	246-376-1			
				590-00-1				
	Trisodium EDTA	0.00075		150-38-9	205-758-8			
	Biotin	0.0002		58-85-5	200-399-3			
2	Decyl Isostearate	4	8	84605-08-3	283-388-6	Emollient/ Skin Conditioning	Crodamol SSA	Croda Chemicals
	Isostearyl Isostearate	4		41669-30-1	255-485-3			
3	Isostearyl Isostearate	7	7	41669-30-1	255-485-3	Binding/ Skin Conditioning/ Emollient	Croda Chemicals	Crodamol ISIS
4	Isostearyl Alcohol	2.706	6	27458-93-1	248-470-8	Emollient/ Skin Conditioning/ Viscosity Controlling/ Binding	Gattfossé (Incosmetics)	Emulfree CBG
	Butylene Glycol Cocoate	3		73138-39-3	277-288-1			
	Ethylcellulose	0.294		9004-57-3	#			
5	Aqua (Water)	0	5	7732-18-5	231-791-2	Skin Conditioning/ Viscosity Controlling/ Emulsifying	Chemyunion (C-Tec)	Bioskinup Contour
	Butylene Glycol	0.84		107-88-0	203-529-7			
	PEG-40 Hydrogenated Castor Oil	1.5		61788-85-0	#			
	Pfaffia Paniculata Root Extract	1		999999-99-4	310-127-6			
	Ptychopetalum Olacioides Bark/Stem Extract	1		84929-46-4	284-529-4			
	Lilium Candidum Flower Extract	0.575		84776-67-0	283-996-1			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Phenoxyethanol	0.04		122-99-6	204-589-7			
	Potassium Sorbate	0.025		24634-61-5	246-376-1			
	Disodium EDTA	0.02		139-33-3	205-358-3			
6	Hydrogenated Vegetable Oil	2.75	5	68334-28-1	269-820-6	Skin Conditioning/ Emollient	(Marcel) Millchem	Oliwax
	Olea Europaea (Olive) Fruit Oil	1.75		8001-25-0	232-277-0			
	Olea Europaea (Olive) Oil Unsaponifiables	0.5		8001-25-0	232-277-0			
7	Cetyl Alcohol	2.97	3	36653-82-4	253-149-0	Emulsifying/ Viscosity Controlling	Godrej Industries Limited	Ginol 16
	Stearyl Alcohol	0.03		253-149-0	36653-82-4			
8	Opuntia Ficus-Indica Stem Extract	0.0495	2	90082-21-6	290-109-1	Skin Conditioning/ Skin Protecting	Mibelle Biochemistry (Carst & Walker)	AquaCacteen
	Glycerin	0.99		56-81-5	200-289-5			
	Phenoxyethanol	0.02		122-99-6	204-589-7			
	Aqua (Water)	0.9405		7732-18-5	231-791-2			
9	Glycerin	2	2	56-81-5	200-289-5	Humectant/ Skin Protecting	Various	Glycerine
10	Phenoxyethanol	0.975	1.5	122-99-6	204-589-7	Preservative/Emmolient	Thor (Actichem)	Microcare PHG
	Caprylyl Glycol	0.525		1117-86-8	214-254-7			
11	Carbomer	1	1	9007-20-9 9003-01-4 76050-42-5 9062-04-8 9007-16-3 9007-17-4	#	Emulsion Stabilising/ Viscosity Controlling	Lubrizol (Caarst & Walker)	Carbopol ETD 2050
12	Aqua (Water)	0.4	0.5	231-791-2	231-791-2	Buffering/ Denaturant	Various	Sodium Hydroxide Solution
	Sodium Hydroxide	0.1		1310-73-2	215-185-5			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
								20% in Water
13	Xanthan Gum	0.3	0.3	11138-66-2	234-394-2	Binding/ Emulsifying/ Viscosity Controlling	Jungbunzlauer	Xanthan Gum
14	Tocopherol	0.1	0.1	10191-41-0	200-201-5	Antioxidant/ Skin Conditioning	DSM Nutritional Products	DL-Alpha Tocopherol
15	Aqua (Water)	48.6	48.6	7732-18-5	231-791-2	Solvent	In House	Deionised Water

not assigned

Ingredient order for the label: Aqua (Water), Isostearyl Isostearate, Decyl Isostearate, Glycerin, Butylene Glycol Cocoate, Cetyl Alcohol, Hydrogenated Vegetable Oil, Isostearyl Alcohol, Olea Europaea (Olive) Fruit Oil, PEG-40 Hydrogenated Castor Oil, Phenoxyethanol, Carbomer, Pfaffia Paniculata Root Extract, Ptychopetalum Olaciodes Bark/Stem Extract, **Butylene Glycol, Lilium Candidum Flower Extract, Caprylyl Glycol, Olea Europaea (Olive) Oil Unsaponifiables, Pinus Pinaster Seed Oil, Xanthan Gum, Ethylcellulose, Hydrolyzed Wheat Protein, PVP, Sodium Hydroxide, Tocopherol, Opuntia Ficus-Indica Stem Extract, Potassium Sorbate, Stearyl Alcohol, Disodium EDTA, Trisodium EDTA, 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 Eye Opener 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	Lotion
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	o/w emulsions
3 organoleptic properties (colour, odour, whenever relevant)	Light brown lotion with a characteristic odour
4 pH (at 25°C)	5.69
5 viscosity (at 25°C)	17200 cPs
6 thermal stability (glass bottle)	Stable at 50°C for 12 weeks
7 Specific gravity (at 25°C)	0.967 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 with all test conditions over the 12 weeks, however this was not considered to affect the safety or use of the product over the assigned shelf-life.

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 Eye Opener Serum is a product designed to make the signs of ageing less pronounced. It is a leave-on product that in normal circumstances will be used twice daily to the whole eye area.

A.6 Exposure to the Cosmetic Product

Site of application	Whole eye area
Surface area of application (cm ²)	141.25 cm ² (this is a conservative estimate based on 25% of the surface area of the face (565cm ²))
Volume of product applied (ml)	0.25ml (1 pump depression)
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)	0.5 ml exposure daily Estimated exposure based on 60 kg adult = 8.34
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 [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Isostearyl Isostearate 41669-30-1	11	8.34	1	0.92
Decyl Isostearate 84605-08-3	4	8.34	1	0.33
Glycerin 56-81-5	3.49	8.34	1	0.29
Butylene Glycol Cocoate 73138-39-3	3	8.34	1	0.25
Cetyl Alcohol 36653-82-4 253-149-0	2.97	8.34	1	0.25
Hydrogenated Vegetable Oil 68334-28-1	2.75	8.34	1	0.23
Isostearyl Alcohol 27458-93-1	2.706	8.34	1	0.23
Olea Europaea (Olive) Fruit Oil 8001-25-0	1.75	8.34	1	0.15
PEG-40 Hydrogenated Castor Oil 61788-85-0	1.5	8.34	1	0.13
Phenoxyethanol 122-99-6	1.165	8.34	1	0.10
Carbomer 9007-20-9	1	8.34	1	0.08
Pfaffia Paniculata Root Extract 999999-99-4	1	8.34	1	0.08
Ptychopetalum Olaciodes Bark/Stem Extract 84929-46-4	1	8.34	1	0.08
Butylene Glycol 107-88-0	0.84	8.34	1	0.07
Lilium Candidum Flower Extract 84776-67-0	0.575	8.34	1	0.05
Caprylyl Glycol 1117-86-8	0.525	8.34	1	0.04
Olea Europaea (Olive) Oil Unsaponifiables 8001-25-0	0.5	8.34	1	0.04
Pinus Pinaster Seed Oil 999999-99-4	0.4	8.34	1	0.03
Xanthan Gum 11138-66-2	0.3	8.34	1	0.03
Ethylcellulose 9004-57-3	0.294	8.34	1	0.02
Hydrolyzed Wheat Protein 94350-06-8	0.25	8.34	1	0.02

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
PVP 9003-39-8	0.2	8.34	1	0.02
Sodium Hydroxide 1310-73-2	0.1	8.34	1	0.0083
Tocopherol 10191-41-0	0.1	8.34	1	0.0083
Opuntia Ficus-Indica Stem Extract 90082-21-6	0.0495	8.34	1	0.0041
Potassium Sorbate 24634-61-5	0.038	8.34	1	0.0032
Disodium EDTA 139-33-3	0.02	8.34	1	0.0017
Stearyl Alcohol 204-017-6	0.03	8.34	1	0.0025
Trisodium EDTA 150-38-9	0.00075	8.34	1	0.0001
Biotin 58-85-5	0.0002	8.34	1	0.00002

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 ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Isostearyl Isostearate 41669-30-1	A	2014 CIR Compendium, Safe (when formulated to be non-irritating), Final report 03/2013 (CIR)								
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								
Glycerin 56-81-5	A	Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin								
Butylene Glycol Cocoate 73138-39-3	A	2014 CIR Compendium, Safe for use up to 2%, IJT 30(S1):5S-16S, 2011								
Cetyl Alcohol 36653-82-4 253-149-0	A	2014 CIR Compendium, safe at use up to 50% , JACT 7(3):359-413, 1988 confirmed 12/05								
Hydrogenated Vegetable Oil 68334-28-1	A	2014 CIR Compendium, safe up to 60%, Final report 03/2011 (CIR)								
Isostearyl Alcohol 27458-93-1	A	2014 CIR Compendium, safe at use up to 50%, JACT 7(3):359-413, 1988 confirmed 12/05								
Olea Europaea (Olive) Fruit Oil 8001-25-0	A	2014 CIR Compendium safe up to 100%, Final report 03/2011 (CIR)								
PEG-40 Hydrogenated Castor Oil 61788-85-0	A	Safe (when formulated to be non-irritating), Amended safety assessment of PEGylated oils as used in cosmetics, CIR 2012								
Phenoxyethanol 122-99-6	B	2014 CIR Compendium safe up to 1%, JACT 9(2):259-77, 1990								
Carbomer 9007-20-9	A	Safe when used up to 2%, JACT 1(2)109-41, 1982 confirmed 11/02 IJT 22(S1):1-35, 2003								
Pfaffia Paniculata Root Extract 999999-99-4	##	Other; read-across to information on Pfaffia Paniculata root studies confirms predicted safe use at SED (see Appendix 4)								
Ptychopetalum Olacioides	## ¹	Other; read-across to information on Ptychopetalum Olacioides confirms predicted safe use at SED (see Appendix 4)								

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Bark/Stem Extract 84929-46-4										
Butylene Glycol 107-88-0	A									
Lilium Candidum Flower Extract 84776-67-0	## ²									
Caprylyl Glycol 1117-86-8	A									
Olea Europaea (Olive) Oil Unsaponifiables 8001-25-0	A									
Pinus Pinaster Seed Oil 999999-99-4	## ³									
Xanthan Gum 11138-66-2	A									
Ethylcellulose 9004-57-3	A									
Hydrolyzed Wheat Protein 94350-06-8	B									
PVP 9003-39-8	A									
Sodium Hydroxide 1310-73-2	B									
Tocopherol 10191-41-0	A									
Opuntia Ficus-Indica Stem Extract 90082-21-6	## ⁴									
Potassium Sorbate 24634-61-5	A									
Disodium EDTA	A									

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
139-33-3										
Stearyl Alcohol 204-017-6	A									2014 CIR Compendium, Safe for use up to 25%, JACT 4(5):1-29, 1985 confirmed 03/04 IJT 25(S2), 2006
Trisodium EDTA 150-38-9	A									2014 CIR Compendium, Safe for use at less than 1%
Biotin 58-85-5	A									Safe up to 1%, International Journal of Toxicology 20(S4), 1-12, 2001

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

^b all possible routes of exposure should be considered

^c A MoS of greater than 100 is considered to represent safe use

Food item, hazard and exposure data not required.

Other; read-across to information on Pfaffia Paniculata root studies confirms predicted safe use at SED (see Appendix 4)

##¹ Other; read-across to information on Ptychopetalum Olaciodes confirms predicted safe use at SED (see Appendix 4)

##² Other; read-across to information on the family, other products and commercial availability/uses confirms predicted safe use at SED (see Appendix 4)

##³ Other; read-across to information on clinical use of Pinus Pinaster confirms predicted safe use at SED (see Appendix 4)

##⁴ Other; read-across to information on in vivo studies of Opuntia Ficus-Indica extract and oil and the Opuntia family confirms predicted safe use at SED (see Appendix 4)

Fragrances:

Zone Eye Opener 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 Eye Opener Serum was released in August 2015. Over the period August 2015 to August 2016, 6747 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 Eye Opener Serum will cause damage to human health when used as directed.

It is therefore concluded that Zone Eye Opener Serum can be placed on the market in the EU as a leave-on eye 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

‘Do not apply to damaged/broken skin’

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

AM & PM: Cleanse with RégimA. Apply a small amount of Eye Opener Serum to the whole of the eye area. May be used in conjunction with RégimA Zone New Expression-365, which may be applied to the under eye area and crow's feet over the top of Eye Opener Serum.

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 an eye serum.

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, 9th Revision, 29 September 2015 (SCCS/1564/15)
European Commission database on cosmetic ingredients (CosIng)
<http://ec.europa.eu/consumers/cosmetics/cosing/>
Cosmetic ingredient review <http://www.cir-safety.org/>

METHOD OF MANUFACTURE / GMP CERTIFICATION



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

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

Daily Intelligent Sebum-Solver + β Beta-Endorphin Stimulator

Prepared: December 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: Daily Intelligent Sebum-Solver + β -Endorphin Stimulator

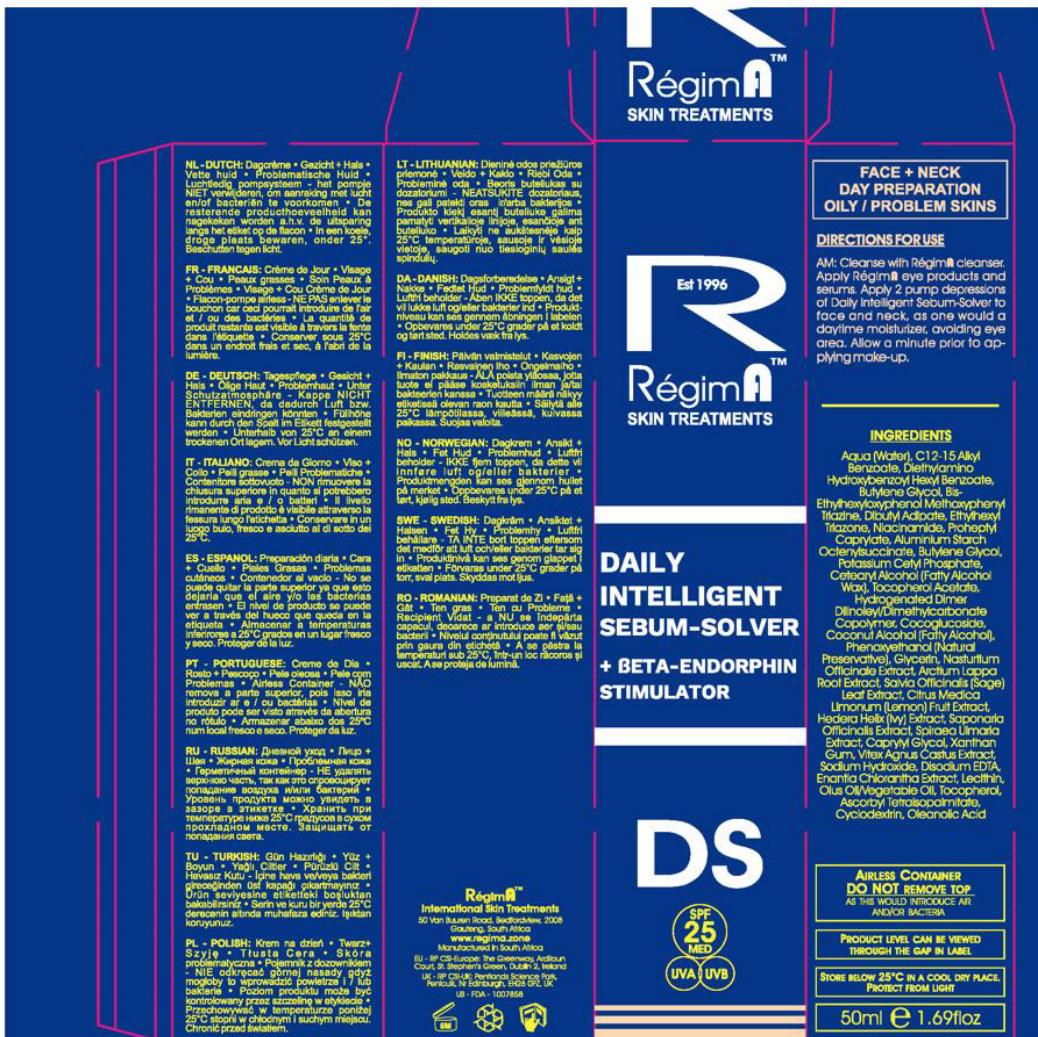
Product type	Oil control with sun protector
Form	Oil in water emulsion
Colour	Pale yellow
Pack size	15 and 50 mL
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	RUM 003
Normal use	Leave-on

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 oily and problematic skins, whilst providing protection 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:

Daily Intelligent Sebum-Solver + 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	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	Butylene Glycol	3.675	7	107-88-0	203-529-7	Solvent/ Skin Conditioning	Greentech (Natchem)	Phytelene Complex EGX 247 BG
	Water	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			
4	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	6	6	187393-00-6	425-950-7	UV Absorber/ UV Filter	BASF (Chemgrit)	Tinosorb S
5	Propylheptyl Caprylate	3	3	868839-23-0	#	Emollient	BASF (Chemgrit)	Cetiol Sensoft
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	Butylene Glycol	2.5	5	107-88-0	203-529-7	Skin Conditioning/	Silab	Sebonormine

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Aqua (Water)	2.3575		7732-18-5	231-791-2	Humectant/ Viscosity Controlling	(Meganede)	
	Spiraea Ulmaria Extract	0.1425		84775-57-5	283-886-3			
10	Butylene Glycol	2.8491	3	107-88-0	203-529-7	Skin Conditioning/ Humectant/ Viscosity Controlling	Sederma (Croda Chremicals)	Evermat
	Enantia Chlorantha Extract	0.15		#	#			
	Oleanolic Acid	0.0009		508-02-1	208-081-6			
11	Aluminium Starch Octenylsuccinate	2.58	3	9087-61-0	#	Absorbent/ Anticaking/ Viscosity Controlling	Akzo Nobel Beauty Care (IMCD)	Dry-Flo PC Starch
	Aqua (Water)	0.42		7732-18-5	231-791-2			
12	Cocoglucoside and Coconut Alcohol	2	2	68425-37-6	270-351-4	Emollient/ Emulsifying/ Emulsion Stabilising	Seppic (Sharon Bolel Chemical Marketing)	Montanov S
13	Potassium Cetyl Phosphate	2.5	2.5	84861-79-0 19035-79-1	284-374-2 242-768-	Emulsifying/ Surfactant	DSM Nutritional Products (Chempure)	Amphisol K
14	Cetearyl Alcohol	2	2	67762-27-0 005-44-5	267-008-6	Emollient/ Emulsifying/ Emulsion Stabilising	Croda Chemicals	Crodacol CS50
15	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
16	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			
	Ascorbyl Tetraisopalmitate	0.005		183476-82-6	#			
	Tocopherol	0.01		59-02-9	200-412-2			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Vegetable Oil	0.02		68956-68-3	273-313-5			
	Cyclodextrin	0.005		7585-39-9	231-493-2			
	Alcohol	0.34		64-17-5	200-578-6			
	Aqua (Water)	0.728		7732-18-5	231-791-2			
17	Butylene Glycol	2	2	107-88-0	203-529-7	Humectant/ Skin Conditioning	Various	Butylene Glycol
18	Hydrogenated Dimer Dilinoleyl/ Dimethylcarbonate Copolymer	2	2	436803-57-5	#	Water Resistance	BASF (Chemgrit)	Cosmedia DC
19	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			
20	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	0.35	0.35	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)	24.25	24.25	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

not assigned

Ingredient order for the label: Aqua (Water), Butylene Glycol, C12-15 Alkyl Benzoate, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Dibutyl Adipate, Ethylhexyl Triazone, Niacinamide, Propylheptyl Caprylate, Aluminium Starch Octenylsuccinate, Potassium Cetyl Phosphate, Cetearyl Alcohol, Cocogluscoside and Coconut Alcohol, Hydrogenated Dimer Dilinoleyl/ Dimethylcarbonate Copolymer, Tocopheryl Acetate, **Phenoxyethanol, Glycerin, Caprylyl Glycol, Xanthan Gum, Alcohol, Vitex Agnus Castus Extract, Disodium EDTA, Sodium Hydroxide, Enantia Chlorantha Extract, Spiraea**

Ulmaria Extract, Lecithin, Vegetable Oil, Citrus Limon (Lemon) Fruit Extract, Nasturtium Officinale Extract, Tocopherol, Ascorbyl Tetraisopalmitate, Cyclodextrin, Arctium Lapa Root Extract, Hedera Helix (Ivy) Extract, Salvia Officinalis (Sage) Leaf Extract, Saponaria Officinalis Extract, Oleanolic Acid.

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>

* Daily Intelligent Sebum-Solver + ßeta-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	Viscous emulsion
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Oil in water emulsion
3 organoleptic properties (colour, odour, whenever relevant)	Pale yellow with bland (fragrance free) odour
4 pH (at 25°C)	5.50
5 viscosity (at 25°C)	32,000 mPas
6 thermal stability (glass bottle)	Stable at 50°C for 12 weeks
7 Specific gravity	0.970

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 50°C for 12 weeks, with an increase in pH of 0.2 and a decrease in viscosity by 5000 mPas observed.

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/substance name 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

Daily Intelligent Sebum-Solver + Beta-Endorphin Stimulator is a product designed to help oily and problematic skins, 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.

A.6 Exposure to the Cosmetic Product

Site of application	Face and neck (avoiding the eye area)
Surface area of application (cm ²)	565 cm ² (not including neck as there are no standard values available for this)
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 [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Butylene Glycol 107-88-0	8.5	8.34	1	0.71
C12-15 Alkyl Benzoate 68411-27-8	8	8.34	1	0.67
Diethylamino Hydroxybenzoyl Hexyl Benzoate 302776-68-7	8	8.34	1	0.67
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine 187393-00-6	6	8.34	1	0.50
Dibutyl Adipate 105-99-7	5	8.34	1	0.42
Ethylhexyl Triazone 88122-99-0	5	8.34	1	0.42
Niacinamide 98-92-0	5	8.34	1	0.42
Propylheptyl Caprylate 868839-23-0	3	8.34	1	0.25
Aluminium Starch Octenylsuccinate 9087-61-0	2.58	8.34	1	0.2152
Potassium Cetyl Phosphate 84861-79-0	2.5	8.34	1	0.21
Cetearyl Alcohol 67762-27-0	2	8.34	1	0.17
Cocoglucoside and Coconut Alcohol 68425-37-6	2	8.34	1	0.17
Hydrogenated Dimer Dilinoleyl/ Dimethylcarbonate Copolymer 436803-57-5	2	8.34	1	0.17
Tocopheryl Acetate 7695-91-2	2	8.34	1	0.17
Phenoxyethanol 22-99-6	0.78	8.34	1	0.07
Glycerin 56-81-5	0.58	8.34	1	0.05

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Caprylyl Glycol 214-254-7	0.42	8.34	1	0.04
Xanthan Gum 11138-66-2	0.35	8.34	1	0.03
Alcohol 64-17-5	0.34	8.34	1	0.03
Vitex Agnus Castus Extract 91722-47-3	0.25	8.34	1	0.02
Disodium EDTA 139-33-3	0.2	8.34	1	0.02
Sodium Hydroxide 1310-73-2	0.2	8.34	1	0.02
Enantia Chlorantha Extract (no CAS number available)	0.15	8.34	1	0.01
Spiraea Ulmaria Extract 84775-57-5	0.1425	8.34	1	0.01
Lecithin 8002-43-5	0.062	8.34	1	0.01
Vegetable Oil 68956-68-3	0.02	8.34	1	0.002
Citrus Limon (Lemon) Fruit Extract 84929-31-7	0.01491	8.34	1	0.001
Nasturtium Officinale Extract 84775-70-2	0.01491	8.34	1	0.001
Tocopherol 59-02-9	0.01	8.34	1	0.001
Ascorbyl Tetraisopalmitate 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 84012-13-5	0.003045	8.34	1	0.0003
Hedera Helix (Ivy) Extract 84082-54-2	0.003045	8.34	1	0.0003
Salvia Officinalis (Sage) Leaf Extract 84082-79-1	0.003045	8.34	1	0.0003
Saponaria Officinalis Extract 84775-97-3	0.003045	8.34	1	0.0003
Oleanolic Acid 508-02-1	0.0009	8.34	1	0.0001

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

A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Referenc e for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoSC ^c	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 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
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. While niacinamide is present in this formulation at 5%, further reading of the discussions in the 2014 Compendium show the ingredient was negative for sensitization at 20% in guinea pigs, no stinging was observed at 10% and no irritancy at 5% in clinical trials. <u>In addition it is a GRAS food additive.</u>

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Referenc e for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoSC ^c	comment	
		The safety evaluation of the supplier has determined that the ingredient is safe for use up to 5% in sun-care formulations (see Appendix 4).									
Propylheptyl Caprylate 868839-23-0	-	-	Slightly irritatin g to rabbit eyes	Moderatel y irritating- however ingredient was applied neat (amount not specified) on 3 female SPF albino rabbits after a 4h semi- occlusive patch. Dermal application of 2000 mg/kg bw	Non-sensitize r (LLNA)	Non- irritant, 48h occlusive application with 50% propylhept yl (0.2ml test material applied)- no dermal effects.	≥1000 mg/mg bw/day	0.2502 mg'kg bw/da y	>300 0	Maximum concentratio n of use for a leave on product was 13% up to 2012. Not mutagenic with/without metabolic activation (Ames), not clastogenic (Chromosom e aberration test). Reference: Amended Safety Assessment of Alkyl Esters as Used in	

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
				(applied semi-occlusive and neat) had no reported irritation (Wistar rats)						Cosmetics, 03/2013.
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, Final Report 09/2014, Cosmetic Ingredient Review								
Cetearyl Alcohol 67762-27-0	A	2014 CIR Compendium, safe at use up to 25% JACT 7(3):359-413, 1988 confirmed 12/05								
Cocoglucoside and Coconut Alcohol 68425-37-6	A	Coconut Alcohol is safe for use up to 0.9%, IJT 30(S1): 5S-16S, 2011 and cocoglucoside is safe for use in cosmetics when formulated to be non-irritating, IJT 32 (S3): 22-48, 2013.								
Hydrogenated Dimer Dilinoleyl/ Dimethylcarbonate Copolymer 436803-57-5	## ¹	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%).								

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
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								
Phenoxyethanol 22-99-6	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								
Caprylyl Glycol 214-254-7	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								
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 Hydroxide 1310-73-2	B	Safe for restricted use according to CosIng Annex III/15a								

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Referenc e for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoSC ^c	comment
Spiraea Ulmaria Extract 84775-57-5	A									Old botanical name for Meadowsweet (<i>Filipendula ulmaria</i>). No experimental toxicity data available, in view of preclinical study results and long standing use without adverse reactions being reported, considered not to be harmful by the EMEA. http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_HMPC_assessment_report/2011/09/WC500115355.pdf Also, extracts have been found to be non-genotoxic at up to 80 mg/ml. https://www.ncbi.nlm.nih.gov/pubmed/26303017
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)
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.
Tocopherol 59-02-9	A									Safe when used up to 1%; IJT 21(S3):51-116, 2002; Final report 03/2014 CIR Compendium, 2014
Ascorbyl Tetraisopalmitate 183476-82-6	A									2014 CIR Compendium, safe for use up to 10%, International Journal of Toxicology, 24 (2): 51-111, 2005
Cyclodextrin	A									As a dietary supplement the total oral dose may reach 500 mg/day. Studies in human volunteers have

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoSC ^c	comment
7585-39-9			shown that cyclodextrins have a significant safety margin in dermal application, in which cyclodextrins in water or vaseline were applied on the skin for 24 hrs and their effects on cutaneous microcirculation were evaluated by laser Doppler velocimetry. Moreover, β-CD is proven not to induce either irritation or allergic contact dermatitis as evaluated by a repeated insult occlusive patch test in human volunteers; Background review for cyclodextrins used as excipients, EMA/CHMP/333892/2013, GRAS							
Arctium Lappa Root Extract 84012-13-5	## ¹		2014 CIR Compendium, Arctium Lappa Seed Oil is expected as safe for use in product categories and concentrations comparable to others in these groups. Assessment report on Arctium lappa L., radix, EMA/HMPC/246764/2009; a carcinogenicity study showed rats treated with a diet containing 33% of roots of Arctium lappa L. for 120 days had no tumours detected in any animal. Other in vivo focused on other parts of the plant, however the available data does not point to any serious concern with respect to safety. Preparations of Arctium lappa root can be considered as safe.							
Hedera Helix (Ivy) Extract 84082-54-2	A		Used as oral medicinal use as expectorant. GRAS for topical use with warning regarding discontinue use if irritation or itching occurs. http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_HMPC_assessment_report/2012/01/WC500120648.pdf							
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.							
Aluminium Starch	B		2014 CIR Compendium, safe as used provided that established limitations imposed on heavy metal							

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Octenylsuccinate 9087-61-0										concentrations are not exceeded, International Journal of Toxicology 21 (S1): 1-7, 2002.
Enantia Chlorantha Extract (no CAS number available)	C									Enantia chlorantha extract has been deemed safe for oral ingestion at doses below 1000 mg/kg in rats. The SED for the extract in this formulation is 0.01 mg/kg bw/day (100,000 times less than the safe oral dose) and thus is not expected to induce toxicity when applied dermally. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3967441/
Oleanolic Acid 508-02-1	##1									Oleanolic acid is a triterpene which naturally occurs in olive fruit oil and leaves. Olive oil is a food item. As there is no toxicology information available for Oleanolic acid in the public domain, read across to Olea Europaea (Olive) Fruit Oil is applicable (safe for use up to 100%, 2014 CIR Compendium). http://www.centerchem.com/Products/DownloadFile.aspx?FileID=6648

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

^b all possible routes of exposure should be considered

^c A MoS of greater than 100 is considered to represent safe use

Food item, hazard and exposure data not required.

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

Fragrances:

Daily Intelligent Sebum-Solver + 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

Daily Intelligent Sebum-Solver + βeta-Endorphin Stimulator was released in 2016. Over the period 22 June 2016 to 30 September 2016, 1936 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 Daily Intelligent Sebum-Solver + β -Endorphin Stimulator will cause damage to human health when used as directed.

It is therefore concluded that Daily Intelligent Sebum-Solver + β -Endorphin Stimulator can be placed on the market in the EU as a blend of plant extracts working synergistically to help oily and problematic skins, whilst providing protection from the drying, ageing effects of the sun.

Review of human data on the product

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

B.2 Label Warnings and Instructions for Use

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

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

Warnings: Discontinue use if irritation occurs.

B.3 Reasoning

This product contains many ingredients with a positive reputation for their properties which help oily and problematic skins, whilst providing protection from the drying, ageing effects of the sun, 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 an oil controller with sun protector.

A handwritten signature in black ink, reading "Shirley H", is placed over a yellow horizontal line. To the right of the signature is a vertical yellow line forming a corner.

List of References

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

METHOD OF MANUFACTURE / GMP CERTIFICATION



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

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*

RégimA

Laser Azu-Gel

Prepared: 23 June 2015
(Label and packaging update June 2021)

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

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INTRODUCTION

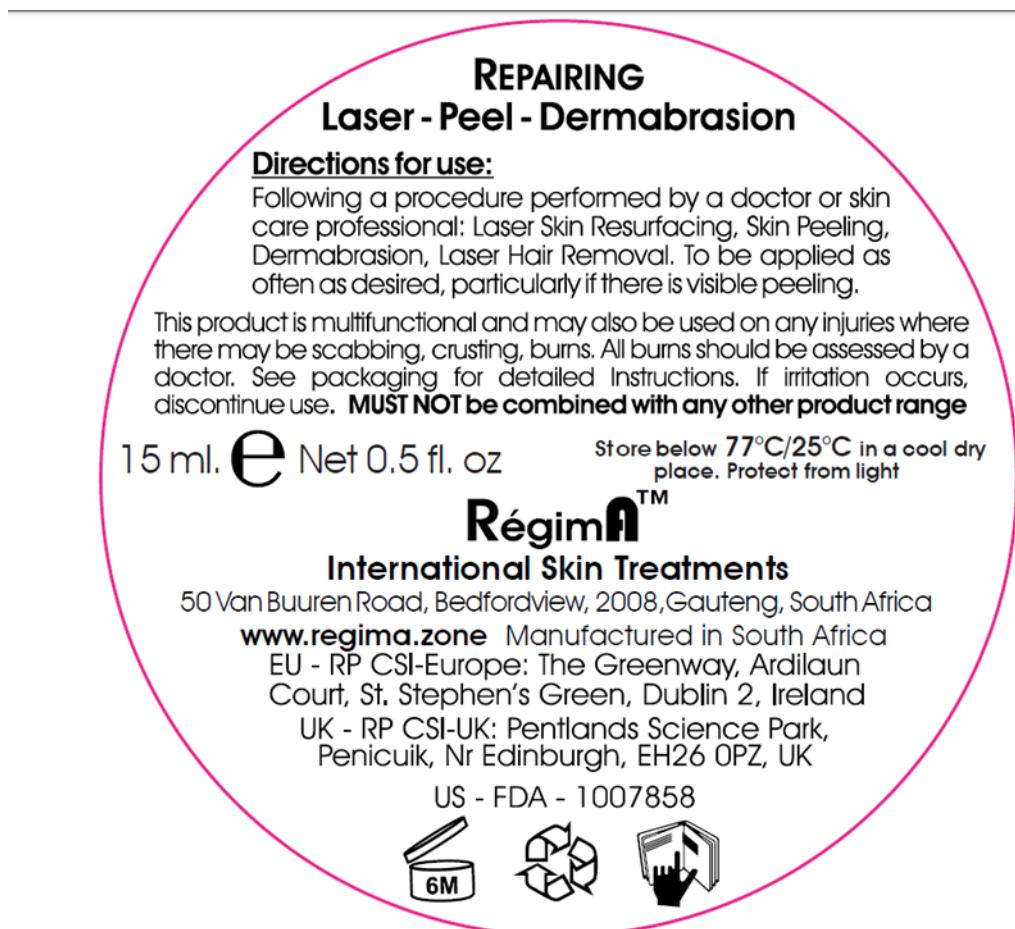
PRODUCT DESCRIPTION

Product Name:

Product type	Moisturising Post-Laser Gel
Form	Gel
Colour	Blue
Pack size	15 & 100 ml
Pack type	Jar
Dispenser type	Not applicable
Part of a set	No
Manufacturer code	PLGO002
Normal use	Frequent use, leave-on product

Pictures of the Item:

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 makes no direct or implied claims.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Laser Azu-Gel base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EINECS No.	Function	Supplier (Agent)	Tradename
1	Aqua	0.6	20.0	CAS: 7732-18-5	EINICS: 231-791-2	Skin conditioning	Alfa Chemicals (Carst & Walker)	Sucragel AOF
	Sucrose Laurate	1.4		CAS: 25339-99-5	EINICS: 246-873-3			
	Prunus Amygdalus Dulcis (Sweet Almond) Oil	7.0		CAS: 8007-69-0	EINICS: 273-313-5			
	Glycerine	11.0		CAS: 56-81-5	EINICS: 200-289-5			
2	Cocos Nucifera (Coconut) Oil	20.00	20.00	CAS: 8001-31-8	#	Skin conditioning	Lipo Chemicals	Lipovol C-76
3	Cera Alba (Beeswax)	8.00	8.00	CAS: 8012-89-3	EINICS: 232-383-7	Emollient	Kahl Wax (Savannah Fine Chemicals)	Kahlwax 8108
4	Persea Gratissima (Avocado) Oil	5.00	5.00	CAS: 8024-32-6	EINICS: 232-428-0	Skin conditioning	Textron Technica (Sharon Bolel Chemical Marketing)	Avocado Oil
5	Borago Officinalis Seed Oil	5.00	5.00	CAS: 84012-16-8 / 225234-12-8	EINICS: 281-661-4	Emollient	Textron Technica (Sharon Bolel Chemical Marketing)	Borage Oil
6	Macadamia Ternifolia Seed Oil	5.00	5.00	CAS: 128497-20-1, 129811-19-4	#	Emollient	Lipo Chemicals	Macadamia Nut Oil
7	Punica Granatum (Pomegranate) Seed Oil	5.00	5.00	CAS: 84961-57-9	EINICS: 284-646-0	Emollient	Augustus Oils	Pomegranate Oil
8	Tocopheryl Acetate	5.00	5.00	CAS: 7695-91-2	EINICS: 231-710-0	Antioxidant / Skin conditioning	DSM Nutritional Products (Chempure)	DL-Alpha-Tocopheryl Acetate
9	Silica Dimethyl Silylate	2.00	2.00	CAS: 68611-44-9	EINICS: 271-893-4	Anticaking / antifoaming / emollient / emulsion stabilizing / viscosity controlling	Evonik Degussa (Protea Speciality Chemicals)	Aerosil R 972

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EINECS No.	Function	Supplier (Agent)	Tradename
10	Bisabolol	0.200	0.200	CAS: 515-69-5	EINICS: 208-205-9	Masking / perfuming	Symrise	Dragosantol
	Farnesol	0.0002		CAS: 4602-84-0	EINICS: 225-004-1			
11	Guaiazulene	0.200	0.200	CAS: 489-84-9	EINICS: 207-701-2	Antimicrobial / perfuming	Symrise	Azulene Pure (659833)
12	Tocopherol	0.100	0.100	CAS: 10191-41-0, 54-28-4	EINICS: 233-466-0, 200-201-5	Antioxidant	DSM Nutritional Products (Chempure)	DL-Alpha-Tocopherol
13	Butyrospermum Parkii Butter (Shea Butter)	24.50	24.50	CAS: 68920-03-6, 194043-92-0	EINICS: 293-515-7	Skin conditioning	BASF (Chemgrits)	Cetiol SB 45

not assigned

Ingredient order for the label:

Butyrospermum Parkii (Shea Butter), Cocos Nucifera (Coconut) Oil, Glycerine, Cera Alba (Beeswax), Prunus Amygdalus Dulcis (Sweet Almond) Oil, Punica Granatum (Pomegranate) Seed Oil, Persea Gratissima (Avocado) Oil, Borago Officinalis Seed Oil, Tocopheryl Acetate, Macadamia Ternifolia Seed Oil, Silica Dimethyl Silylate, Sucrose Laurate, Aqua, **Guaiazulene, Bisabolol, Farnesol, Tocopherol**.

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

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

Fragrance allergens*

<i>INCI (EU) Name</i>	<i>CAS number</i>	<i>EC number</i>	<i>Concentration % w/w</i>
Farnesol	CAS: 4602-84-0	EINICS: 225-004-1	0.0002**

** below the level for reporting, included for completeness

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	Anhydrous Gel
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Paste
3 organoleptic properties (colour, odour, whenever relevant)	Blue with a characteristic odour
4 pH (at °C)	N/A due to the physical state of the product (anhydrous gel)
5 viscosity (at °C) for liquid forms	N/A due to the physical state of the product (anhydrous gel)
6 thermal stability (glass bottle)	Stable for 12 weeks at 50°C.
7 Specific gravity	0.93 to 0.95 g/ml

Stability of the product

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

Stability tests are currently ongoing to measure 6 month analyses up to 18 months at room temperature.

A.3 Microbiological Quality

Microbial contamination of the product is unlikely due to its anhydrous physical state. In addition, the ingredients Azulene (Guaiaculene) and Bisabolol present in the product have natural anti-microbial properties, and will exhibit some preservative action should the product become contaminated with water during storage after use.

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.

Laser Azu-Gel is packaged in 15 ml and 100 ml Poly Methyl Methacrylate (PMMA) jars (WO-15J and WO-100J respectively), with Acrylonitrile-Butadiene-Styrene (ABS) plastic lids. Both the jars and the lids are lined with polypropylene. The materials used comply with Directive 94/62/EC (heavy metal content). The packaging is approved for use with aqueous and oily products by the manufacturer and is considered suitable for cosmetic product packaging use.

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

Laser Azu-Gel is a moisturizing post-laser gel that will be used in normal circumstances frequently (up to 4 times daily) to help alleviate dry or flaky skin:

Directions for use:

Massage a small pea-sized drop (0.25 ml) of ‘the blue gel’ onto the skin as often as desired (up to 4 times daily) to help alleviate dry or flaky skin.

A.6 Exposure to the Cosmetic Product

Site of application	Face
Surface area of application (cm ²)	565 cm ²
Volume of product applied (ml)	0.25 ml (maximum)
Frequency of application/use per day	4
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	1 ml exposure daily Estimated exposure based on 60 kg adult = 16.67 mg/kg bw /day

Dermal absorption information	Unknown, assume 100%.
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 [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Sucrose Laurate	1.40	16.67	1	0.233
Prunus Amygdalus Dulcis (Sweet Almond) Oil	7.00	16.67	1	1.167
Glycerine	11.00	16.67	1	1.834
Cocos Nucifera (Coconut) Oil	20.00	16.67	1	3.334
Cera Alba (Beeswax)	8.00	16.67	1	1.334
Persea Gratissima (Avocado) Oil	5.00	16.67	1	0.834
Borago Officinalis Seed Oil	5.00	16.67	1	0.834
Macadamia Ternifolia Seed Oil	5.00	16.67	1	0.834
Punica Granatum (Pomegranate) Seed Oil	5.00	16.67	1	0.834
Tocopheryl Acetate	5.00	16.67	1	0.834
Silica Dimethyl Silylate	2.00	16.67	1	0.333
Bisabolol	0.200	16.67	1	0.033
Farnesol	0.0002	16.67	1	0.000
Guaiazulene	0.200	16.67	1	0.033
Tocopherol	0.100	16.67	1	0.017
Butyrospermum Parkii (Shea Butter)	24.50	16.67	1	4.084

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 ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Butyrospermum Parkii Butter (Shea Butter) (CAS 68920-03-6, 194043-92-0)	A	Safe when used up to 60% , Final report 03/11 CIR Compendium, 2014								
Cocos Nucifera (Coconut) Oil (CAS 8001-31-8)	A	Safe when used up to 80% (2011), JACT 5(3):103-21, 1986 (original report); IJT 30 (s1): 5s-16s, 2011; also included in the Plant Derived Fatty Acid Oils report 03/11								
Glycerine (CAS 56-81-5)	A	Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin								
Cera Alba (Beeswax) (CAS 8012-89-3)	A	Safe when used up to 56%, JACT 3(3):1-41, 1984 confirmed 06/03 IJT 24(S1):48-52, 2005								
Prunus Amygdalus Dulcis (Sweet Almond) Oil (CAS 8007-69-0)	A	Safe when used up to 76% , JACT 2(5):85-99, 1983 confirmed 11/02 IJT 24(S1):98-101, 2005								
Persea Gratissima (Avocado) Oil (CAS 8024-32-6)	A	Safe when used up to 98%, Final amended report 03/11 available from CIR; JEPT 4(4):93-103, 1980 (original) re-review IJT 22(S1):1-35, 2003								
Borago Officinalis Seed Oil (CAS 84012-16-8)	A	Safe when used up to 1%, Final report 03/11 CIR Compendium, 2014. The supplier has provided certificates to demonstrate purity and freedom from contaminants for their source of this oil and on this basis inclusion at 5% in this formulation is not considered to be hazardous to health when used as directed for a topical skin conditioner.								
Macadamia Ternifolia Seed Oil (CAS 128497-20-1, 129811-19-4)	A	Safe when used up to 30%, Final report 03/11 CIR Compendium, 2014								
Punica Granatum (Pomegranate) Seed Oil (CAS 84961-57-9)	A	Safe when used up to 1%, Final report 03/11 CIR Compendium, 2014. Source of this oil confirms food grade and GRAS, tested for heavy metal impurity, free from recognised food allergens. Increased use at 5% in this formulation is also considered acceptable however, higher usage concentrations may have potential for irritation and therefore a warning regarding irritation and discontinued is recommended.								
Tocopheryl Acetate (CAS 7695-91-2)	A	2014 CIR compendium, safe at use up to 36% (100% in Vitamin E oil) IJT 21(S3):51-116, 2002								
Silica Dimethyl Silylate (CAS 68611-44-9)	A	2014 CIR safe when formulated and delivered in the final product not to be irritating or sensitizing to the respiratory tract, IJT 32(S1):5-24, 2013								
Sucrose Laurate (CAS 25339-99-5)	A	Safe, GRAS, FDA approved food additive, non irritant to skin and eyes at usage concentration in cosmetics.								
Bisabolol (CAS 515-69-5)	A	Safe when used up to 1%; International Journal of Toxicology 18(S3); 33-40. 1999								
Farnesol	B	CosIng Annex III/82, restricted concentration must be listed when greater than 0.001% (Dermal sensitizer.). Current inclusion concentration is 0.0002%								

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
(CAS 4602-84-0)										
Guaiaculene (CAS 489-84-9)	A	FDA approved colour agent, 21 CFR section 73.2180. Source is free from heavy metal impurities.								
Tocopherol (CAS 10191-41-0)	A	Safe when used up to 1%; IJT 21(S3):51-116, 2002; Final report 03/2014 CIR Compendium, 2014								

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

^b all possible routes of exposure should be considered

^c A MoS of greater than 100 is considered to represent safe use

Fragrances:

The product 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 to moisturize skin up to 4 times daily.

A.10 Information on the Cosmetic Product

Laser Azu-Gel was released in 2014 and no adverse reactions have been reported from sale of more than 4000 units. There have been no adverse reactions reported to RégimA International Skin Treatments. The product insert carries the warning ‘if irritation occurs, discontinue use’ and it is not expected that Laser Azu-Gel will cause any tolerance problems on the market.

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 manufacturer

Safety information is available to support use of the majority of the ingredients. Where there is a potential for local tolerance issues then the label should have a warning regarding discontinuing use should irritation or redness occur.

It is not expected that Laser Azu-Gel will cause damage to human health. The product insert carries the warning ‘if irritation occurs, discontinue use’ and on this basis it may be assumed that consumers will stop using the product if local irritation occurs and that any possible irritation would be reversible after cessation of use. This is confirmed as RégimA International Skin Treatments have received no reports of adverse reactions following sales of at least 4000 units.

It is therefore concluded that Laser Azu- Gel can be placed on the market in the EU as a post-laser treatment skin moisturizing gel 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

Warnings – *'If irritation occurs, discontinue use'*

Directions for use are given on the product insert.

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 post-laser treatment moisturizing face gel.



List of References

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

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.

RégimA Skin Treatments

CK92/05371/23
VAT No. 4590131043

Tel: 011 615 2869 **or** 011 622 7827
Fax: 011 616 8008
Cell: 0836537020
e-mail: jax@regima.com

POSTAL ADDRESS: PO BOX 9523 Edenglen 1613

PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA

Animal Testing Compliance Statement

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

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

Appendix 1: Safety Data Sheets or Ingredient Specifications

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

Appendix 2: Microbial Challenge Test

Not applicable

Appendix 3: Certificates of Allergen Content

There are no fragrances in this product.

Appendix 4: Miscellaneous

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

PRODUCT INFORMATION FILE*

RegimA

Zone New Expression-365

Prepared: August 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 New Expression-365

Product type	Cream to help make the signs of ageing less pronounced
Form	Cream
Colour	Yellow
Pack size	20 mL
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	NE 31003
Normal use	Leave-on eye cream

Pictures of the Item: On following page

Container label

NL: Alle Huidtypes • Anti-Ageing Oogverzorging
FR: Tous Types de Peau • Antiâge Soins des Yeux
DE: Alle Hauttypen • Anti-Ageing Augenpflege
IT: Tutti i Tipi di Pelle • Anti-Età Cura per il Contorno Occhi
ES: Todo tipo de pieles • Antiedad Cuidado de los ojos
PT: Todos Os Tipos De Pele • Antienvelhecimento Cuidados de Olhos
RU: Для всех типов кожи • Противесохранный Уход за кожей вокруг глаз
TR: Tüm Ciltler Tipi • Yaşlanma Karşıtı Göz Bakımı
PL: Wszystkie typy skóry • Przedwczesnego starzenia oczu
LT: Visiems odos tipams • Senčiamo požymus mažinant priemonė
AKJ: prezura
DA: Alle hudtyper • Anlægning Øjenpleje
FI: Kalkkihuoltyper • Ikkäntymisen merkejä enkäsevä silmien huo
NO: Alle hudtyper • Aldringsmotvirrende Øyenpleie
SWE: Alla hudtyper • Antiyrkak Ogonvård
RO: Toate Tipurile de Ten • Anti-imbatranire Ingrijire a Ochilor

Régim™
International Skin Treatments
50 Van Buuren Road, Bedfordview, 2008
Gauteng, South Africa
www.regima.zone www.regima.eu
Manufactured In South Africa
EU - RP CS1-Europe: The Greenway, Ardilaun
Court, St. Stephen's Green, Dublin 2, Ireland
UK - RP CS1-UK: Pentlands Science Park,
Penicuik, Nr Edinburgh, EH26 0PZ, UK
US - FDA - 1007858

NEW

EXPRESSION-365

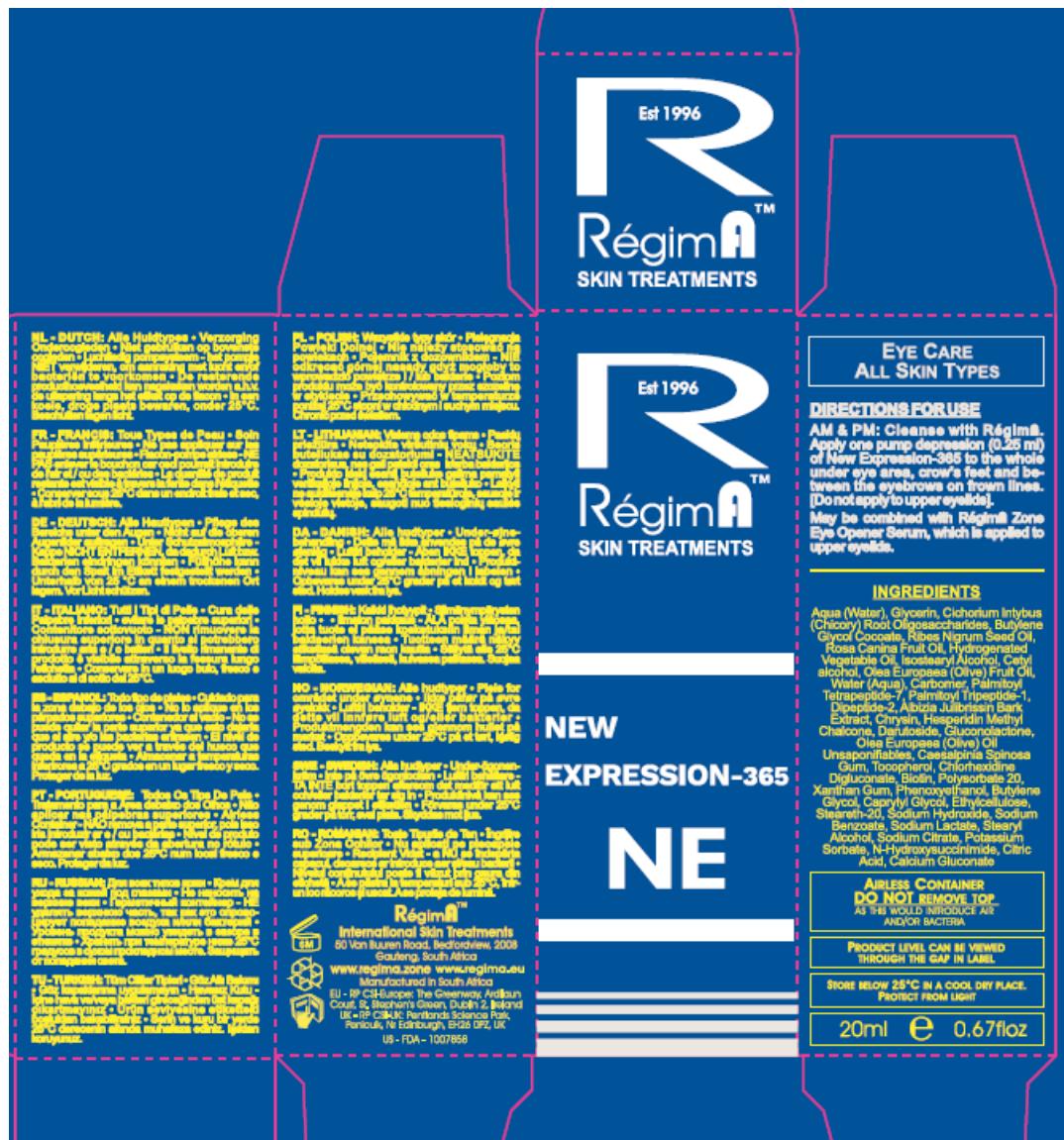
**ANTI-AGEING EYE CARE
ALL SKIN TYPES**

DIRECTIONS FOR USE
AM & PM: Cleanse with Régim™. Apply one pump depression (0.25 ml) of New Expression-365 to the whole under eye area, crow's feet and between the eyebrows on frown lines. [Do not apply to upper eyelids]. May be combined with Régim™ Zone Eye Opener Serum, which is applied to upper eyelids.

**STORE BELOW 25°C IN A COOL DRY PLACE.
PROTECT FROM LIGHT**

20ml e 0.67floz

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 make the signs of ageing less pronounced.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Zone New Expression-365 base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Cichorium Intybus (Chicory) Root Oligosaccharides	5.2	10	#	#	Skin Conditioning/ Skin Protecting	Provital (Savannah Fine Chemicals)	Ten's Up
	Aqua (Water)	2.0928		7732-18-5	231-791-2			
	Glycerin	2.5		56-81-5	200-289-5			
	Caesalpinia Spinosa Gum	0.1		39300-88-4	254-409-6			
	Sodium Benzoate	0.028		532-32-1	208-534-8			
	Gluconolactone	0.078		90-80-2	202-016-5			
	Calcium Gluconate	0.0012		299-28-5	206-075-8			
2	Isostearyl Alcohol	2.706	6	27458-93-1	248-470-8	Emollient/ Skin Conditioning/ Viscosity Controlling/ Binding	Gattfossé (Inc cosmetics)	Emulfree CBG
	Butylene Glycol Cocoate	3		73138-39-3	277-288-1			
	Ethylcellulose	0.294		9004-57-3	#			
3	Hydrogenated Vegetable Oil	2.75	5	68334-28-1	269-820-6	Skin Conditioning/ Emollient	(Marcel) Millichem	Oliwax
	Olea Europaea (Olive) Fruit Oil	1.75		8001-25-0	232-277-0			
	Olea Europaea (Olive) Oil Unsaponifiables	0.5		8001-25-0	232-277-0			
4	Ribes Nigrum Seed Oil	3	3	68606-81-5	271-749-0	Emollient		
5	Rosa Canina Fruit Oil	3	3	84696-47-9/ 84603-93-0	283-652-0	Emollient/ Skin Conditioning	Seatons (Croda)	Rose Hips Oil
6	Aqua (Water)	2.2806	3	7732-18-5	231-791-2	Skin Conditioning/ Cleansing/ Emulsifying/ Antioxidant/ Skin Protecting	Sederma (Croda Chemicals)	Eyeliss
	Glycerin	0.45		56-81-5	200-289-5			
	Hesperidin Methyl Chalcone	0.15		24292-52-2	246-128-2			
	Steareth-20	0.09		9005-00-9	#			
	Dipeptide-2	0.003		24587-37-9	#			
	Palmitoyl Tetrapeptide-7	0.0009		221227-05-0	#			
	Chlorhexidine Digluconate	0.006		18472-51-0	242-354-0			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
7	Potassium Sorbate	0.003		24634-61-5/ 590-00-1	246-376-1		Sederma (Croda Chemicals)	Beautifye
	Citric Acid	0.0015		77-92-9/ 5949-29-1	201-069-1			
	Sodium Citrate	0.015		68-04-2	6132-04-3			
8	Glycerin	2.184	3	56-81-5	200-289-5	Humectant/ Skin Protecting/ Skin Conditioning	Sederma (Croda Chemicals)	Matrixyl 3000
	Albizia Julibrissin Bark Extract	0.81		#	#			
	Darutoside	0.0015		59219-65-7	#			
	Sodium Benzoate	0.0045		532-32-1	208-534-8			
9	Glycerin	1.57455	3	56-81-5	200-289-5	Humectant/ Skin Protecting/ Skin Conditioning/ Emulsion Stabilising/ Emulsifying	Sederma (Croda Chemicals)	Matrixyl 3000
	Aqua (Water)	0.75		7732-18-5	231-791-2			
	Butylene Glycol	0.6		107-88-0	203-529-7			
	Carbomer	0.03		9003-01-4	#			
	Polysorbate 20	0.015		9005-64-5	#			
	Palmitoyl Tripeptide-1	0.0003		147732-56-7	#			
	Palmitoyl Tetrapeptide-7	0.00015		221227-05-0	#			
	Sodium Lactate	0.03		72-17-3/ 867-56-1	200-772-0/ 212-762-3			
	Aqua (Water)	1.59246	2	7732-18-5	231-791-2	Humectant/ Skin Protecting/ Cleansing/ Skin Conditioning/ Antimicrobial/ Antiseborrhoeic	Sederma (Croda Chemicals)	Haloxyl
	Glycerin	0.3		56-81-5	200-289-5			
	Steareth-20	0.08		9005-00-9	#			
	N-Hydroxysuccinimide	0.004		6066-82-6	228-001-3			
	Chrysin	0.0002		480-40-0	207-549-7			
	Palmitoyl Tripeptide-1	0.0002		147732-56-7	#			
	Palmitoyl Tetrapeptide-7	0.0001		221227-05-0	#			
	Chlorhexidine Digluconate	0.02		18472-51-0	242-354-0			
	Potassium Sorbate	0.002		24634-61-5 590-00-1	246-376-1			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Citric Acid	0.000001		77-92-9 5949-29-1	201-069-1			
	Sodium Citrate	0.001		68-04-2 6132-04-3	200-675-3			
	Biotin	0.00004		58-85-5	200-399-3			
10	Cetyl alcohol	1.98	2	36653-82-4	253-149-0	Emulsifying/ Viscosity Controlling	Godrej Industries Limited	Ginol 16
	Stearyl Alcohol	0.02		253-149-0	36653-82-4			
11	Glycerin	2	2	56-81-5	200-289-5	Humectant/ Skin Protecting	Various	Glycerine
12	Phenoxyethanol	0.975	1.5	122-99-6	204-589-7	Preservative/Emmolient	Thor (Actichem)	Microcare PHG
	Caprylyl Glycol	0.525		1117-86-8	214-254-7			
13	Carbomer	1	1	9007-20-9 9003-01-4 76050-42-5 9062-04-8 9007-16-3 9007-17-4	#	Emulsion Stabilising/ Viscosity Controlling	Lubrizol (Caarst & Walker)	Carbopol ETD 2050
14	Aqua (Water)	0.4	0.5	231-791-2	231-791-2	Buffering/ Denaturant	Various	Sodium Hydroxide Solution 20% in Water
	Sodium Hydroxide	0.1		1310-73-2	215-185-5			
15	Xanthan Gum	0.3	0.3	11138-66-2	234-394-2	Binding/ Emulsifying/ Viscosity Controlling	Jungbunzlauer	Xanthan Gum
16	Tocopherol	0.1	0.1	10191-41-0	200-201-5	Antioxidant/ Skin Conditioning	DSM Nutritional	DL-Alpha Tocopherol

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
							Products	
17	Aqua (Water)	54.6	54.6	7732-18-5	231-791-2	Solvent	In House	Deionised Water

not assigned

Ingredient order for the label: Aqua (Water), Glycerin, Cichorium Intybus (Chicory) Root Oligosaccharides, Butylene Glycol Cocoate, Ribes Nigrum Seed Oil, Rosa Canina Fruit Oil, Hydrogenated Vegetable Oil, Isostearyl Alcohol, Cetyl alcohol, Olea Europaea (Olive) Fruit Oil, Water (Aqua), Carbomer, **Phenoxyethanol, Albizia Julibrissin Bark Extract, Butylene Glycol, Caprylyl Glycol, Olea Europaea (Olive) Oil Unsaponifiables, Xanthan Gum, Ethylcellulose, Steareth-20, Hesperidin Methyl Chalcone, Caesalpinia Spinosa Gum, Sodium Hydroxide, Tocopherol, Gluconolactone, Sodium Benzoate, Sodium Lactate, Chlorhexidine Digluconate, Stearyl Alcohol, Sodium Citrate, Polysorbate 20, Potassium Sorbate, N-Hydroxysuccinimide, Dipeptide-2, Citric Acid, Darutoside, Calcium Gluconate, Palmitoyl Tetrapeptide-7, Palmitoyl Tripeptide-1, Chrysins, 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 New Expression-365 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 emulsion
3 organoleptic properties (colour, odour, whenever relevant)	Yellow cream with a characteristic odour
4 pH (at 25°C)	5.59
5 viscosity (at 25°C)	40000 cPs
6 thermal stability (glass bottle)	Stable at 50°C for 12 weeks
7 Specific gravity	0.988 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, with slightly increased viscosity and a stronger odour.

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 New Expression-365 is a product designed to help make the signs of ageing less pronounced. It is a leave-on product that in normal circumstances will be used twice daily on the under eye area, crow's feet and between the eyebrows on the frown lines.

A.6 Exposure to the Cosmetic Product

Site of application	Under eye area, crow's feet and between the eyebrows on the frown lines
Surface area of application (cm ²)	141.25 cm ² (this is a conservative estimate based on 25% of the surface area of the face (565cm ²)
Volume of product applied (ml)	0.25ml (1 pump depression)
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)	0.5 ml exposure daily Estimated exposure based on 60 kg adult = 8.34
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 [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Glycerin 56-81-5	9.0086	8.34	1	0.75
Cichorium Intybus (Chicory) Root Oligosaccharides #	5.2	8.34	1	0.43
Butylene Glycol Cocoate 73138-39-3	3	8.34	1	0.25
Ribes Nigrum Seed Oil 68606-81-5	3	8.34	1	0.25
Rosa Canina Fruit Oil 84696-47-9	3	8.34	1	0.25
Hydrogenated Vegetable Oil 68334-28-1	2.75	8.34	1	0.23
Isostearyl Alcohol 27458-93-1	2.706	8.34	1	0.23
Cetyl alcohol 36653-82-4	1.98	8.34	1	0.17
Olea Europaea (Olive) Fruit Oil 8001-25-0	1.75	8.34	1	0.15
Carbomer 9003-01-4	1.03	8.34	1	0.09
Phenoxyethanol 122-99-6	0.975	8.34	1	0.08
Albizia Julibrissin Bark Extract #	0.81	8.34	1	0.07
Butylene Glycol 107-88-0	0.6	8.34	1	0.05
Caprylyl Glycol 1117-86-8	0.525	8.34	1	0.04
Olea Europaea (Olive) Oil Unsaponifiables 8001-25-0	0.5	8.34	1	0.04
Xanthan Gum 11138-66-2	0.3	8.34	1	0.03

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Ethylcellulose 9004-57-3	0.294	8.34	1	0.02
Steareth-20 9005-00-9	0.17	8.34	1	0.01
Hesperidin Methyl Chalcone 24292-52-2	0.15	8.34	1	0.01
Caesalpinia Spinosa Gum 39300-88-4	0.1	8.34	1	0.01
Sodium Hydroxide 1310-73-2	0.1	8.34	1	0.01
Tocopherol 10191-41-0	0.1	8.34	1	0.0083
Gluconolactone 90-80-2	0.078	8.34	1	0.0065
Sodium Benzoate 532-32-1	0.0325	8.34	1	0.0027
Sodium Lactate 72-17-3	0.03	8.34	1	0.0025
Chlorhexidine Digluconate 18472-51-0	0.026	8.34	1	0.0022
Stearyl Alcohol 253-149-0	0.02	8.34	1	0.0017
Sodium Citrate 68-04-2	0.016	8.34	1	0.0013
Polysorbate 20 9005-64-5	0.015	8.34	1	0.00125
Potassium Sorbate 24634-61-5	0.005	8.34	1	0.00042
N-Hydroxysuccinimide 6066-82-6	0.004	8.34	1	0.00033
Dipeptide-2 24587-37-9	0.003	8.34	1	0.00025
Citric Acid 77-92-9	0.0015	8.34	1	0.00013
Darutoside 59219-65-7	0.0015	8.34	1	0.00013
Calcium Gluconate 299-28-5	0.0012	8.34	1	0.00010
Palmitoyl Tetrapeptide-7 221227-05-0	0.0012	8.34	1	0.00010

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Palmitoyl Tripeptide-1 147732-56-7	0.0005	8.34	1	0.00004
Chrysin 480-40-0	0.0002	8.34	1	0.00002
Biotin 58-85-5	0.00004	8.34	1	0.000003

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

A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Glycerin 56-81-5	A									
Cichorium Intybus Root Oligosaccharides #	B									
Butylene Glycol Cocoate 73138-39-3	B									
Ribes Nigrum Seed Oil 68606-81-5	A									
Rosa Canina Fruit Oil 84696-47-9	A									
Hydrogenated Vegetable Oil 68334-28-1	A									
Isostearyl Alcohol 27458-93-1	A									
Cetyl alcohol 36653-82-4	A									
Olea Europaea (Olive) Fruit Oil 8001-25-0	A									
Carbomer 9003-01-4	A									
Phenoxyethanol 122-99-6	B									
Albizia Julibrissin Bark Extract #	## ¹									
Butylene Glycol 107-88-0	A									
Caprylyl Glycol	A									

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
1117-86-8		(S2), 1475-1685, 2012								
Olea Europaea (Olive) Oil Unsaponifiables 8001-25-0	A	2014 CIR Compendium safe up to 3%, Final report 03/2011 (CIR)								
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								
Ethylcellulose 9004-57-3	A	2014 CIR Compendium, safe for use up to 4%, Amended safety assessment 03/09 (CIR)								
Steareth-20 9005-00-9	B	2014 CIR Compendium, safe for use in cosmetics when formulated to be non- irritating, International Journal of Toxicology 31(S2):169-244, 2012								
Hesperidin Methyl Chalcone 24292-52-2	## ¹	Read across to secondary sources of information. Typical dose is 500 mg orally with no reported side effects: SED in Zone New Expression- 365 is 833 time less than the recommended oral dose. No side effects expected when applied to the skin.								
Caesalpinia Spinosa Gum 39300-88-4	B	Safe for use in the present practices of use and concentration, Safety Assessment of Galactomannans as Used in Cosmetics, International Journal of Toxicology, 34(S 1) 355-655, 2015.								
Sodium Hydroxide 1310-73-2	B	Safe for restricted use according to CosIng Annex III/15a								
Tocopherol 10191-41-0	A	Safe when used up to 1%; IJT 21(S3):51-116, 2002; Final report 03/2014 CIR Compendium, 2014								
Gluconolactone 90-80-2	#	GRAS- EU approved food additive (E575): Toxicity following application to the skin when formulated to be non-irritating, is unlikely. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1130&from=EN								
Sodium Benzoate 532-32-1	A	2014 CIR Compendium, safe for use up to 1%, IJT 20(S3):23-50, 2001								
Sodium Lactate 72-17-3	B	Safe with restrictions: Glycolic and Lactic Acid, their common salts and their simple esters, are safe for use in cosmetic products at concentrations <=10%, at final formulation pH >=3.5, when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection. IJT 17(S1):1-242, 1998. Included in formulation at 0.09%.								
Chlorhexidine Digluconate 18472-51-0	A	2014 CIR Compendium, safe for use up to 0.20%, JACT 12(3):201-23, 1993 IJT 18(2):69, 1999 (Note)								
Stearyl Alcohol 253-149-0	A	2014 CIR Compendium, safe for use up to 25%, JACT 4(5): 1-29, 1985 confirmed 03/04 International Journal of Toxicology 25(S2), 2006								
Sodium Citrate 68-04-2	A	2014 CIR Compendium, safe for use up to 10%, IJT 33 (S2): 16-46, 2014								

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Polysorbate 20 9005-64-5	A	2014 CIR Compednium, safe for use >50%, JACT 3(5):1-82, 1984								
Potassium Sorbate 24634-61-5	A	2014 CIR Compendium safe up to 1%, JACT 7(6):837-80, 1988 confirmed 04/06								
N-Hydroxysuccinimide 6066-82-6	A	Classed as not expected to be potentially toxic or harmful and does not meet human health categorization criteria; Environment Canada Domestic Substance List. https://www.ec.gc.ca/lcpe-cepa/eng/subs_list/DSL/DSLsearch.cfm								
		In addition, N-Hydroxysuccinimide is used as an ingredient in surgical patches, over wounds and is an ingredient in many cosmetic products selling many units to the market place, for example L’Oreal e.g http://www.tesco.com/groceries/product/details/?id=285173174								
Dipeptide-2 24587-37-9	A	Dipeptide-2 is a peptide composed of two amino acids, valine and tryptophan. Both are L-amino acids, which are noted as GRAS food additives by the FDA. Safe in the present practices of use and concentrations in cosmetics. Safety Assessment of α-Amino Acids as Used in Cosmetics, International Journal of Toxicology 32 (S 4) 415-645, 2013								
Citric Acid 77-92-9	A	Safe up to 39%, International Journal of Toxicology 33(S2), 16-46, 2014								
Darutoside 59219-65-7	## ¹	Read across to Siegesbeckia orientalis (Darutoside is an extract). Typical dose is 12 g orally with no reported side effects: SED in Zone New Expression- 365 is 1538461 time less than the recommended oral dose. Toxicity following application to the skin when formulated to be non-irritating, is unlikely								
Calcium Gluconate 299-28-5	B	2014 CIR Compendium, safe in the present practices of use and concentration in cosmetics, GRAS, Final Report 03/2014 available from CIR.								
Palmitoyl Tetrapeptide-7 221227-05-0	B	2014 CIR Compednium, safe in the present practices of use and concentration in cosmetics, Final Report 06/2014 available from CIR								
Palmitoyl Tripeptide-1 147732-56-7	B	2014 CIR Compednium, safe in the present practices of use and concentration in cosmetics, Final Report 06/2014 available from CIR								
Chrysin 480-40-0	A	Health food supplement, bioflavonoid found in honey. Poorly absorbed after human oral exposure, ≤ 0.02% https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2014445/ . Human oral dose of 500 mg/day (8.33 mg/kg bw) did not exert any toxic effects which could be attributed to Chrysin. SED of Chrysin in Zone New Expression- 365= 0.0002 mg/kg bw, 416500 times less than the SED in the study http://www.ncbi.nlm.nih.gov/pubmed/16003560 .								
Biotin 58-85-5	A	Safe up to 1%, Interational Journal of Toxicology 20(S4), 1-12, 2001								

^a Some ingredients are excluded from a formal risk assessment where a recognized authority has published a review of the ingredient under similar conditions of use and concluded on safe use at the level of inclusion in the cosmetic product (Hazard ID=A). Hazard ID

category B is for recognized authority reviews of the ingredient under similar conditions of use with restricted use or where the ingredient is contained in the annexes to Regulation (EC) No 1223/2009 (Hazard ID=B). Where hazard ID A or B is reported, the maximum allowed usage concentration should be stated.

^b all possible routes of exposure should be considered

^c A MoS of greater than 100 is considered to represent safe use

Food item, hazard and exposure data not required.

##¹ other; read-across to information on components, see Appendix 4

Fragrances:

Zone New Expression-365 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 New Expression-365 was released in 2015. Over the period August 2015 to August 2016, 7015 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 New Expression-365 will cause damage to human health when used as directed.

It is therefore concluded that Zone New Expression-365 *can* be placed on the market in the EU as an eye cream.

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).

Directions for use:

AM & PM: Cleanse with RegimA. Apply one pump depression (0.25 ml) of New Expression- 365 to the whole under eye area, crow's feet and between the eyebrows on frown lines. [do not apply to upper eyelids].

May be combined with RegimA Zone Eye Opener Serum, which is applied to upper eyelids.

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 an eye cream.

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 yellow line forming a corner of a rectangular box.

List of References

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

METHOD OF MANUFACTURE / GMP CERTIFICATION



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

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*

RégimA

Zone Omega High Impact
Night Complex

Prepared: 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 Omega High impact Night Complex

Product type	Anti-Ageing Cream
Form	Cream
Colour	Off-White
Pack size	50 mL
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	NBO003
Normal use	Leave-on face cream

Pictures of the Item: On following page

Container label

NL: Niet gebruiken op een beschadigde huid • In combinatie met dit product, is een RégimA-dagcrème met UVA- en UVB-bescherming noodzakelijk • Beschermt tegen temperaturen boven 40°C

FR: Ne pas utiliser sur les peaux abîmées ou éraflées • Ce soin doit être suivi d'un produit de jour RégimA avec une protection UVA et UVB • Protéger des températures supérieures à 40°C

DE: Nicht auf beschädigte/rissige Haut auftragen • Im Anschluss muss eine RégimA Tagespflege mit UVA- und UVB-Schutz angewandt werden • Vor Temperaturen über 40°C schützen

IT: Da non applicarsi su pelli danneggiate o su ferite • Proseguire obbligatoriamente con un prodotto da giorno RégimA dotato di protezione UVA e UVB • Proteggere da temperature superiori ai 40°C

ES: No aplicar sobre esquís dañado / roto • Deberá ir seguido de un producto de RégimA que contenga protección UVA y UVB • Proteger de temperaturas superiores a 40°C

PT: Não se aplicam a danos / ski quebrado • Deve ser seguido por um produto de dia RégimA com proteção UVA e UVB • Proteger de temperaturas acima de 40°C

RU: Не наносить на поврежденную / спомянутые выше линии • Далее использовать продукт из линии ежевечернего ухода RégimA с содержанием веществ, защищающих от воздействия ультрафиолетовых лучей спектра А и В • Не допускать воздействия температуры выше 40°C

TU: hasarı/buzuk kavak için uceri değildir • UVA ve UVB koruma içeren bir RégimA günlik ürün ile beraber kullanılmalıdır • 40°C'den yüksek sıcaklıkların koruyunuz

PL: Nie nalezy stosowac na skórze uszkodzonej/o przewanej ciągleści • Muszą być stosowane z produktami na dzień RégimA zawierającymi ochronę UVA i UVB • Chronić przed wzrostem temperatury powyżej 40°C

LT: Nelepkite nuo pažeistos įtrukusios odos • Būtina naudoti RégimA dienos kremą su UVA ir UVB apsauga • Leikytis ne aktyvumas virš 40°C temperatūroje

DA: Pasør ikke på beskadiget/ødelagt hud • Skal følges op af et RégimA-produkt, der indeholder UVA og UVB-beskyttelse • Skal beskyttes mod temperaturer over 40°C

FI: Älä levitä tuotetta vahingoittuneelle iholle • Lisäksi on käytettävä RégimA-päivävoiteita, jossa on UVA- ja UVB-suojia • Suojaa tuote yli 40 °C lämpötiloilta

NO: Må ikke brukes på skadet/ødelagt hud • Må følges opp med et RégimA-dagprodukt som inneholder UVA- og UVB-beskyttelse • Beskyt mot temperaturer over 40°C

SWE: Apliceras inte på skadad hud • Måste följas upp med en RégimA-dagkräm som innehåller UVA- och UVB-skydd • Skyddas för temperaturer över 40 grader

RO: Nu se aplică în cazul pielii deteriorate / rupte • Trebuie urmat de un produs RégimA pentru îngrijirea de zi, ce oferă protecție UVA și UVB • Ace protejează de temperaturi de peste 40°C

HELPS TARGET
THE SIGNS OF AGEING
ALL SKIN TYPES
EXCEPT SENSITIVE

DIRECTIONS FOR USE

PM: Cleanse with RégimA cleanser. Apply eye products and serums, then apply one pump depression of Omega High Impact to the face, avoiding the eye area and neck. May tingle a little on application.

Do not apply to damaged/broken skin.

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



RégimA™
International Skin Treatments
50 Van Buren Road, Bedfordview, 2008
Gauteng, South Africa
www.regima.zone
Manufactured in South Africa
EU - RP CS1-Europe: The Greenway, Ardilaun
Court, St. Stephen's Green, Dublin 2, Ireland
UK - RP CS1-UK: Penicuik Science Park,
Penicuik, Nr Edinburgh, EH26 0PZ, UK
US - FDA - 1007858

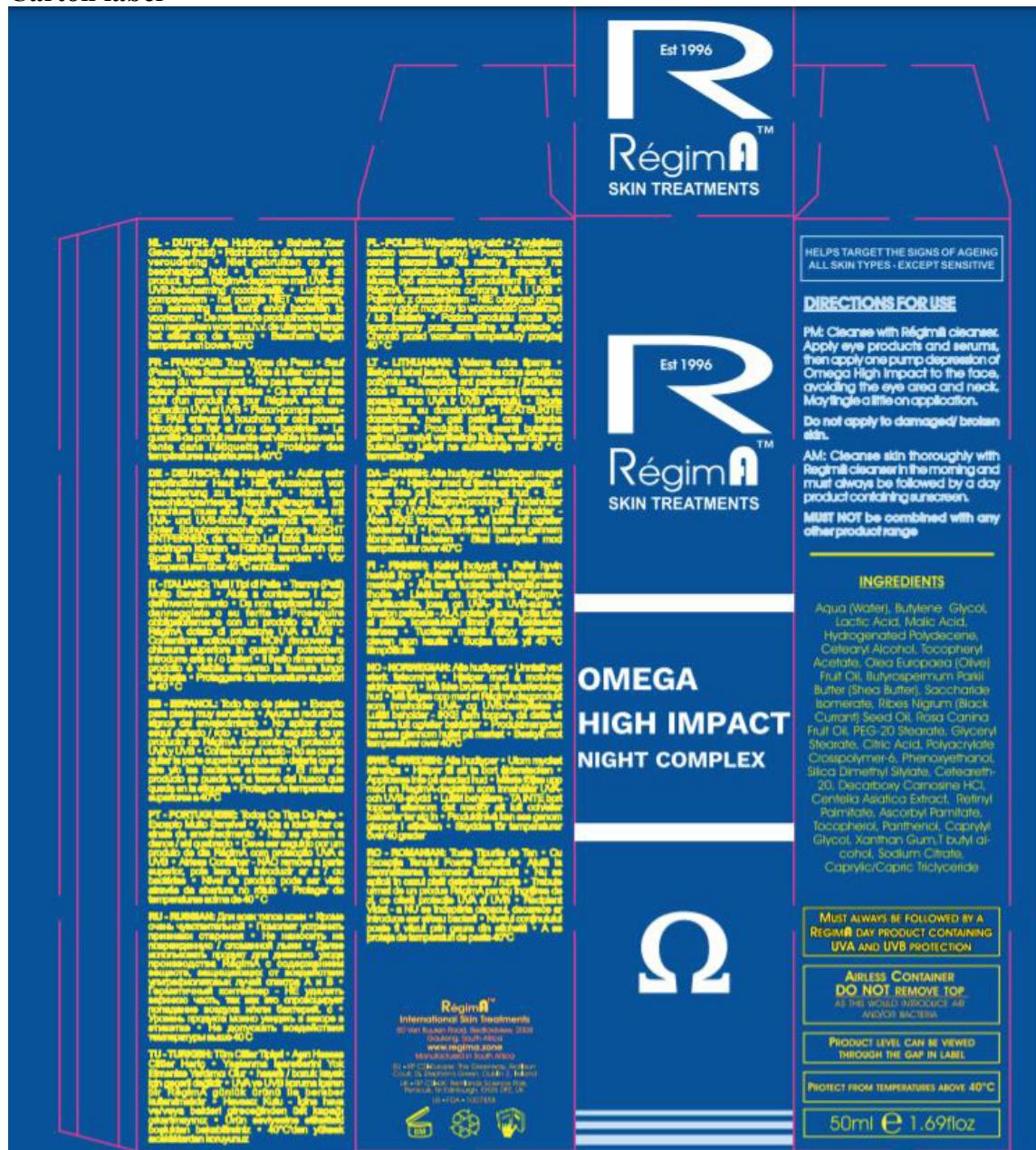
AIRLESS CONTAINER
DO NOT REMOVE TOP
AS THIS WOULD INTRODUCE AIR
AND/OR BACTERIA

PRODUCT LEVEL CAN BE VIEWED
THROUGH THE GAP IN LABEL

PROTECT FROM TEMPERATURES ABOVE 40°C

50ml e 1.69floz

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:

The product insert states that this complex helps visibly give the skin a freshened appearance.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Zone Omega High impact Night Complex base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Aqua	0.1500	7.5000	7732-18-5	231-791-2	Skin conditioning	Purac	L(+)-Lactic Acid
	Lactic Acid	7.3500		79-33-4 50-21-5	201-196-2 200-018-0			
2	Malic Acid	6.7500	6.7500	6915-15-7 97-67-6	230-022-8 202-601-6	Skin conditioning	Merck KGaA	DL-Malic Acid
3	Ceteareth-20	1.0000	5.0000	68439-49-6	#	Primary Emulsifier	Croda Chemicals	Cosmowax D
	Cetearyl Alcohol	4.0000		67762-27-0 8005-44-5	267-008-6			
4	Hydrogenated Polydecene	5.0000	5.0000	68037-01-4	500-183-1	Emollient	IMCD	Dekanex 2006 FG
5	Citric Acid	0.0500	5.0000	77-92-9 5949-29-1	201-069-1	Humectant	DSM Nutritional Products (Chempure)	Pentavitin
	Sodium Citrate	0.0500		68-04-2 6132-04-3	200-675-3			
	Aqua	2.4000		7732-18-5	231-791-2			
	Saccharide Isomerate	2.5000		100843-69-4	#			
6	Centella Asiatica Extract	0.0900	5.0000	84696-21-9	283-640-5	Skin conditioning	Greentech (Natchem)	Cosmelene of Centella
	Butylene Glycol	4.9100		107-88-0	203-529-7			
7	Glyceryl Stearate	2.0000	4.0000	31566-31-1	250-705-4, 286-490-9	Secondary Emulsifier	Croda Chemicals	Arlacel 165
	PEG-20 Stearate	2.0000		9004-99-3	#			
8	Butyrospermum Parkii Butter (Shea Butter)	3.0000	3.0000	68920-03-6, 194043-92-0	293-515-7	Skin conditioning	AA Fratelli Parodi	Cetiol SB-45
9	Butylene Glycol	3.0000	3.0000	107-88-0	203-529-7	Humectant	Daicel	1,3-Butylene Glycol
10	Olea Europaea (Olive) Fruit Oil	3.0000	3.0000	8001-25-0	232-277-0	Skin conditioning	Textron	Extra Virgin Olive Oil
11	Tocopheryl Acetate	3.0000	3.0000	7695-91-2	231-710-0	Antioxidant	DSM Nutritional Products (Chempure)	DL-Alpha-Tocopheryl Acetate
12	Rosa Canina Fruit Oil	2.0000	2.0000	84603-93-0	#	Emollient	Crodarom	Rose Hips Oil
13	Ribes Nigrum (Black Currant) Seed Oil	2.0000	2.0000	68606-81-5 97676-19-2	271-749-0	Emollient	Goerlich Pharma International GmbH	Blackcurrant Seed Oil
14	Phenoxyethanol	0.0200	2.0000	122-99-6	204-589-7	Skin Conditioning	Exsymol (Akulu Marchon)	Alistin P5
	Butylene Glycol	0.1636		107-88-0	203-529-7			
	Aqua	1.6164		7732-18-5	231-791-2			
	Decarboxy Carnosine HCl	0.2000		57022-38-5	415-470-6			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
15	Panthenol	0.2000	2.0000	81-13-0	201 327 3	Skin conditioning	Zhejiang Xinfu Biochemical	D-Panthenol
16	Citric Acid	1.5000	1.5000	77-92-9	201-069-1	Buffer	RZBC	Citric Acid Anhydrous
17	T-butyl alcohol	0.0750	1.5000	75-65-0	200-889-7	Rheological Modifier	Seppic (CJP)	SepiMax ZEN
	Polyacrylate Crosspolymer-6	1.4250		#	#			
18	Caprylyl Glycol	0.5300	1.5000	1117-86-8	214-254-7	Preservative	Acti-Chem	Microcare PHG
	Phenoxyethanol	0.9800		122-99-6	204-589-7			
19	Silica Dimethyl Silylate	1.0000	1.0000	68611-44-9	271-893-4	Anticaking/antifoaming/emollient/emulsion stabilizing/viscosity controlling	Evonik Degussa (Protea Speciality Chemicals)	Aerosil R 972
20	Retinyl palmitate	0.2775	0.5000	79-81-2	201-228-5	Skin conditioning	DSM	Vitamin A Palmitate 1.0 MIU/g (stabilized with tocopherol)
	Caprylic/Capric Triglyceride	0.0050		73398-61-5	277-452-2			
	Tocopherol	0.2175		10191-41-0	240-747-1			
21	Xanthan Gum	0.3000	0.3000	11138-66-2	234-394-2	Binding/emulsifying/emulsion stabilizing/gel forming/surfactant/viscosity controlling	Jungbunzlauer	Xanthan Gum
22	Ascorbyl Palmitate	0.2000	0.2000	137-66-6	205-305-4	Antioxidant	DSM Nutritional Products (Chempure)	Ascorbyl Palmitate
23	Tocopherol	0.2000	0.2000	10191-41-0	240-747-1	Antioxidant	DSM Nutritional Products (Chempure)	DL-Alpha-Tocopherol
24	Aqua	35.0500	35.050	7732-18-5	231-791-2	Vehicle	In-House	Deionised Water

not assigned

Ingredient order for the label: Aqua, Butylene Glycol, Lactic Acid, Malic Acid, Hydrogenated Polydecene, Cetearyl Alcohol, Tocopheryl Acetate, Olea Europaea (Olive) Fruit Oil, Butyrospermum Parkii Butter (Shea Butter), Saccharide Isomerate, Ribes Nigrum (Black Currant) Seed Oil, Rosa Canina Fruit Oil, PEG-20 Stearate, Glyceryl Stearate, Citric Acid, Polyacrylate Crosspolymer-6, Phenoxyethanol, Silica Dimethyl Silylate, Ceteareth-20, Decarboxy Carnosine HCl, Caprylyl Glycol, Xanthan Gum,

Retinyl Palmitate, Tocopherol, Panthenol, Ascorbyl Palmitate, Centella Asiatica Extract, T butyl alcohol, Sodium Citrate, Caprylic/Capric Triglyceride.

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 Omega High impact Night Complex does not contain a fragrance

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

Physical and chemical characteristics of the ingredients have been listed in the safety data sheets which are presented in the report appendices as shown in the base formula table.

Physical and Chemical Characterization of the product

1 Physical state	Cream
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Cream
3 organoleptic properties (colour, odour, whenever relevant)	Off-white with a characteristic odour
4 pH (at 25°C)	ca. 2.19
5 viscosity (at 25°C) for liquid forms	ca. 156000 cPs
6 thermal stability (glass bottle)	Stable at 40°C for 12 weeks but with pH reduction 2.19 to 2.09
7 Specific gravity	ca. 0.984 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 40°C for 12 weeks although a reduction in pH of around 15% was noted at 50° C and

therefore a warning regarding storage temperature to be below 50° C will be presented on the product 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

Product insert directions for use: Fruity acids must be cleansed off in the morning and a day product containing sun protection should always be applied.

Zone Omega High impact Night Complex is a night treatment product designed to help visibly give the skin a freshened appearance. It is a leave-on product that in normal circumstances will be used once daily on the face avoiding the eye area. This product is washed off in the morning and in the day time sun protection must be used.

A.6 Exposure to the Cosmetic Product

Site of application	Face (avoiding eye area)
Surface area of application (cm ²)	565 cm ²
Volume of product applied (ml)	0.25 ml (1 pump depression)
Frequency of application/use per day	1
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance	0.25 ml exposure daily Estimated exposure based on 60 kg adult

tables (mg/kg bw/day)	= 4.17 mg/kg bw /day
Dermal absorption information	Unknown
other	

A.7 Exposure to the Substances

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

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Lactic Acid 79-33-4	7.35	4.17	1	0.306
Malic Acid 6915-15-7	6.75	4.17	1	0.281
Hydrogenated Polydecene 68037-01-4	5.00	4.17	1	0.209
Butylene Glycol 107-88-0	8.57	4.17	1	0.357
Cetearyl Alcohol 67762-27-0	4.00	4.17	1	0.167
Butyrospermum Parkii Butter (Shea Butter) 68920-03-6, 194043-92-0	3.00	4.17	1	0.125
Olea Europaea (Olive) Fruit Oil 8001-25-0	3.00	4.17	1	0.125
Tocopheryl Acetate 7695-91-2	3.00	4.17	1	0.125
Saccharide Isomerate 100843-69-4	2.50	4.17	1	0.104
Glyceryl Stearate 31566-31-1	2.00	4.17	1	0.083
PEG-20 Stearate 9004-99-3	2.00	4.17	1	0.083
Rosa Canina Fruit Oil 84603-93-0	2.00	4.17	1	0.083
Ribes Nigrum (Black Currant) Seed Oil 68606-81-5	2.00	4.17	1	0.083
Citric Acid 77-92-9	1.55	4.17	1	0.065
Polyacrylate Crosspolymer-6 No CAS available on CosIng	1.425	4.17	1	0.059
Ceteareth-20 68439-49-6	1.00	4.17	1	0.042
Silica Dimethyl Silylate 68611-44-9	1.00	4.17	1	0.042

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Phenoxyethanol 122-99-6	1.00	4.17	1	0.042
Decarboxy Carnosine HCl 57022-38-5	0.66	4.17	1	0.028
Caprylyl Glycol 1117-86-8	0.53	4.17	1	0.022
Tocopherol 10191-41-0	0.418	4.17	1	0.017
Xanthan Gum 11138-66-2	0.30	4.17	1	0.013
Retinyl Palmitate 79-81-2	0.278	4.17	1	0.012
Panthenol 81-13-0	0.20	4.17	1	0.008
Ascorbyl Palmitate 137-66-6	0.20	4.17	1	0.008
Centella Asiatica Extract 84696-21-9	0.09	4.17	1	0.004
T-butyl-alcohol 75-65-0	0.075	4.17	1	0.003
Sodium Citrate 68-04-2	0.05	4.17	1	0.002
Caprylic/Capric Triglyceride 73398-61-5	0.005	4.17	1	0.0002

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 ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Lactic Acid 79-33-4	B	2014 CIR compendium, αHAs included at ca. 15% - safe up to ≤10%, at final formulation pH >=3.5, when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection. safe for use in salon products at concentrations ≤30%, at final formulation pH ≥3.0, in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection ¹ ; 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)								
Malic Acid 6915-15-7	B									
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								
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) 68920-03-6, 194043-92-0	A	Safe when used up to 60% , Final report 03/11 CIR Compendium, 2014								
Olea Europaea (Olive) Fruit Oil 8001-25-0	A	2014 CIR Compendium safe up to 100%, Final report 03/2011 (CIR)								
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								
Saccharide Isomerate 100843-69-4	A	Contains mainly glucose and fructose, GRAS food substances, Safety assessment of monosaccharides, disaccharides and related ingredients as used in cosmetics, CIR, April 4, 2014. PDS recommends use up to 5% in skin care preparations.								
Glyceryl Stearate CAS: 31566-31-1	A	Safe up to 50%; JACT 1(4), 169-192, 1982								
PEG-20 Stearate 9004-99-3	A	Safe up to 4%; JACT 2(7). 17-60, 1983 and confirmed 11/02 International Journal of Toxicology 24(S1), 74-80, 2005								

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Rosa Canina Fruit Oil 84603-93-0	A	2014 CIR Compendium, safe up to 19%, Final report 03/2013 (CIR)								
Ribes Nigrum (Black Currant) Seed Oil 68606-81-5	A	2014 CIR Compendium, safe up to 0.3% ² , Final report 03/2013 (CIR) current formulation has 2%, Food item GRAS#.								
Citric Acid 77-92-9	A	Safe up to 39%, International Journal of Toxicology 33(S2), 16-46, 2014								
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 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
Ceteareth-20 68439-49-6	B	Safe when formulated to be non-irritating; 2014 CIR Compendium, Final Report 12/10 (CIR); International Journal of Toxicology 18(S3), 41-49, 1999 and International Journal of Toxicology 31 (S2), 169-244, 2012								
Silica Dimethyl Silylate 68611-44-9	A	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	A	2014 CIR Compendium safe up to 1%, JACT 9(2):259-77, 1990								
Decarboxy Carnosine HCl		A natural peptide, Included in Health Canada drug and health products as a skin conditioning agent with no restrictions, Product Data								

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment	
57022-38-5		Sheet reports not irritant skin or eye, (tested in vitro), tested in vivo volunteers well tolerated to 1.5% concentration.									
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									
Panthenol 81-13-0	A	Safe up to 25%, JAQCT 6(1): 139-62, 2006									
Ascorbyl Palmitate 137-66-6	A	Safe up to 0.2%; International Journal of Toxicology 18(S3), 1-26, 1999									
Tocopherol 10191-41-0	A	Safe when used up to 1%; IJT 21(S3):51-116, 2002; Final report 03/2014 CIR Compendium, 2014									
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	
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)									
Sodium Citrate 68-04-2	A	2014 CIR Compendium, safe for use up to 10%, IJT 33 (S2): 16-46, 2014									
Caprylic/Capric Triglyceride 73398-61-5	A	2014 CIR Compendium, safe for use up to 84% JEPT 4 (4): 105-20, 1980 confirmed 06/01 IJT 22 (S1): 1-35, 2003									
Retinyl Palmitate 79-81-2	A	Safe up to 5%; JACT, 6(3), 279-320, 1987; confirmed 06/06									

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

^b all possible routes of exposure should be considered

^c A MoS of greater than 100 is considered to represent safe use

Food item, hazard and exposure data not required.

¹ Exceeds recommended safe usage, see Statement of tolerability, Section B.1

Fragrances:

Zone Omega High impact Night Complex 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

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 Omega High impact Night Complex was released in 2014. Over the period October 2014 to February 2015 1322 units have been sold and there have been no adverse reactions reported to RégimA International Skin Treatments.

B: Part Cosmetic Product Safety Assessment

B.1 Assessment Conclusion

Review of the ingredients

After analysis of all the available information including:

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

Ingredients no. 1 (a mixture containing Lactic Acid) and 4 (Malic Acid) declare up to 7.35% and 6.75% alpha hydroxyl acid (AHA) content respectively, which would equate to a maximum of 15% content in the formulated product which has a pH of 2.19.

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.

As the concentration of AHA is higher than 10 percent and the pH is lower than 3.5, it is advised that the product insert and labelling contains the advice to use daily protection from the sun.

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 15% AHA formulation without adverse effects such as irritation being reported.

Richard J Van Der Poel reports 'There may be a tingling sensation on application (particularly to very dry skin) or a slight flakiness of the skin within the first few weeks of use (generally in patients with solar keratosis). There has been generally no erythema observed, even with nightly use and no adverse reactions with any [patients who have used the product on a continual basis. As the product is cleansed off thoroughly in the

morning and is always followed by the daily application of a RegimA product with sun protection, the tolerability can be accepted.'

The statement is included in Appendix 4.

It is not expected that Zone Omega High impact Night Complex will cause damage to human health when used as directed.

It is therefore concluded that Zone Omega High impact Night Complex can be placed on the market in the EU as a skin conditioning product.

B.2 Label Warnings and Instructions for Use

Product insert: Fruity acids must be cleansed off in the morning and a day product containing sun protection should always be applied.

Label warning should contain the message:

'Protect from temperatures above 40°C'

'Cleanse skin thoroughly with RegimA cleanser in the morning and follow with use of daily sun protection when using this product' (or similar)

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

PM: Cleanse with RegimA cleanser. Apply eye products and serums, then apply one pump depression of Omega High Impact to the face, avoiding the eye area and neck. May tingle a little on application.

AM: Cleanse with RegimA cleanser. Follow with compatible RegimA preparations, which must include a day product providing sun protection.

B.3 Reasoning

This product contains ingredients with a positive reputation for their skin conditioning and naturally exfoliating properties and with good local tolerance. There are no reasons to anticipate tolerance problems with use when used according to the label instructions.

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 an anti-aging cream.

A handwritten signature in black ink, reading "Shirley H", is placed within a yellow rectangular border. The border has a thin vertical line on the right side and a horizontal line at the bottom, creating a frame around the signature.

List of References

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

METHOD OF MANUFACTURE / GMP CERTIFICATION



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

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 challenge microbial report for the product is maintained electronically with the PIF by the Responsible Person and is available on request.

Appendix 3: Certificates of Allergen Content

There are no fragrances in this product.

Appendix 4: Miscellaneous

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