

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 -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

NL - NEDERLANDS: Droog - Gedroogd/verdroogde Huid • Gezicht • Hals
 Dagcreme • Luchtloze pompcontainer • Het
 gezicht NIET wassen, om een nieuw
 lucht- en/of bacteriële te voorkomen • De
 resterende producthoeveelheid kan ingesmeerd
 worden op de uitgang lange het etiket op de
 fles • In een koele, droge plaats bewaren,
 onder 25° • Beschut tegen licht.

FR - FRANÇAIS: Peaux Sèches /
 Déshydratées • Visage • Cou • Crème de Jour
 • Flacon-pompe airless - NE PAS laver le
 visage car cela pourrait introduire de l'air et/ou
 des bactéries • La quantité de produit
 restante est visible à travers le film dans
 l'étiquette • Conserver sous 25° degrés C
 dans un endroit frais et sec, à l'abri de la
 lumière

DE - DEUTSCH: Trocken / Dehydrierte Haut
 • Gesicht • Hals Tagespflege • Unter
 Schutzatmosphäre • Flasche NICHT
 ENTLEEREN, da sonst Luft, Bakterien
 eindringen könnten • Flakoha kann
 durch den Spalt an Etikett restliches Produkt
 sichtbar sein • Unter 25°C an einem trockenen Ort
 lagern, Vor Licht schützen

Regim®
 International Skin Treatments
 50 Van Nuys Road, Bedford, MA 01830
 Gaiting, South Africa
 www.regimzone.com www.regimzone.eu
 Manufactured in South Africa
 EU - RP C84-Supel: The Greenway, Adkison
 Court, 25 Western Green, Dublin 2, Ireland
 UK - RP C84-Supel: Penfolds Science Park,
 Penfold, Nr Edinburgh, EH26 0PZ, UK
 US - FDA - 1007858

**DAILY ULTRA
 DEFENCE
 + BETA-ENDORPHIN
 STIMULATOR**

DD

**DRY / DEHYDRATED / MATURE SKINS
 FACE + NECK DAY PREPARATION**

Directions for use:
 AM: Cleanse with Régim®
 cleanser. Apply Régim® eye
 products and serums. Apply Daily
 Ultra Defence to face and neck,
 as one would a daytime moistur-
 izer, avoiding the eye area.
 Allow a minute prior to applying
 make-up.
 When exposed to extreme sun-
 shine reapply as necessary.
 Use in conjunction with other
 Régim® Zone home care.
**MUST NOT be combined with
 any other product range**



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

**PRODUCT LEVEL CAN BE VIEWED
 THROUGH THE GAP IN LABEL**

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

50ml e 1.69fl.oz

Base layer

IT - ITALIANO: Pelli Secche / Disidratate • Faccia • Collo
 • Crema da Giorno • Contenitore sottovuoto • NON rimuovere
 la chiusura superiore in quanto si potrebbero introdurre aria e
 / o batteri • Il livello rimanente di prodotto è visibile attraverso
 la fessura lungo l'etichetta • Conservare in un luogo buio,
 fresco e asciutto al di sotto dei 25°C

ES - ESPAÑOL: Pielres secas / deshidratadas • Cara • Cuello
 Preparación
 diaria • Contenedor al vacío • No se puede quitar la parte
 superior ya que esto dejaría que el aire y/o las bacterias
 entrasen • El nivel de producto se puede ver a través del
 hueco que queda en la etiqueta • Almacenar a temperaturas
 inferiores a 25 grados en un lugar fresco y seco. Proteger
 de la luz

PT - PORTUGUÊS: Pielres secas / desidratadas • Cara •
 Pescoço • Creme de Dia • Airless Container - NÃO remover a
 parte superior, pois isso iria introduzir ar e / ou bactérias •
 Nível de produto pode ser visto através da abertura no rótulo
 • Armazenar abaixo dos 25°C num local fresco e seco. Proteger
 da luz

RU - РУССКИЙ: Для сухой/обезвоженной кожи • Лицо +
 шея • Дневной уход • Термостойкий контейнер • НЕ
 удалять верхнюю часть, так как это способствует
 попаданию воздуха и/или бактерий • Уровень продукта
 можно увидеть в зазоре в этикетке • Хранить при
 температуре ниже 25° градусов в прохладном месте,
 защищая от попадания света

TU - TÜRKİ: Kuru/Susuz Kalın Otlar • Yüz • Boyun Gün
 Hazırlığı • Havasız Kutu • İçine hava veya bakteri
 gireceğinden üst kapak çıkartmayınız • Ürün seviyesine
 etiketeki boşluktan bakabilirsiniz • Serr ve kuru bir yerde 25°
 derecenin altında muhafaza ediniz. Işıktan koruyunuz

PL - POLSKI: Sucha/Odwodniona skóra • Twarz • Sztyła
 Kiem na dzień • Receptnik z dozownikiem • Nie odrywać
 górnej nasady gdyż mogłoby to wprowadzić powietrze i / lub
 bakterie • Poziom produkt może być kontrolowany przez
 szczelinę w etykiecie • Przechowywać w temperaturze
 poniżej 25° stopni w chłodnym i suchym miejscu. Chronić
 przed światłem

LT - LIETUVOS: Sausi, dehidruoti odai • Veidas + kaklas
 Dieninė odos priežiūros priemonė • Beoris buteliukas su
 dozatoriumi • NEATSUKITE dozatoriaus, nes gali patekti
 oras ir / arba bakterijos • Produkto kiekį esant buteliuko
 palima pamatytį vertikalioje linijoje, esančioje ant buteliuko
 Laikyti ne aukštesnėje kaip 25°C temperatūroje, sausoje ir
 vėsioje vietoje, saugot nuo tiesioginių saulės spindulių

DA - DANSK: Tørdehydreret hud • Ansigt + Hals
 Dagstørberedelse • Luft beholder • Åben IKKE toppen, da
 det vil lukke luft og/eller bakterier ind • Produkt-niveauet kan
 ses gennem åbningen i labelen • Opbevares under 25°
 grader på et koldt og tørt sted. Holdes væk fra lys

FI - SUOMALAINEN: Kuivat ihot • Kasvot + niska Päivän
 valmisleik • Ilmaton pakkaus • ÄLÄ poista yläosaa, jotta
 tuote ei pääse kosketuksiin ilman jättä bakteerien kanssa •
 Tuotteen määrä näkyy etiketissä olevan raon kautta • Säilytä
 alle 25 °C lämpötilassa, viileässä, kuivassa paikassa. Suojaa
 valolta

NO - NORSK: Tørr/dehydrert hud • Ansikt + Nakke Daglinn
 • Luft beholder • IKKE fjern toppen, da dette vil innføre luft
 og/eller bakterier • Produktmengden kan ses gjennom hullet
 på merket • Oppbevares under 25° på et tørt, kjølig sted.
 Beskytt fra lys

SWE - SVENSKA: Torr hudtyper • Ansikte + Nacke
 Dagkräm • Luft behållare • TA INTE bort toppen eftersom
 det medför att luft och/eller bakterier tar sig in • Produktnivå
 kan ses genom glaset i etiketten • Förvaras under 25°
 grader på torr, sval plats. Skyddas mot ljus

RO - ROMÂNĂ: Ten Uscat/Deshidratat • Față + Gât Preparat
 de Zi • Receptiv • Vidat - a NU se îndepărta capacul,
 deoarece ar introduce aer și/sau bacterii • Nivelul conținutului
 poate fi văzut prin gaura din etichetă • A se păstra la
 temperaturi sub 25°, într-un loc răcoros și uscat. A se proteja
 de lumină

Carton label



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

Product claims:

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

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Zone Daily Ultra Defence + Beta-Endorphin Stimulator base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	C12-15 Alkyl Benzoate	8.00	8.00	68411-27-8	270-112-4	Emollient UV filter	BASF (Chemgrit)	Cetiol AB
2	Diethylamino Hydroxybenzoyl Hexyl Benzoate	8.00	8.00	302776-68-7	443-860-6	Emollient UV filter	BASF (Chemgrit)	UNIVUL A PLUS GRANULAR
3	Butylene Glycol	3.95	8.00	107-88-0	203-529-7	Skin Conditioning/ Skin Protecting	Greentech (Natchem)	PHYTELENE COMPLEXE EGX 773 (BG)
	Aqua (Water)	3.95		7732-18-5	231-791-2			
	Chondrus Crispus (Carrageenan) Extract	0.02808		244023-79-8	306-561-0			
	Ulva Lactuca Extract	0.02064		97281-59-9	#			
	Enteromorpha compressa Extract	0.01704		#	#			
	Palmaria Palmata Extract	0.01704		223751-74-4	#			
	Undaria Pinnatifida Extract	0.01320		#	#			
4	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	6.00	6.00	187393-00-6	425-950-7	UV Absorber/UV Filter	BASF (Chemgrit)	Tinosorb S
5	Dibutyl Adipate	5.00	5.00	105-99-7	203-350-4	Emollient/Skin Conditioning	BASF (Chemgrit)	Cetiol B
6	Ethylhexyl Triazone	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 Stabilsiiing/ 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 Dilinoylel/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	Safe up to 59%, International Journal of Toxicology 31(3), 342-372, 2012								
Diethylamino Hydroxybenzoyl Hexyl Benzoate 302776-68-7	A	Use of diethylaminohydroxybenzoyl hexyl benzoate at a maximum concentration of 10% w/w in cosmetic products, including sunscreen products does not pose a risk to the health of the consumer; SCCP/1166/08.								
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine 187393-00-6	A	Safe for use in cosmetic products as a UV light absorber at a maximum concentration of 10%, SCCNFP/0082/98								
Butylene Glycol 107-88-0	A	Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006								
Cetearyl Alcohol 67762-27-0	A	2014 CIR Compendium, safe at use up to 25% JACT 7(3):359-413, 1988 confirmed 12/05								
Butyrospermum Parkii (Shea Butter) 67701-30-8	A	Safe when used up to 60% , Final report 03/11 CIR Compendium, 2014								
Dibutyl Adipate 105-99-7	A	2014 CIR Compendium, concentration not reported in 2010; safe for use up to 8% in 1996; IJT 25(S1):129-134, 2006 JACT, 15(4):295-300, 1996 (original Report); Final report 12/10 available from CIR								
Ethylhexyl Triazone 88122-99-0	A	Maximum concentration in ready for use concentration 5%, Annex VI of Regulation (EC) 1223/2009								
Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate 872182-46-2	## ¹	Described as non-absorbing by the manufacturer. Single controlled patch test (human) with 2% of this ingredient for 48h: none of the test subjects (n=50) showed a positive or doubtful reaction. No serious adverse events were reported. Clinical, Cosmetic and Investigational Dermatology. 2012; 5: 101-9. "Sebusuppressive efficacy of the antioxidant bis-ethylhexyl hydroxydimethoxy benzylmalonate in the treatment of oily and blemished skin." SDS Sheet: Negative for sensitization, irritation, genotoxicity (Ames) and mutagenicity (mammal cell test). Considered safe for use in this product (when formulated to be a non-irritating cream or lotion) although present at 4% which exceeds the skin patch test concentration.								
Potassium Cetyl Phosphate 19035-79-1	A	Safe for use when formulated to be non-irritating, Safety Assessment of Alkyl Phosphates as Used in Cosmetics, Final Report 09/2014, Cosmetic Ingredient Review								
Hydrogenated Dimer	## ¹	QSAR analysis in the supplier SDS, predicted that the ingredient does not have properties that would be irritating or corrosive to the								

Ingredient (INCI name & CAS number)	Haz ard ID and list ^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
Dilinoylel/Dimethyl carbonate Copolymer 436803-57-5		skin. The chemical structure did not present a specific alert for mutagenicity or carcinogenicity. A human patch test gave a non-sensitizing result. As this is a large molecule, one can predict low dermal penetration/absorption. The raw material basis of the ingredient consists of coconut/palm oil/ soy oil/ rapeseed oil (food items) and dimethylcarbonate (low acute toxicity- LD50 > 10,000 mg/kg bw in mice and rats and NOAEL= 890mg/kg bw/day. No structural alerts for genotoxic effects; EFSA Journal 2015; 13(12): 4319. MoS= 5336. The ingredient can be considered safe at the concentration in this product (2%).								
Tocopheryl Acetate 7695-91-2	A	2014 CIR compendium, safe at use up to 36% (100% in Vitamin E oil) IJT 21(S3):51-116, 2002								
Caprylyl Glycol 1117-86-8	A	Safe when used up to 5%, Safety assessment of 1,2-glycols as used in cosmetics, International Journal of Toxicology 31 (S2), 1475-1685, 2012								
Phenoxyethanol 122-99-6	B	Safe for use when included up to 1%, CosIng Annex V/29								
Glycerin 56-81-5	A	GRAS#, FDA approved food additive, FDA approved over the counter (OTC) for skin								
Cetearyl Glucoside 67762-27-0	A	2014 CIR Compendium, safe for use when formulated to be non-irritating, International Journal of Toxicology, 32 (S3): 22-48, 2013								
Xanthan Gum 11138-66-2	A	2014 CIR Compendium safe up to 6%, Safety Assessment of Microbial Polysaccharide Gums as Use in Cosmetics, Final Report, CIR, October, 2012								
Alcohol 64-17-5	A	2014 CIR Compendium, safe for use up to 99% (when denatured). IJT 27 (S1):1-43, 2008								
Vitex Agnus Castus Extract 91722-47-3	A	Well tolerated at the recommended dosage (40-240mg) when administered orally, in 40 clinical studies involving about 8000 women over the past 50 years. Accepted for general sale, internal or external use (UK), British Herbal Compendium, Volume 2, Peter Bradley. The NOAEL was 40mg/kg in a 26 week chronic study, therefore the MoS is 40mg/0.0209 mg/kg bw/day= 1913.87, which implies a high level of safety. Also, genotoxic-mutagenic activity was not observed in the Ames/micronucleus test after treatment with 370mg/kg bw/day of the tree for 12 weeks; The Essential Guide to Herbal Safety, Simon Mills and Kerry Bone, pages 333-336								
Disodium EDTA 139-33-3	A	2014 CIR Compendium safe up to 1%, IJT 21(S2):95-142, 2002								
Sodium Hyaluronate 9067-32-7	A	Safe when used at up to 2%, IJT 28 (1): 5-67, 2009								
Sodium Hydroxide 1310-73-2	B	Safe for restricted use according to CosIng Annex III/15a								

Ingredient (INCI name & CAS number)	Haz ard ID and list ^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	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)								
Glucose 50-99-7	A	Safety Assessment of Monosaccharides, Disaccharides, and Related Ingredients as Used in Cosmetics, Final Report 03/2014, Glucose is listed in Annex IV of the European Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) which “sets out substances that are exempted from the registration, evaluation and downstream user provisions of REACH as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties. GRAS.								
Vegetable Oil 68956-68-3	A	2014 CIR Compendium, safety of vegetable oil as used in cosmetic formulations has been established, GRAS								
Chondrus Crispus (Carrageenan) Extract 244023-79-8	##	Large molecule, likely low skin absorption. In addition, Carrageenan GRAS for use in food, including use in infant formula at concentrations up to 1000 mg/L by The Joint Expert Committee on Food Additives and the World Health Organization, JECFA/79/SC. Considered acceptable for use topically.								
Ulva Lactuca Extract 97281-59-9	## ¹	Safe for use when formulated to be non-irritating. Seaweeds have a long historical use as a food source noted from the 4 th Century. France has established a specific regulation concerning the human consumption of seaweeds, the 12 authorized seaweeds include Ulva spp., Enteromorpha spp., Palmaria palmate and Undaria pinnatifida. J. Environ. Agric. Food Chem. Nutritional Value of Seaweeds. ISSN: 1579-4377.								
Enteromorpha compressa Extract ##										
Palmaria Palmata Extract 223751-74-4										
Undaria Pinnatifida Extract ##										
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 7585-39-9	A	As a dietary supplement the total oral dose may reach 500 mg/day. Studies in human volunteers have shown that cyclodextrins have a significant safety margin in dermal application, in which cyclodextrins in water or vaseline were applied on the skin for 24 hrs and their effects on cutaneous microcirculation were evaluated by laser Doppler velocimetry. Moreover, β -CD is proven not to induce either irritation or allergic contact dermatitis as evaluated by								

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	-	-	Slightly irritating to rabbit eyes	Mod. irritant - 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/kg bw/day	0.25 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 + Beta-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 + Beta-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 eta-Endorphin Stimulator will cause damage to human health when used as directed.

It is therefore concluded that Zone Daily Ultra Defence + β eta-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 cursive script, reading "Shirley H", enclosed within 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

Certificate ZA15/209535

The management system of

**Prime Product Manufacturing
(Pty) Ltd**

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

Has been assessed and certified as meeting the requirements of

ISO 22716
**Cosmetics – Guidelines on
Good Manufacturing Practices (GMP)**
(First edition 2007-11-15)

For the following activities

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

The responsibility for the quality of the individual batches of the cosmetic products labelled, packed and
stored lies with the organization

This certificate is valid from 6 August 2015 until 5 August 2018 and
remains valid subject to satisfactory surveillance audits
Re certification audit due before 10 December 2017
Issue 1. Certified since 6 August 2015

Authorised by



Peter Wierings
Certification Manager
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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.