

PRODUCT INFORMATION FILE*

RegimA

Zone Daily Ultra Defence +
βeta-Endorphin Stimulator

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

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

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INTRODUCTION

PRODUCT DESCRIPTION

Product Name: Zone Daily Ultra Defence + β eta-Endorphin Stimulator

Product type	Moisturiser with sun protector
Form	Cream
Colour	Yellow
Pack size	15 ml and 50 ml
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	RDS002
Normal use	Leave-on face cream

Pictures of the Item: On following page

Container label

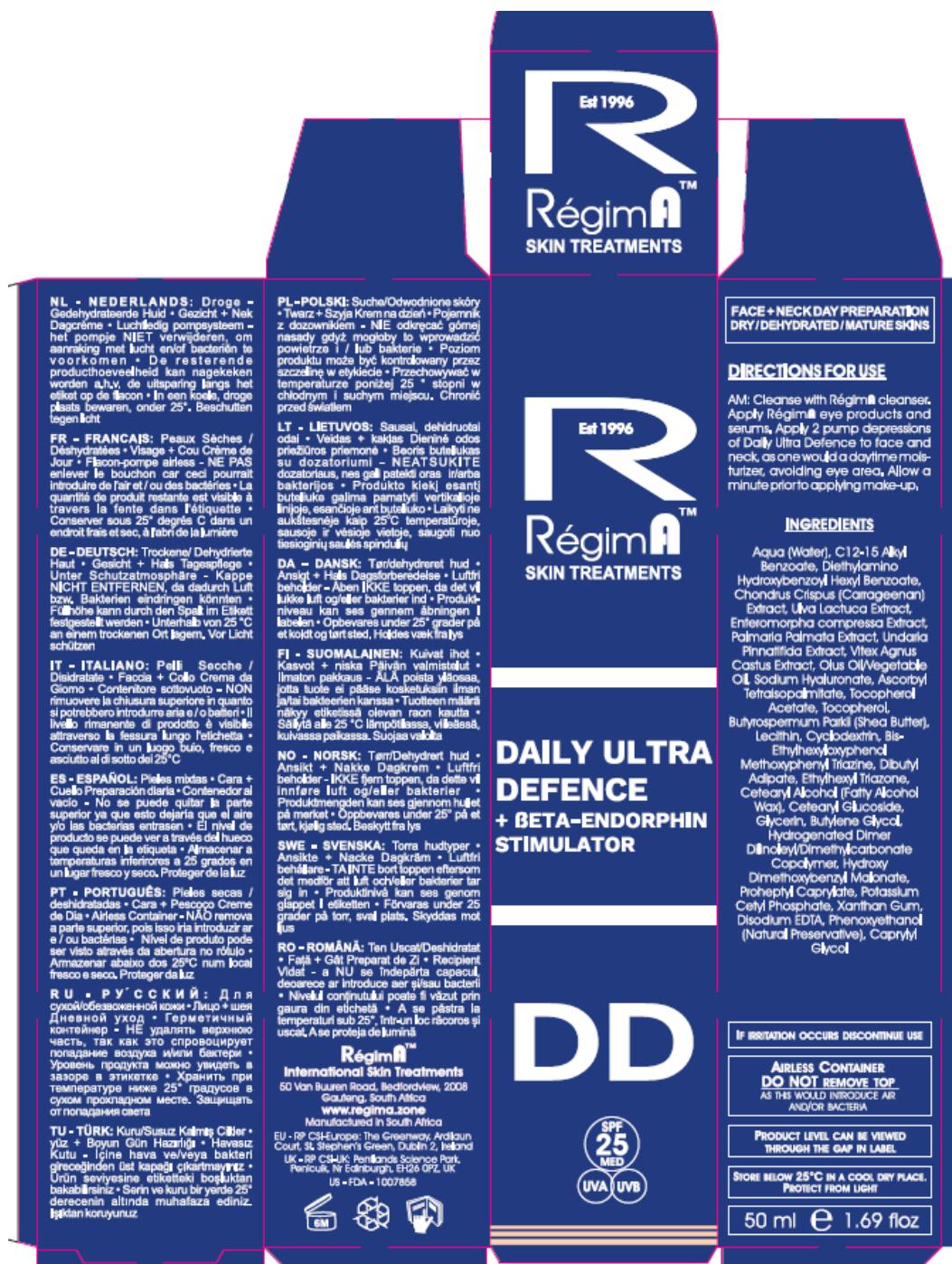
Top layer



Base layer

NO PRINT AREA	<p>IT - ITALIANO: Pelli, Secche / Disidratate • Faccia + Collo Crema da Giorno • Contenitore sottovuoto - NON rimuovere la chiusura superiore in quanto è potenzialmente un'arma a fuoco. Non aprire il contenitore di vetro e tenere lontano dalla fessura lungo l'etichetta • Conservare in un luogo buio, fresco e asciutto al di sotto dei 25°C</p> <p>E3 - ESPAÑOL: Pieles mixtas • Cara + Cuello Crema de Día • Contenedor vedado - NO quitar la parte superior ya que es potencialmente una arma de fuego. No abrir el recipiente de vidrio y mantener alejado del hueco que queda en la etiqueta • Almacenar a temperaturas inferiores a 25 grados en un lugar fresco y seco. Proteger de la luz</p> <p>PT - PORTUGUÉS: Peles secas / desidratadas • Cara + Pescoço Creme de Dia • Embalagem vedada - NÃO remova a parte superior, por que é potencialmente uma arma de fogo. Nível do produto pode ser visto através da abertura no roto. • Armazenar abaixo dos 25°C num local fresco e seco. Proteger da luz</p> <p>RU - РУССКИЙ: Для сухой/обезвоженной кожи • Лицо + шея Дневной крем • Контейнер герметичный - Не снимайте верхнюю крышку, так как это может стать потенциальной вспышкой или взрывом бактерий • Уровень продукта можно увидеть в зазоре на этикетке • Хранить при температуре ниже 25° градусов в сухом прохладном месте. Защищать от попадания света</p> <p>TU - TÜRK: Kuru/Susam Kalmış Çiftlik - yüz + Boyun Gündüz Kremi • Kapalı konteyner - Üst kapağı çıkartmadan önce, içeriye giren gerginlik ıstaklı kapak patlayıcı olabilir. • Kapalı konteynerin içi etiketin arka tarafında bir boşluk bırakılmıştır. Bu boşlukta ürün seviyesini görebilirsiniz. • Sıvı kuru bir hava içinde 25° derecelerdeki orta sıcaklıkta saklayın. İstikrar koruyunuz.</p> <p>PL - POLSKI: Suchie/Obwodzone skóry • Twarz + Szyja Krem na dzień • Pojemnik z zamknięciem - NIE odrywaj górną pokrywę, ponieważ jest potencjalnie broń palna. Nie otwieraj produktu szklanego i utrzymuj daleko od etykiety, w której jest przekrój w kształcie litery "U" lub bakterii. Produktu można zobaczyć kontrolując poziom płynu w etykiecie • Przechowuj w temperaturze, poniżej 25 stopni w chłodnym i suchym miejscu. Chronic przed światłem</p>	<p>LT - LIETUVOS: Sausai, dehidruoti odaži • Veidas + kaklas Dienine odos prežiūros priemonė • Beoris buteliukas su dozatoriumi - NE ATAKSUOKITE dozatoriu, nes gal palekti žibintas. Ne atverite stiklo paketo ir išlaikykite užraugą nuo etiketės, kuria yra vertikali linija, esanti ant buteliuko. Laičių ne aukštesneje kaip 25°C temperatūroje, sausieje ir vesioje vietoje, saugot nuo tiesioginių saulės spindulių</p> <p>DA - DANSK: Tørdehydreret hud. + Ansigt + Hals Dagsforberedelse • Lættim beholder - Åben ikke den øverste del af tilkøle luft og/eller bakterier ind. • Produktniveau kan ses gennem åbningen i etiketten. • Opteppe under 25° grader på et godt og tørt sted. Holdes væk fra lys</p> <p>FI - SUOMALAINEN: Kuivat ihot. + Kasvoi + niska Päivän kosteuttaja • Sulistyvä pakkaus - Älä poista yläpalkkaa, jotta voit nähdä leivon korkeuden läpi. • Tuoteen määrää näkyy etiketistä olevan röntgen kauha. • Säilytä alle 25 °C lämpötilassa, väistävä, kuivassa pakkaus. Suaaja v a l i o i t t a</p> <p>NO - NORSK: Tørr/Dehydrert hud + Ansikt + Nakk Dagkräm • Lukket beholder - IKKE tem oppen, da dette vil løsne luft og/eller bakterier • Produktinnniveau kan ses gjennom hullet på merket • Oppbevares under 25° på et tørt, koldt sted. Beskytt fra lys</p> <p>SWE - SVENSKA: Torkad/hudhydrerad hud. + Ansikt + Nack Dagkräm • Stängt behållare - Ta inte bort den översta delen av medföljande luft och/eller bakterier tar sig in • Produktiniva kan ses genom glaset i etiketten • Förvaras under 25 grader på torr, sval plats. Skyddas mot ljus</p> <p>RO - ROMÂNĂ: Ten Uscat/Deshidratat • Față + Față Preparat de Zi • Recipient Vidru - A NU se îndepărta capacul, decât pentru introducerea aerului și/sau bacteriei • Nivelul conținutului poate fi vizat prin gaura din etichetă • A se păstra la temperatură sub 25°, într-un loc recalcitrant la uscat. A se proteja de lumina</p>
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Carton label



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

Product claims:

This product claims to help improve the appearance of dry and sun damaged skins whilst helping protect from the drying, ageing effects of the sun.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Zone Daily Ultra Defence + β -Endorphin Stimulator base formula

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

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

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

not assigned

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

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

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

Fragrance allergens*

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

*Zone Daily Ultra Defence + β -Endorphin Stimulator does not contain a fragrance

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

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

Physical and Chemical Characterization of the product

1 Physical state	Cream
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	O/w mixture
3 organoleptic properties (colour, odour, whenever relevant)	Yellow, characteristic odour
4 pH (at 25°C)	5.25
5 viscosity (at 25°C)	75000 cPs
6 thermal stability (glass bottle)	Stable at 50°C for 12 weeks
7 Specific gravity	0.940 g/ml

Stability of the product

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

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass bottles has confirmed stability at 50°C for 12 weeks. The viscosity increased at elevated temperatures (40°C and 50°C) from week 8 onwards from 75000 to 95000 and 94000, respectively.

A.3 Microbiological Quality

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

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

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

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

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

A.5 Normal and reasonably foreseeable use

Zone Daily Ultra Defence + β -Endorphin Stimulator is a product designed to maintain equilibrium of moisturisation, whilst providing protection from the drying, ageing effects of the sun. It is a leave-on product that in normal circumstances will be used once daily on the face and neck, avoiding the eye area.

A.6 Exposure to the Cosmetic Product

Site of application	Face and neck (avoiding the eye area)
Surface area of application (cm ²)	565 cm ²
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)
Aqua (Water) 7732-18-5	34.05	8.34	1	2.8398
C12-15 Alkyl Benzoate 68411-27-8	8.00	8.34	1	0.6672
Diethylamino Hydroxybenzoyl Hexyl Benzoate 302776-68-7	8.00	8.34	1	0.6672
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine 187393-00-6	6.00	8.34	1	0.5004
Butylene Glycol 107-88-0	5.95	8.34	1	0.4962
Cetearyl Alcohol 67762-27-0	5.37	8.34	1	0.4479
Butyrospermum Parkii (Shea Butter) 67701-30-8	5.00	8.34	1	0.4170
Dibutyl Adipate 105-99-7	5.00	8.34	1	0.4170
Ethylhexyl Triazone 88122-99-0	5.00	8.34	1	0.4170
Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate 872182-46-2	4.00	8.34	1	0.3336
Propylheptyl Caprylate 868839-23-0	3.00	8.34	1	0.2502
Potassium Cetyl Phosphate 19035-79-1	2.50	8.34	1	0.2085
Hydrogenated Dimer Dilinoleyl/Dimethylcarbonate Copolymer 436803-57-5	2.00	8.34	1	0.1668
Tocopheryl Acetate 7695-91-2	2.00	8.34	1	0.1668
Caprylyl Glycol 1117-86-8	0.60	8.34	1	0.0500

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

Where no dermal absorption data is available, 100% dermal absorption is used. However, where molecular weight > 500 Da and log Pow is smaller than -1 or higher than 4, the value of 10% dermal

absorption is considered unless the formulation contains penetration enhancers. Dermal absorption of nanomaterials needs to be determined experimentally.

no CAS available

A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Haz ard ID and list ^a	Refere nce for hazard ID	Irrit ant to eyes	Irrit ant to skin	Sensit iser	Hum an data	NOA EL (mg/ kg bw/d ay)	SE D ^b	Mo S ^c	comm ent
C12-15 Alkyl Benzoate 68411-27-8	A									
Diethylamino Hydroxybenzoyl Hexyl Benzoate 302776-68-7	A									
Bis- Ethylhexyloxyphen ol Methoxyphenyl Triazine 187393-00-6	A									
Butylene Glycol 107-88-0	A									
Cetearyl Alcohol 67762-27-0	A									
Butyrospermum Parkii (Shea Butter) 67701-30-8	A									
Dibutyl Adipate 105-99-7	A									
Ethylhexyl Triazone 88122-99-0	A									
Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate 872182-46-2	## ¹									
Potassium Cetyl Phosphate 19035-79-1	A									
Hydrogenated Dimer	## ¹									

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

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

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitizer	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Propylheptyl Caprylate 868839-23-0	-	-	Sligh tly irritat ing to rabbit eyes	Mod. irritatin g- however ingredient was applied neat (amount not specified) on 3 ♀ rabbits after a 4h semi-occlusive patch. Dermal application of 2000 mg/kg bw (applied semi-occlusive and neat) had no reported irritation (Wistar rats)	Non-sensitizer (LLNA)	Non-irritant, 48h occlusive application with 50% propylheptyl (0.2ml test material applied) - no dermal effects.	≥1000 mg/mg bw/day	0.2502 mg/kg bw/day	>3000	Maximum concentration of use for a leave on product was 13% up to 2012. Not mutagenic with/without metabolic activation (Ames), not clastogenic (Chromosome aberration test). Reference: Amended Safety Assessment of Alkyl Esters as Used in Cosmetics, 04/2013, Cosmetic Ingredient Review.

^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 or read-across to information on components

Fragrances:

Zone Daily Ultra Defence + β -Endorphin Stimulator does not contain a fragrance.

A.9 Undesirable Effects and Serious Undesirable Effects

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

A.10 Information on the Cosmetic Product

Zone Daily Ultra Defence + β -Endorphin Stimulator was released in 2015. Over the period September 2015 to July 2016, 8761 units have been sold and there have been no adverse reactions reported to RegimA.

B: Part Cosmetic Product Safety Assessment

B.1 Assessment Conclusion

Review of the ingredients

After analysis of all the available information including:

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

It is not expected that Zone Daily Ultra Defence + β -Endorphin Stimulator will cause damage to human health when used as directed.

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

Review of human data on the product

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

B.2 Label Warnings and Instructions for Use

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

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

B.3 Reasoning

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

This product is intended for external use in adults only.

B.4 Assessors Credentials and Approval of Part B

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

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

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

METHOD OF MANUFACTURE / GMP CERTIFICATION



PROOF OF EFFECT CLAIMED

This product implies that Beta-Endorphins are stimulated. This claim is supported in a review paper (Appendix 4).

ANIMAL TESTING STATEMENT

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

The statement below is a confirmation of the company policy:

RégimA Skin Treatments

CK92/05371/23
VAT No. 4590131043

Tel: 011 615 2869 or 011 622 7827

Fax: 011 616 8008

Cell: 0836537020

e-mail: jax@regima.com

POSTAL ADDRESS: PO BOX 9523 Edenglen 1613

PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA

Animal Testing Compliance Statement

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

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

Appendix 1: Safety Data Sheets or Ingredient Specifications

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

Appendix 2: Microbial Challenge Test

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

Appendix 3: Certificates of Allergen Content

Not applicable as this product does not contain a fragrance.

Appendix 4: Miscellaneous

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