

PRODUCT INFORMATION FILE*

RegimA

Zone ‘Acne Attack’ Rescue
Serum

Prepared: June 2017
(Label & packaging update August 2021)

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

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INTRODUCTION

PRODUCT DESCRIPTION

Product Name: Zone ‘Acne Attack’ Rescue Serum

Product type	Post-peel gel
Form	Cream gel
Colour	Off white
Pack size	50ml
Pack type	WSZ Airless Bottle
Dispenser type	N/A
Part of a set	No
Manufacturer code	RPPG 002
Normal use	Leave-on face cream gel

Pictures of the Item: On following page

Container label



Carton label



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

Product claims:

This product claims to help alleviate the difficulties associated with a problematic skin. An abundance of plants, including Meadowsweet, help control oil production, visibly reducing pore size and minimizing the appearance of blackheads and spots for a more refined appearance.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Zone 'Acne Attack' Rescue Serum base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Isostearyl Alcohol	3.06	6	27458-93-1	248-470-8	Emollient/ Skin Conditioning/ Viscosity Controlling/ Binding	Gattfossé (Inc cosmetics)	Emulfree CBG
	Butylene Glycol Cocoate	2.646		73138-39-3/ 32074-61-6	277-288-1			
	Ethylcellulose	0.294		9004-57-3	#			
2	Butylene Glycol	2.75	5	107-88-0	203-529-7	Humectant/ Masking/ Viscosity Controlling/ Skin Conditioning/ Skin Protecting	Greentech (Natchem)	Cosmelene Passion Flower
	Aqua (Water)	2.1		7732-18-5	231-791-2			
	Passiflora Incarnata Flower Extract	0.15		84012-31-7/ 72968-47-9	277-142-7			
3	Capryloyl Glycine	1.1	4	14246-53-8	238-122-3	Cleansing/ Surfactant/ Skin Conditioning/ Antimicrobial /Antioxidant / Astringent/ Emollient/ Humectant/ Perfuming/ Skin Conditioning/ Skin Protecting	Seppic (CJP)	Sepicontrol A5
	Sarcosine	0.38		107-97-1	203-538-6			
	Cinnamomum Zeylanicum Bark Extract	0.12		84649-98-9	283-479-0			
	Hexylene glycol	0.88		107-41-5	203-489-0			
	Aqua (Water)	1.52		7732-18-5	231-791-2			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
4	Aqua (Water)	1.924	4	7732-18-5	231-791-2	Astringent/ Skin Conditioning/ Tonic/ Humectant/ Masking/ Viscosity Controlling	Silab (Mehanede)	Dermapur HP
	Butylene Glycol	2		107-88-0	203-529-7			
	Spiraea Ulmaria Extract	0.076		84775-57-5	283-886-3			
5	Decyl Isostearate	1.53	3	84605-08-3	283-388-6	Emollient/ Skin Conditioning/ Binding	Croda Chemicals	Crodamol SSA
	Isostearyl Isostearate	1.47		41669-30-1	255-485-3			
6	Caprylyl Methicone	2.997	3	17955-88-3	241-881-3	Skin Conditioning/ Solvent	Momentive (Savannah Fine Chemicals)	Silsoft 034
	Octene	0.003		111-66-0	203-893-7			
7	Rosa Canina Fruit Oil	3	3	84696-47-9/ 84603-93-0	283-652-0	Emollient/ Skin Conditioning	Seatons (Croda)	Rosehip Oil
8	Ribes Nigrum (Black Currant) Seed Oil	3	3	68606-81-5/ 97676-19-2	271-749-0	Emollient	Sharon Bolel Chemical Marketing	Blackcurrant Oil
9	Octyldodecyl Myristate	1.02	2	22766-83-2	245-205-8	Emollient/ Skin Conditioning	Gatlefossé (Carst & Walker)	Gatuline Derma-Sensitive
	Capparis Spinosa Fruit Extract	0.98		89958-23-6	289-646-4			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
10	Glycerin	2	2	56-81-5	200-289-5	Humectant/Perfuming/Skin Conditioning/Viscosity Controlling	Various	Glycerine CP
11	T-Butyl Alcohol	0.08	2	75-65-0	200-889-7	Perfuming/Solvent/Viscosity Controlling/Emulsion Stabilising	Seppic (CJP)	SepiMax ZEN
	Aqua (Water)	0.02		7732-18-5	231-791-2			
	Polyacrylate Crosspolymer-6	1.9		#	#			
12	Phenoxyethanol	0.975	1.5	122-99-6	204-589-7	Emollient/Humectant/Skin Conditioning/Preservative	Thor (Actichem)	Microcare PHG
	Caprylyl Glycol	0.525		1117-86-8	214-254-7			
13	Xanthan Gum	0.5	0.5	11138-66-2	234-394-2	Binding/Emulsifying/Emulsion Stabilising/Gel forming/Skin Conditioning/Surfactant/Viscosity Controlling	CP Kelco (Tranarc)	Keltrol CG-T
14	Aqua (Water)	61	61	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

not assigned

Ingredient order for the label: Aqua (Water), Butylene Glycol, Isostearyl Alcohol, Ribes Nigrum (Black Currant) Seed Oil, Rosa Canina Fruit Oil, Caprylyl Methicone, Butylene Glycol Cocoate, Glycerin, Polyacrylate Crosspolymer-6, Decyl Isostearate, Isostearyl Isostearate, Capryloyl Glycine, Octyldodecyl Myristate, **Capparis Spinosa** Fruit Extract, Phenoxyethanol, Hexylene glycol, Caprylyl Glycol, Xanthan Gum, Sarcosine, Ethylcellulose, Passiflora Incarnata Flower Extract, Cinnamomum Zeylanicum Bark Extract, T-Butyl Alcohol, Spiraea Ulmaria Extract, Octene

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 ‘Acne Attack’ Rescue Serum does not contain a fragrance

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

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

Physical and Chemical Characterization of the product

1 Physical state	Cream gel
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Cream gel
3 organoleptic properties (colour, odour, whenever relevant)	Off white, characteristic odour
4 pH (at 25°C)	5.55
5 viscosity (at 25°C)	65,600 cPs
6 thermal stability (glass bottle)	12 weeks at 50°C
7 Specific gravity	0.974 /ml

Stability of the product

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

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass bottles has confirmed stability at 50°C for 12 weeks. At this time and at an elevated temperature, the product appeared slightly darker and the pH, viscosity and specific gravity dropped slightly, however this is thought not to effect the functionality 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 ‘Acne Attack’ Rescue Serum is a product designed to help alleviate the difficulties associated with a problematic skin. It is a leave-on product that in normal circumstances will be used twice daily on the face and neck if affected, 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	2
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	0.5ml exposure daily Estimated exposure based on 60 kg adult =8.34 mg/kg bw/day
Dermal absorption information	Unknown
other	Face and neck (avoiding the eye area)

A.7 Exposure to the Substances

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

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Butylene Glycol	4.75	16.67	1	0.79
Isostearyl Alcohol	3.06	16.67	1	0.51
Ribes Nigrum (Black Currant) Seed Oil	3	16.67	1	0.50
Rosa Canina Fruit Oil	3	16.67	1	0.50
Caprylyl Methicone	2.997	16.67	1	0.50
Butylene Glycol Cocoate	2.646	16.67	1	0.44
Glycerin	2	16.67	1	0.33
Polyacrylate Crosspolymer-6	1.9	16.67	1	0.32
Decyl Isostearate	1.53	16.67	1	0.26
Isostearyl Isostearate	1.47	16.67	1	0.25
Capryloyl Glycine	1.1	16.67	1	0.18
Octyldodecyl Myristate	1.02	16.67	1	0.17
Capparis Spinosa Fruit Extract	0.98	16.67	1	0.16
Phenoxyethanol	0.975	16.67	1	0.16
Hexylene glycol	0.88	16.67	1	0.15
Caprylyl Glycol	0.525	16.67	1	0.088
Xanthan Gum	0.5	16.67	1	0.083
Sarcosine	0.38	16.67	1	0.063
Ethylcellulose	0.294	16.67	1	0.049
Passiflora Incarnata Flower Extract	0.15	16.67	1	0.025
Cinnamomum Zeylanicum Bark Extract	0.12	16.67	1	0.020

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)
T-Butyl Alcohol	0.08	16.67	1	0.013
Spiraea Ulmaria Extract	0.076	16.67	1	0.013
Octene	0.003	16.67	1	0.0005

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
Butylene glycol CAS:107-88-0	A									Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006
Isostearyl Alcohol 27458-93-1	A									2014 CIR Compendium, safe at use up to 50%, JACT 7(3):359-413, 1988 confirmed 12/05
Ribes Nigrum Seed Oil 68606-81-5	A									2014 CIR Compendium, safe up to 0.3%, Final report 03/2013 (CIR) current formulation has 2%, Food item GRAS.
Rosa Canina Fruit Oil 84696-47-9	A									2014 CIR Compendium, safe up to 19%, Final report 03/2013 (CIR)
Caprylyl Methicone 17955-88-3	A									Read across to stearoxy dimethicone: 2014, CIR Compendium, safe at use up to 3%, IJT 22(S2): 11-35, 2003 and alkyl methicones are considered safe as used in cosmetic formulations. FDA: has approved products which contain this ingredient.
Butylene Glycol Cocoate 73138-39-3	A									2014 CIR Compendium, Safe for use up to 2%, IJT 30(S1):5S-16S, 2011
Glycerin 56-81-5	A									Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin
Polyacrylate Crosspolymer-6 No CAS number available	C	-	Slightly irritating	Non- irritant	Non- sensitizing	Non- sensitizing and non- irritating in humans at ~5%	Not available	Not available	Not available	Not genotoxic (negative bacterial reverse mutation). Based on

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
										assumed low hazard (meets the NICNAS polymer of low concern criteria) and assessed use pattern (up to 5% in cosmetics), not considered to be an unreasonable health risk
Decyl Isostearate 84605-08-3	A	2014 CIR Compendium, Safe for use when formulated to be non-irritating, Final report 03/2013 available from CIR								
Isostearyl Isostearate 41669-30-1	A	2014 CIR Compendium, Safe (when formulated to be non-irritating), Final report 03/2013 (CIR)								
Capryloyl Glycine	A	2014 CIR Compendium, Safe (when formulated to be non-irritating), Final report 12/2013 (CIR)								
Octyldodecyl Myristate	A	2014 CIR Compendium, Safe (when formulated to be non-irritating), Final report 12/2013 (CIR)								
Capparis Spinosa Fruit Extract	#	Capers are a food item and systemic toxicity is acceptable. Considering its food item status, it can be assumed safe systemically when applied dermally. Whilst dermal tolerance when applied topically is unknown the label carries the warning 'if irritation occurs, discontinue use'								
Phenoxyethanol	B	2014 CIR Compendium safe up to 1%, JACT 9(2):259-77, 1990								

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
122-99-6										
Hexylene glycol	A									
Caprylyl Glycol 1117-86-8	A									
Xanthan Gum 11138-66-2	A									
Sarcosine	A									
Ethylcellulose 9004-57-3	A									
Passiflora Incarnata Flower Extract	A									
Cinnamomum Zeylanicum Bark Extract	#									
T-butyl alcohol	A									

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
75-65-0										
Spiraea Ulmaria Flower Extract 84775-57-5	A	Meadowsweet, also known as Dropwort (<i>Filipendula ulmaria</i>): https://www.globalherbalsupplies.com/herb_information/meadowsweet.htm Used as a herbal medicine at up to 6g for tea preparation, considered not harmful considering the long period of marketing experience without reports of adverse effects and the results of preclinical studies by the European Medicines Agency: EMA/HMPC/434892/2010. Topical tolerance of this ingredient is unknown, however, the label carries the warning 'if irritation occurs, discontinue use'.								
Octene	A	No safety concern when ingested through diet at up to 1800 ug/day (= 1.8 mg/day). Exposure to octane in this formulation is 0.005 mg/day. Dermal absorption is unknown, however even considering a 100% absorption rate, the concentration within this product is 360 times less than the dietary threshold of concern; WHO Technical Report Series, Evaluation of certain food additives, seventy-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. http://apps.who.int/iris/bitstream/10665/150883/1/9789241209908_eng.pdf#page=74 Topical tolerance of this ingredient is unknown, however, the label carries the warning 'if irritation occurs, discontinue use'.								

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

^b all possible routes of exposure should be considered

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

Food item, hazard and exposure data not required.

Fragrances:

Zone ‘Acne Attack’ Rescue Serum does not contain a fragrance.

A.9 Undesirable Effects and Serious Undesirable Effects

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

A.10 Information on the Cosmetic Product

Zone ‘Acne Attack’ Rescue Serum was released in 2016. Over the period August 2016 to May 2016, 1927 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 ‘Acne Attack’ Rescue Serum will cause damage to human health when used as directed.

It is therefore concluded that Zone ‘Acne Attack’ Rescue Serum can be placed on the market in the EU as a serum.

Review of human data on the product

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

B.2 Label Warnings and Instructions for Use

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

AM and PM: Cleanse with RegimA. Apply 2 pump depressions of ‘Rescue’ Serum to the face and neck if affected, avoiding the eye area. To be followed by appropriate RegimA day and night care, which must always include a RegimA day product containing sun protection. [if irritation occurs, discontinue use].

Warnings: ‘If irritation occurs, discontinue use’.

‘Avoid contact with eyes’

B.3 Reasoning

This product contains many ingredients with a positive reputation for their properties which help alleviate the difficulties associated with a problematic skin 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 daily moisturizer and sun protectant.

A handwritten signature in black ink, appearing to read "Shirley H". The signature is fluid and cursive, with a large, stylized 'H' at the end.

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

Not applicable.

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.