

PRODUCT INFORMATION FILE*

RegimA

*Zone Daily Radiant Boost
+ β eta-Endorphin Stimulator*

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

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

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INTRODUCTION

PRODUCT DESCRIPTION

Product Name: Zone Daily Radiant Boost + βeta-Endorphin Stimulator

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

Pictures of the Item: On following page

Container label



NO PRINT AREA

IT - ITALIANO: Per Mista + 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 del 25°C

ES - ESPAÑOL: Pieles mixtas • Cara + Cuello
Preparación diaria • Contendido al vacío • No se puede
quitar la parte superior ya que esto dejaría que el aire y/o
las bacterias entrasean • 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: Palavras Mistas + Cara + Pescoco

Creme de Dia • Airless Container – NÃO remova a parte superior, pois isso irá 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: Комбинированная кожа • Лицо + шея Дневной уход • Герметичный контейнер • НЕ удалять верхнюю часть, так как это спровоцирует попадание воздуха и/или бактерий • Уровень продукта можно увидеть в зазоре в этикетке • Хранить при температуре ниже 25° градусов в сухом прохладном месте.

TU - TÜRK: Karma Çıkar + yüz + Boyun Gün Hazırıñ + Havañız Kul + İğne hayañ velevye bakteri girecegünden üst çukuru cikartmamızın + Ürün seviyesinde elketleki boslukta bekâlabiliriz + Serin ve kuru bir yerde 25° derecerin altında sakgefede ediniz. İkinci konu muazz

PL - POLSKI: Cera mleczana - Twarz - Sztywny Krem na dzień - Pojemnik z dozownikiem - **NIE** odkrywać gąbki, nasydi gąbkę możliwie do wprowadzić powietrze / lub bakterium - Podczas produkcji może być kontrolowany przez szczelinę w styropie - Przechowywać w temperaturze poniżej 25 °C stopni w chłodnym i suchym miejscu. Chronić przed światłem.

LTL - LIETUVOS: Mūram odos tipui + Verdas + kalkas
Dieninė odos priežiūros priemonė + Beoris buteliukas su dozatoriumi - NEATSUKITE dozatorius, nes gal patenkinti oras infarba bei kertis . Produktu kiekvieną buteliuko galimą pamaityti vertikaliuoje linijoje, esančioje ant buteliuko . Laikyti ne auksčiau nei 25 °C temperatūro, sausose ir

DA - DANSK: Hud-forbindelser • Ansigt + Hals
Dagsforbedræg • Luftfrí behølder • Åben IKKE loppet,
da det vil lukke luft og slå bakterier ind • Produkt-nivæsu-
kan ses gennem åbningen i beholderen • Opbevarer under 25°

F1 - SUOMALAINEN: Yhdet eläinhot + Kasvot + niskaa
Paluu valmistaja! • Maton paikkaus • ALÄ poista ylössä.
Jotta tuote ei pääse koskettaamaan ilman jataa bakteereiden
jatossa • Tuoteen näkyvä etikettiessä olevan raon
kautta • Säilytä alle 25 °C lämpötilassa, vilissässä, kulvissa
näkkässä. Suositustavalla.

NO - NORSK: Blandede hudtyper • Ansikt + Nakk
Dagkrem • Luttri beholder • KKE frem toppen, da dette vil
innføre mye ogjær bakterier • Produktmengden kan ses
gjennom huller på merket • Oppbevares under 25° på et
stabilt sted.

SWE • SVENSKA: Kombinerade hudtyper • Ansikte + Nacke, Dagkräm • Luftt renna • TA INTÉ bort toppen eftersom det medför att juft och värre bakterier tar sig in • Produktnivå kan ses genom gläppar i etiketten • Förvaras under 25°C • Produktens bestyrke är 10%

RO - ROMÂNĂ: Ten Mix • Față + Găi Preparat de Zi • Recipient Vidat - s NU se îndepărtează capacul, decorație ar introduce aer și/sau bacterii • Nivelul conținutului poate fi vizat prin gaura din etichetă • A se păstra la temperatură

sub 25°, într-un loc ricoros 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 moisturize and protect skin from the drying, aging effects of the sun, giving a natural healthy radiance.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Zone Daily Radiant Boost + βeta-Endorphin Stimulator base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	C12-15 Alkyl Benzoate	8	8	68411-27-8	270-112-4	Emollient	BASF (Chemgrit)	Cetiol AB
2	Diethylamino Hydroxybenzoyl Hexyl Benzoate	8	8	302776-68-7	443-860-6	UV Filter	BASF (Chemgrit)	Uvinul A Plus
3	Propylheptyl Caprylate	8	8	868839-23-0	#	Emollient	BASF (Chemgrit)	Cetiol Sensoft
4	Butylene Glycol	3.675	7	107-88-0	203-529-7	Solvent/ Skin Conditioning	Greentech (Natchem)	Phytelene Complex EGX 247 BG
	Water (Aqua)	3.283		7732-18-5	231-791-2			
	Nasturtium Officinale Extract	0.01491		84775-70-2	283-899-4			
	Arctium Lappa Root Extract	0.003045		84012-13-5	281-658-8			
	Salvia Officinalis (Sage) Leaf Extract	0.003045		84082-79-1	282-025-9			
	Citrus Limon (Lemon) Fruit Extract	0.01491		84929-31-7	284-515-8			
	Hedera Helix (Ivy) Extract	0.003045		84082-54-2	282-000-2			
	Saponaria Officinalis Extract	0.003045		84775-97-3	283-921-2			
5	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	6	6	187393-00-6	425-950-7	UV Absorber/ UV Filter	BASF (Chemgrit)	Tinosorb S
6	Dibutyl Adipate	5	5	105-99-7	203-350-4	Emollient/Skin Conditioning	BASF (Chemgrit)	Cetiol B
7	Ethylhexyl Triazone	5	5	88122-99-0	402-070-1	UV Absorber/ UV Filter	BASF (Chemgrit)	Uvinul T150
8	Niacinamide	5	5	98-92-0	202-713-4	Smoothing	DSM Nutritional Products (Chempure)	Niacinamide PC
9	Cetearyl Alcohol	3	3	67762-27-0 8005-44-5	267-008-6	Emollient/ Emulsifying/ Emulsion Stabilising	PT Musim Mas	Cetyl Stearyl Alcohol
10	Saccharomyces/Xylinum/Black Tea Ferment	2.58294	3	100085-62-9	309-204-7	Skin Conditioning	Sederma (Croda Chemicals)	Kombuchka
	Glycerin	0.3		56-81-5	200-289-5			
	Hydroxyethylcellulose	0.045		9004-62-0	#			
	Phenoxyethanol	0.03		122-99-6	204-589-7			
	Potassium sorbate	0.003		24634-61-5	246-376-			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
11			3	590-00-1		Skin Conditioning/ Skin Protecting	Sederma (Croda Chemicals)	Normaseb
	Citric acid	0.012		77-92-9 5949-29-1	201-069-1			
	Sodium citrate	0.027		68-04-2 6132-04-3	200-675-3			
	Biotin	0.00006		58-85-5	200-399-3			
	Aqua (Water)	2.061		7732-18-5	231-791-2			
12	Hydrolyzed milk protein	0.6	3	92797-39-2	296-575-2	Emulsion Stabilising	Seppic (Sharon Bolel Chemical Marketing)	Montanov L
	Glycerin	0.3		56-81-5	200-289-5			
	Phenoxyethanol	0.039		122-99-6	204-589-7			
	C14-22 Alcohols	2.385		67762-30-5/ 629-96-9/ 661-19-8/ 27836-64-2/ 54549-26-7/ 54549-27-8/ 27836-65-3/ 100231-68-3	267-009-1/ 211-119-4/ 211-546-6/ 248-685-7/ 259-219-7/ 259-220-2/ 248-686-2/ 309-369-5			
	C12-20 Alkyl Glucoside	0.6						
13	Aqua (Water)	0.009	2.5	7732-18-5	231-791-2	Emulsifying/ Surfactant	DSM Nutritional Products (Chempure)	Amphisol K
	Glucose	0.006		50-99-7	200-075-1			
	Potassium Cetyl Phosphate	2.5		84861-79-0 19035-79-1	284-374-2 242-768-			
14	Tocopheryl Acetate	2	2	7695-91-2 58-95-7	231-710-0 200-405-4	Antioxidant/ Skin Conditioning	DSM Nutritional Products (Chempure)	DL-Alpha- Tocopheryl Acetate
15	Lecithin	0.062	2	8002-43-5	232-307-2	Solvent/ Astringent/ Skin Conditioning	Mibelle (Carst & Walker)	Happybelle- PE
	Vitex Agnus Castus Extract	0.25		91722-47-3	#			
	Glycerin	0.58		56-81-5	200-289-5			
	Tetrahexyldecyl Ascorbate	0.005		183476-82-6	#			
	Tocopherol	0.01		59-02-9	200-412-2			
	Vegetable Oil	0.02		68956-68-3	273-313-5			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Cyclodextrin	0.005		7585-39-9	231-493-2			
	Alcohol	0.34		64-17-5	200-578-6			
	Aqua (Water)	0.728		7732-18-5	231-791-2			
16	Butylene Glycol	2	2	107-88-0	203-529-7	Humectant/ Skin Conditioning	Various	Butylene Glycol
17	Hydrogenated Dimer Dilinoleyl/ Dimethylcarbonate Copolymer	2	2	436803-57-5	#	Water Resistance	BASF (Chemgrit)	Cosmedia DC
18	Phenoxyethanol	0.78	1.2	122-99-6	204-589-7	Preservative/ Emollient	Thor (Actichem)	Microcare PHG
	Caprylyl Glycol	0.42		214-254-7	214-254-7			
19	Aqua (Water)	0.8	1	7732-18-5	231-791-2	Buffering	Various 20% Sodium Hydroxide Solution in Water	
	Sodium Hydroxide	0.2		1310-73-2	215-185-5			
21	Xanthan Gum	0.25	0.25	11138-66-2	234-394-2	Binding/ Emulsifying	Jungbunzlauer	Xanthan Gum
22	Disodium EDTA	0.2	0.2	139-33-3	205-358-3	Chelating/ Viscosity Controlling	Trilon BD	EDTA Na2
23	Aqua (Water)	22.55	22.55	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

not assigned

Ingredient order for the label: Aqua (Water), C12-15 Alkyl Benzoate, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Proheptyl Caprylate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Butylene Glycol, Dibutyl Adipate, Ethylhexyl Triazone, Niacinamide, Cetearyl Alcohol, Saccharomyces/Xylinum/Black Tea Ferment, Potassium Cetyl Phosphate, C14-22 Alcohols, Hydrogenated Dimer Dilinoleyl/ Dimethylcarbonate Copolymer, Tocopheryl Acetate, Glycerin, Phenoxyethanol, C12-20 Alkyl Glucoside, Hydrolyzed milk protein, Caprylyl Glycol, Alcohol, Melissa Officinalis Leaf Oil, Vitex Agnus Castus Extract, Xanthan Gum, Disodium EDTA, Sodium Hydroxide, Lecithin , Hydroxyethylcellulose, Sodium citrate, Vegetable Oil, Citrus Limon (Lemon) Fruit Extract, Nasturtium Officinale Extract, Citric acid, Tocopherol, Glucose, Tetrahexyldecyl Ascorbate, Cyclodextrin, Arctium Lappa Root Extract, Hedera Helix (Ivy) Extract, Salvia Officinalis (Sage) Leaf Extract, Saponaria Officinalis Extract, Potassium sorbate, Biotin.

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

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

Fragrance allergens*

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

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

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

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

Physical and Chemical Characterization of the product

1 Physical state	Cream
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Cream
3 organoleptic properties (colour, odour, whenever relevant)	Yellow, characteristic odour
4 pH (at 25°C)	5.65
5 viscosity (at 25°C)	18000 cPs
6 thermal stability (glass bottle)	Stable at 50°C for 4 weeks
7 Specific gravity	0.943 g/ml

Stability of the product

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

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass bottles has confirmed stability at 50°C for 4 weeks at which time point there was minor changes in odour and viscosity. The pH value did not affect the safety and tolerability of the product.

A.3 Microbiological Quality

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

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

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

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

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

A.5 Normal and reasonably foreseeable use

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

A.6 Exposure to the Cosmetic Product

Site of application	Face and neck (avoiding the eye area)
Surface area of application (cm ²)	565 cm ² (note there are no default values for the neck)
Volume of product applied (ml)	0.50 ml (2 pump depressions)
Frequency of application/use per day	1
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	0.50 ml exposure daily Estimated exposure based on 60kg adult= 8.34 mg/kg bw/day
Dermal absorption information	Unknown
other	

A.7 Exposure to the Substances

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

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
C12-15 Alkyl Benzoate 68411-27-8	8.0	8.34	1	0.6672
Diethylamino Hydroxybenzoyl Hexyl Benzoate 302776-68-7	8.0	8.34	1	0.6672
Propylheptyl Caprylate 868839-23-0	8.0	8.34	1	0.6672
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine 187393-00-6	6.0	8.34	1	0.5004
Butylene Glycol 107-88-0	5.7	8.34	1	0.4733
Dibutyl Adipate 105-99-7	5.0	8.34	1	0.4170
Ethylhexyl Triazone 88122-99-0	5.0	8.34	1	0.4170
Niacinamide 98-92-0	5.0	8.34	1	0.4170
Cetearyl Alcohol 67762-27-0	3.0	8.34	1	0.2502
Saccharomyces/Xylinum/Black Tea Ferment 100085-62-9	2.6	8.34	1	0.2154
Potassium Cetyl Phosphate 84861-79-0	2.5	8.34	1	0.2085
C14-22 Alcohols 67762-30-5/629-96-9/661-19- 8/27836-64-2/54549-26-7/54549-27- 8/27836-65-3/100231-68-3	2.4	8.34	1	0.1989
Hydrogenated Dimer Dilinoleyl/ Dimethylcarbonate Copolymer 436803-57-5	2.0	8.34	1	0.1668
Tocopheryl Acetate 7695-91-2	2.0	8.34	1	0.1668
Glycerin 56-81-5	1.2	8.34	1	0.0984
Phenoxyethanol 122-99-6	0.85	8.34	1	0.0708

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

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
84012-13-5				
Hedera Helix (Ivy) Extract 84082-54-2	0.003	8.34	1	0.0003
Salvia Officinalis (Sage) Leaf Extract 84082-79-1	0.003	8.34	1	0.0003
Saponaria Officinalis Extract 84775-97-3	0.003	8.34	1	0.0003
Potassium sorbate 24634-61-5	0.003	8.34	1	0.0003
Biotin 58-85-5	0.0001	8.34	1	0.00001

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

A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^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 diethylamino hydroxybenzoyl hexyl benzoate at a maximum concentration of 10% w/w in cosmetic products, including sunscreen products does not pose a risk to the health of the consumer; SCCP/1166/08.				
Propylheptyl Caprylate 868839-23-0	-	-	Slightly irritating to rabbit eyes	Moderately irritating- however ingredient was applied neat (amount not specified) on 3 female SPF albino rabbits after a 4h semi-occlusive patch. Dermal application of 2000 mg/kg bw (applied semi-occlusive	Non-sensitizer (LLNA)	Non-irritant, 48h occlusive application with 50% propylheptyl (0.2ml test material applied)- no dermal effects.	≥1000 mg/mg bw/day	0.6672 mg/kg bw/day	1498.8	Maximum concentration of use for a leave on product was 13% up to 2012. Not mutagenic with/without metabolic activation (Ames), not clastogenic (Chromosome aberration test). Reference: Amended Safety Assessment of Alkyl Esters as Used in Cosmetics, 03/2013.

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
				and neat) had no reported irritation (Wistar rats)						
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine 187393-00-6	A			Safe for use in cosmetic products as a UV light absorber at a maximum concentration of 10%, SCCNFP/0082/98						
Butylene Glycol 107-88-0	A			Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006						
Dibutyl Adipate 105-99-7	A			2014 CIR Compendium, concentration not reported in 2010; safe for use up to 8% in 1996; IJT 25(S1):129-134, 2006 JACT, 15(4):295-300, 1996 (original Report); Final report 12/10 available from CIR						
Ethylhexyl Triazone 88122-99-0	A			Maximum concentration in ready for use concentration 5%, Annex VI of Regulation (EC) 1223/2009						
Niacinamide 98-92-0	A			2014 CIR Compendium, Safe for use up to 3%, International Journal of Toxicology 24(S5): 1-31, 2005						
Cetearyl Alcohol 67762-27-0	A			2014 CIR Compendium, safe at use up to 25% JACT 7(3):359-413, 1988 confirmed 12/05						
Saccharomyces/Xylinum/Black Tea Ferment 100085-62-9	#			Traditional food item, GRAS, contains preservative to control possible bacterial contamination.						
Potassium Cetyl Phosphate 84861-79-0	A			Safe for use when formulated to be non-irritating, Safety Assessment of Alkyl Phosphates as Used in Cosmetics, 09/2014						
C14-22 Alcohols 67762-30-5/629-96-9/661-19- 8/27836-64-2/54549-26- 7/54549-27-8/27836-65- 3/100231-68-3	## ¹			2014 CIR Compendium, C14, is safe up to 5% (JACT 7(3):359-413, 1988 confirmed, 12/05), C16 is safe up to 50% (JACT 7(3):359-413, 1988 confirmed 12/05), C18 is safe up to 25% (JACT 4(5):1-29, 1985 confirmed 03/04 IJT 25(S2), 2006) and C22 is safe up to 50% (JACT 7(3):359-413, 1988 confirmed 12/05). The maximum concentration of C14-22 Alcohols in this product is 2.385%- which is <50% of the worst case % presented in the CIR compendium. Therefore it is not expected that any of the other C _n - alcohols would be present at a % unsafe for use, especially considering there is a mix of 9						

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment		
			alcohols in 2.385%.									
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%).										
Tocopheryl Acetate 7695-91-2	A	2014 CIR compendium, safe at use up to 36% (100% in Vitamin E oil) IJT 21(S3):51-116, 2002										
Glycerin 56-81-5	A	Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin										
Phenoxyethanol 122-99-6	B	Safe for use when included up to 1%, CosIng Annex V/29										
C12-20 Alkyl Glucoside 67762-30-5/629-96-9/661-19- 8/27836-64-2/54549-26- 7/54549-27-8/27836-65- 3/100231-68-3	A	Safe for use in cosmetics when formulated to be non-irritating; International Journal of Toxicology 32 (S3): 22-48, 2013										
Hydrolyzed milk protein 92797-39-2	#	Hydrolyzed Source Proteins as Used in Cosmetics, 05/2012; Milk intended for human consumption, a human skin prick test of 2160 adults showed no adverse reactions, considered non-sensitizing, GRAS.										
Caprylyl Glycol 1117-86-8	A	Safe when used up to 5%, Safety assessment of 1,2-glycols as used in cosmetics, International Journal of Toxicology 31 (S2), 1475-1685, 2012										
Alcohol 64-17-5	A	2014 CIR Compendium, safe for use up to 99% (when denatured). IJT 27 (S1):1-43, 2008										
Melissa Officinalis Leaf Oil 84082-61-1	A	Assessment report on Melissa officinalis L., folium, EMA/HMPC/196746/2012; Long-standing medicinal use and experience of Melissa officinalis L., folium has been documented within the EU. During this time, no clinical signals that Melissa officinalis L., folium is harmful under the specified conditions of use have been identified (oral doses up to 4.5g taken several times a day identified).										

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment	
Vitex Agnus Castus Extract 91722-47-3	A					Well tolerated at the recommended dosage (40-240mg) when administered orally, in 40 clinical studies involving about 8000 women over the past 50 years. Accepted for general sale, internal or external use (UK), British Herbal Compendium, Volume 2, Peter Bradley. The NOAEL was 40mg/kg in a 26 week chronic study, therefore the MoS is 40mg/0.0209 mg/kg bw/day= 1913.87, which implies a high level of safety. Also, genotoxic-mutagenic activity was not observed in the Ames/micronucleus test after treatment with 370mg/kg bw/day of the tree for 12 weeks; The Essential Guide to Herbal Safety, Simon Mills and Kerry Bone, pages 333-336					
Xanthan Gum 11138-66-2	A					2014 CIR Compendium safe up to 6%, Safety Assessment of Microbial Polysaccharide Gums as Use in Cosmetics, Final Report, CIR, October, 2012					
Disodium EDTA 139-33-3	A					2014 CIR Compendium safe up to 1%, IJT 21(S2):95-142, 2002					
Sodium Hydroxide 1310-73-2	B					Safe for restricted use according to CosIng Annex III/15a					
Lecithin 8002-43-5	A					2014 CIR compendium safe as 15% in leave-on products but not to be used in products where N-nitroso compounds may be formed. IJT 20(S1):21-45, 2001. Note formulation contains N-nitroso inhibitors such as Tocopherol and potassium sorbate)					
Hydroxyethylcellulose 9004-62-0	A					Safe when used up to 6%; JACT 5(3):1-59, 1986					
Sodium citrate 68-04-2	A					2014 CIR Compendium, safe for use up to 10%, IJT 33 (S2): 16-46, 2014					
Vegetable Oil 68956-68-3	A					2014 CIR Compendium, safety of vegetable oil as used in cosmetic formulations has been established, GRAS					
Citrus Limon (Lemon) Fruit Extract 84929-31-7	#					Annex II/358 R1, Furocoumarines (e.g. trioxysalen (INN), 8-methoxypsonalen, 5-methoxypsonalen) except for normal content in natural essences used. Restriction does not apply as this ingredient is a natural essence; GRAS					
Nasturtium Officinale Extract 84775-70-2	#					Watercress is a food item and systemic toxicity is acceptable. The supplier notes it is a non-irritant and considering its oral consumption, it can be assumed that watercress is safe for dermal use.					
Citric acid 77-92-9	A					Safe up to 39%, International Journal of Toxicology 33(S2), 16-46, 2014					
Tocopherol	A					Safe when used up to 1%; IJT 21(S3):51-116, 2002; Final report 03/2014 CIR Compendium, 2014					

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Extract 84082-79-1										(up to 3g leaf steeped in water) under the conditions specified in the monograph. Also, traditional medicinal use of sage leaf has been found to fulfil the requirement of medicinal use for at least 30 years according to Directive 2004/24/EC for numerous indications including the traditional herbal medicinal product for relief of minor skin inflammations. Doc. Ref.: EMA/HMPC/330383/2008.
Saponaria Officinalis Extract 84775-97-3	A									Herbal use: long used as gentle soap, used in brewing to create 'head' on beer. Can be regarded as GRAS due to long history of external use for skin problems, psoriasis, eczema etc. Reference unavailable.
Potassium sorbate 24634-61-5	A									2014 CIR Compendium safe up to 1%, JACT 7(6):837-80, 1988 confirmed 04/06
Biotin 58-85-5	A									Safe up to 1%, International Journal of Toxicology 20(S4), 1-12, 2001

^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:

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

A.9 Undesirable Effects and Serious Undesirable Effects

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

A.10 Information on the Cosmetic Product

Zone Daily Radiant Boost + βeta-Endorphin Stimulator was released in 2015. Over the period June 2015 to April 2016, 5734 units have been sold and there have been no adverse reactions reported to RegimA.

B: Part Cosmetic Product Safety Assessment

B.1 Assessment Conclusion

Review of the ingredients

After analysis of all the available information including:

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

It is not expected that Zone Daily Radiant Boost + βeta-Endorphin Stimulator will cause damage to human health when used as directed.

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

Review of human data on the product

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

B.2 Label Warnings and Instructions for Use

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

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

No label warnings are required.

B.3 Reasoning

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

This product is intended for external use in adults only.

B.4 Assessors Credentials and Approval of Part B

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

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

A handwritten signature in black ink, appearing to read "Shirley H", is written over a horizontal line. To the right of the signature is a vertical line forming a small rectangular box.

List of References

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 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.