

PRODUCT INFORMATION FILE*

RegimA

Zone 50 Power Peel
Natural Exfoliating Gel
- Advanced Masque

Prepared: May 2016
(Label & packaging update August 2021)

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

TABLE OF CONTENTS

Contents

INTRODUCTION	3
PRODUCT DESCRIPTION.....	3
COSMETIC PRODUCT SAFETY REPORT	7
Part A: Cosmetic Product Safety Information	7
A.1 Quantitative and qualitative composition of the cosmetic product:	7
A.2 Physical /chemical characteristics and stability of the cosmetic product	10
A.3 Microbiological Quality	11
A.4 Impurities, traces, information about the packaging material	11
A.5 Normal and reasonably foreseeable use	11
A.6 Exposure to the Cosmetic Product.....	11
A.7 Exposure to the Substances	12
A.8 Toxicological Profile of the Substances	14
A.9 Undesirable Effects and Serious Undesirable Effects	18
A.10 Information on the Cosmetic Product	18
B: Part Cosmetic Product Safety Assessment.....	19
B.1 Assessment Conclusion	19
B.2 Label Warnings and Instructions for Use	20
B.3 Reasoning	21
B.4 Assessors Credentials and Approval of Part B	21
List of References	22
METHOD OF MANUFACTURE / GMP CERTIFICATION.....	23
PROOF OF EFFECT CLAIMED.....	24
ANIMAL TESTING STATEMENT	24
Appendix 1: Safety Data Sheets or Ingredient Specifications	25
Appendix 2: Microbial Challenge Test.....	26
Appendix 3: Certificates of Allergen Content	27
Appendix 4: Miscellaneous.....	28

INTRODUCTION

PRODUCT DESCRIPTION

Product Name: Zone 50 Power Peel Natural Exfoliating Gel - Advanced Masque

Product type	Exfoliating masque
Form	Gel
Colour	Brown
Pack size	50ml
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	50P 002
Normal use	In-salon use only. Apply 2 pump depressions to the face, avoiding the eye area and neck. Allow 10 to 15 minutes before removing by cleansing thoroughly with RegimA cleanser. This is an in-salon masque applied as part of a RegimA facial, ideally every 4-6 weeks.

Pictures of the Item: On following page

Container label

THE **ZONE**

**POWER
PEEL**

50

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

RÉGIMA IS AGAINST ANIMAL TESTING

**NATURAL EXFOLIATING TREATMENT
IN-SALON PRODUCT**

Directions for use:

To be used by Medical Practitioners and Trained Skin Care Professionals following comprehensive RégimA training and instructions for application, removal and post-peel care.

Only applied to clients on RégimA home care essentials.

IN-SALON: Cleanse with RégimA. Apply 2 pump depressions of the Power Peel to the face, avoiding the eye area and neck. (May tingle and itch on application) Allow 10 to 15 minutes before removing by cleansing thoroughly with RégimA cleanser.

Follow with RégimA home care, which must include a product containing sun protection.

MUST NOT be combined with any other product range

NOT FOR RETAIL
 STRICTLY IN-SALON MASQUE FOR USE BY A RÉGIM A
 TRAINED PROFESSIONAL SKIN CARE THERAPIST

SUITABLE FOR ADULTS ONLY
 KEEP OUT OF REACH OF CHILDREN

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 77°F / 25°C IN A COOL
 DRY PLACE. PROTECT FROM LIGHT

50 ml. e Net 1.69 fl. oz.

Carton label

Ingredients

Lactic Acid, Aqua (Water), Malic Acid, Hydrogenated Polydecene, Citric Acid, Propylene Glycol, Butylene Glycol, Panthenol, Polyacrylate Crosspolymer-6, Silica Dimethyl Silylate, Decarboxy Carnosine HCl, Prunus Persica (Peach) Leaf Extract, Rubus Idaeus (Raspberry) Fruit Extract, Pyrus Malus (Apple) Fruit Extract, Centella Asiatica Extract, Hypericum Perforatum Extract, Ascorbic Acid, Xanthan Gum, Phenylethanol, Caprylyl Glycol, T-Butyl Alcohol

This New Generation peeling system incorporates a host of actives which impart added healing and rejuvenation effects. The unique gel consistency allows for easy application, excellent patient/client tolerance, shorter down time. The Power Peel offers a combination of 8 powerful fruit acids including Peach, Raspberry and Apple, which have a lightening effect superior to hydroquinone with 100% safety. With the addition of healing plants, renowned for essential anti-inflammatory and antioxidant action, RégimA takes skin peeling to a more therapeutic level, but with safety.

- Totally New Generation Treatment
- Contains 8 Natural Acids:** Peach, Raspberry, Apple, plus healing, exfoliating, smoothing active ingredients
- More Rapid Exfoliating Action
- Shorter Treatment Time
- Minimized Down Time
- Smooths Fine Lines And Wrinkles
- Rapid Radiance, Instant smoothing
- Peeling with Healing
- Skin Lightening, Brightening
- Helps Eliminate & Control Pigmentation
- Helps Treat Breakouts
- Helps Improve Scarring
- Safe For Face & Body
- Natural Formula, Not Chemically Buffered

NATURAL EXFOLIATING TREATMENT

Directions for use:


To be used by Medical Practitioners and Trained Skin Care Professionals following comprehensive RégimA training and instructions for application, removal and post-peel care.

Only applied to clients on RégimA home care essentials.

IN-SALON: Cleanse with RégimA. Apply 2 pump depressions of the Power Peel to the face, avoiding the eye area and neck. (May tingle and itch on application). Allow 10 to 15 minutes before removing by cleansing thoroughly with RégimA cleanser.

Follow with RégimA home care, which must include a product containing sun protection.

MUST NOT be combined with any other product range



POWER PEEL

In-Salon Treatment

50

50 ml. e Net 1.69 fl. oz.

RégimA™
International Skin Treatments
50 Van Buren Road, Westborough, MA 01581
Scouting, South Africa
www.regima.zone
Manufactured in South Africa
EU - RFI CS Europe: The Greenway, Millbury Court, St. Stephens Green, Dublin, Ireland
US - RFI CS USA: The Greenway, Millbury Court, St. Stephens Green, Dublin, Ireland
UK - FDA - T-Butyl Alcohol

RégimA IS AGAINST ANIMAL TESTING.

50 Power Peel - 50ml

0 781718 199087

NOT FOR RETAIL
SPECIAL IN-SALON TREATMENT FOR TRAINED PROFESSIONALS ONLY
SUSCEPTIBLE TO ADULTS ONLY
RESPONSIBLE OF REACH FOR CHILDREN

AIRLESS CONTAINER
DO NOT REMOVE TOP.
DO NOT REWASH INTO PRODUCT ANY
ADULTOR BACTERIA

PRODUCT LEVEL CAN BE VIEWED THROUGH THE GAP IN LABEL

STORE BELOW 77°F / 25°C IN A COOL DRY PLACE. PROTECT FROM LIGHT

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 visibly help improve the appearance of most skins and make the signs of aging less prominent.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Zone 50 Power Peel NE Gel- Advanced Masque base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Lactic Acid	24.5	25	79-33-4 50-21-5	201-196-2 200-018-0	Skin conditioning	Purac	Lactic Acid 90%
	Aqua (Water)	0.5		7732-18-5	231-791-2			
2	Malic Acid	22.5	22.5	6915-15-7 97-67-6	230-022-8 202-601-5	Skin conditioning	Merck KGaA	Malic Acid BP
3	Hydrogenated Polydecene	10	10	68037-01-4	500-183-1	Emollient	IMCD	Dekanex 2006
4	Citric Acid	5	5	77-92-9	201-069-1	Buffering	Merck KGaA	Citric Acid BP
5	Aqua (Water)	2.4175	5	7732-18-5	231-791-2	Humectant/ Skin conditioning	Greentech (Natchem)	Rayolys D
	Propylene Glycol	2.4675		57-55-6	200-338-0			
	Prunus Persica (Peach) Leaf Extract	0.08		84012-34-0	281-678-7			
	Rubus Idaeus (Raspberry) Fruit Extract	0.01		84929-76-0	284-554-0			
	Pyrus Malus (Apple) Fruit Extract	0.01		85251-63-4	286-475-7			
	Ascorbic Acid	0.015		50-81-7	200-066-2			
6	Butylene Glycol	3	3	107-88-0	107-88-0	Humectant	Daicel Chemical Industries Ltd	Butylene Glycol
7	Aqua (Water)	0.97	2	7732-18-5	231-791-2	Solvent/ Antimicrobial/ Skin protecting/ Soothing	Greentech (Natchem)	St. John's Wort Hydroglycolic Extract (300837)
	Propylene Glycol	0.971		57-55-6	200-338-0			
	Hypericum Perforatum Extract	0.059		84082-80-4	282-026-4			
8	Decarboxy Carnosine HCl	0.2	2	57022-38-5	415-470-6	Skin conditioning	Exsymol	Alistin P5

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Butylene Glycol	0.1636		107-88-0	203-529-7		(Akulu Marchon)	
	Water	1.6164		7732-18-5	231-791-2			
	Phenoxyethanol	0.02		122-99-6	204-589-7			
9	Aqua (Water)	0.926	2	7732-18-5	231-791-2	Humectant/ Skin conditioning	Greentech SA (Natchem)	Phytelene EG 356 Centella Asiatica
	Propylene Glycol	1.05		57-55-6	200-338-0			
	Centella Asiatica Extract	0.024		84696-21-9	283-640-5			
10	Panthenol	2	2	81-13-0	201-327-3	Skin conditioning	Zhejiang Xinfu Biochemical	D-Panthenol
11	Polyacrylate Crosspolymer-6	1.9	2	#	#	Emulsion stabilising	Seppic (CJP)	SepiMax ZEN
	T-butyl alcohol	0.1		75-65-0	200-889-7			
12	Phenoxyethanol	0.75	1.5	122-99-6	204-589-7	Emollient/ Preservative	Acti-Chem	Microcare PHG
	Caprylyl Glycol	0.75		1117-86-8	214-254-7			
13	Silica Dimethyl Silylate	1	1	68611-44-9	271-893-4	Anticaking	Evonik Degussa (Protea Speciality Chemicals)	Aerosil R 972
14	Xanthan Gum	0.3	0.3	11138-66-2	234-394-2	Binding	Jungbunzlauer	Xanthan Gum
15	Aqua (Water)	16.7	16.7	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

not assigned

Ingredient order for the label: Lactic Acid, Aqua (Water), Malic Acid, Hydrogenated Polydecene, Citric Acid, Propylene Glycol, Butylene Glycol, Panthenol, Polyacrylate Crosspolymer-6, Silica Dimethyl Silylate, **Phenoxyethanol, Caprylyl Glycol, Xanthan Gum, Decarboxy Carnosine HCl, T-butyl alcohol, Prunus Persica (Peach) Leaf Extract, Hypericum Perforatum Extract, Centella Asiatica Extract, Ascorbic Acid, Pyrus Malus (Apple) Fruit Extract, Rubus Idaeus (Raspberry) Fruit Extract**

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 50 Power Peel Natural Exfoliating Gel- Advanced Masque 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	Gel
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Gel
3 organoleptic properties (colour, odour, whenever relevant)	Brown with a characteristic odour
4 pH (at 25°C)	1.03
5 viscosity (at 25°C)	50000 cPs
6 thermal stability (glass bottle)	Stable at room temperature for 12 weeks but with a pH increase from 1.03 to 1.22
7 Specific gravity	1.137 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 room temperature for 12 weeks although an increase in pH of around 29% was noted at 40°C and therefore a warning regarding storage temperature to be below 25°C will be presented on the label.

A.3 Microbiological Quality

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

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

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

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

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

A.5 Normal and reasonably foreseeable use

Zone 50 Power Peel NE Gel- Advanced Masque is a product designed to visibly help improve the appearance of most skins and make the signs of aging less prominent. It is a wash off product that in normal circumstances will be applied by professional in-salon therapists who have been trained according to a RegimA training program (see Appendix 4). It is used once every 4-6 weeks **in the salon only** on the face, avoiding the eye area and neck.

A.6 Exposure to the Cosmetic Product

Site of application	Face (avoiding eye area and neck)
Surface area of application (cm ²)	565 cm ²
Volume of product applied (ml)	0.5 ml (2 pump depressions)
Frequency of application	1 application/4 weeks (maximum)
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	0.5 ml exposure per 4 weeks Estimated exposure based on 60 kg adult= 8.34 mg/kg bw
Dermal absorption information	Unknown
other	None

A.7 Exposure to the Substances

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

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw)
Lactic Acid 79-33-4 50-21-5	24.5	8.34	1	2.0433
Malic Acid 6915-15-7 97-67-6	23.1299	8.34	1	1.9290
Hydrogenated Polydecene 68037-01-4	10	8.34	1	0.8340
Citric Acid 77-92-9	5	8.34	1	0.4170
Propylene Glycol 57-55-6	4.4885	8.34	1	0.3743
Butylene Glycol 107-88-0	3.1636	8.34	1	0.2638
Panthenol 81-13-0	2	8.34	1	0.1668
Polyacrylate Crosspolymer-6 #	1.9	8.34	1	0.1585
Silica Dimethyl Silylate 68611-44-9	1	8.34	1	0.0834
Phenoxyethanol 122-99-6	0.77	8.34	1	0.0642
Caprylyl Glycol 1117-86-8	0.75	8.34	1	0.0626
Xanthan Gum 11138-66-2	0.3	8.34	1	0.0250
Decarboxy Carnosine HCl 57022-38-5	0.2	8.34	1	0.0167
T-butyl alcohol 75-65-0	0.1	8.34	1	0.0083
Prunus Persica (Peach) Leaf Extract 84012-34-0	0.08	8.34	1	0.0067
Hypericum Perforatum Extract 84082-80-4	0.059	8.34	1	0.0049
Centella Asiatica Extract 84696-21-9	0.024	8.34	1	0.0020
Ascorbic Acid 50-81-7	0.015	8.34	1	0.0013

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw)
Pyrus Malus (Apple) Fruit Extract 85251-63-4	0.01	8.34	1	0.0008
Rubus Idaeus (Raspberry) Fruit Extract 84929-76-0	0.01	8.34	1	0.0008

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

A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
Lactic Acid 79-33-4 50-21-5	B	2014 CIR compendium, αHAs included at ca. 15% - safe up to ≤10%, at final formulation pH >=3.5, when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection. safe for use in salon products at concentrations ≤30%, at final formulation pH ≥3.0, in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection 1; International Journal of Toxicology 17(S1): 1-242, 1998 Safe use in this product is supported by human usage information and strictly in-salon use by Regima trained professionals (see section A.10 and B.1).								
Malic Acid 6915-15-7 97-67-6	B									
Hydrogenated Polydecene 68037-01-4	C	-	Non- irritant	Not a primary irritant/non- corrosive	Non- sensitizing	Non- irritant, non- genotoxic	1000- 6771 4620 for females in a 90- day study	0.209	22105	Safety assessment of polyene group as used in cosmetics, CIR, 2014
Citric Acid 77-92-9	A	2014 CIR Compendium, safe for use up to 39%, IJT 33 (S2): 16-46, 2014								
Propylene Glycol 57-55-6	A	Safe (when formulated to be non-irritating), Safety assessment of propylene glycol tripropylene glycol and PPGs as Used in Cosmetics, Fiume, M. et al., International Journal of Toxicology 31(S 2), 2012								
Butylene Glycol 107-88-0	A	Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006								
Panthenol 81-13-0	A	Safe up to 25%, JAQCT 6(1): 139-62, 2006								
Polyacrylate Crosspolymer-6 #	C	-	Slightly irritating	Non-irritant	Non- sensitizing	Non- sensitizing and non- irritating in humans	Not available	Not available	Not available	Not genotoxic (negative bacterial reverse

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
						at ~5%				mutation). Based on assumed low hazard (meets the NICNAS polymer of low concern criteria) and assessed use pattern (up to 5% in cosmetics), not considered to be an unreasonable health risk
Silica Dimethyl Silylate 68611-44-9	A	2014 CIR safe when formulated and delivered in the final product not to be irritating or sensitizing to the respiratory tract, IJT 32(S1):5-24, 2013								
Phenoxyethanol 122-99-6	B	2014 CIR Compendium safe up to 1%, JACT 9(2):259-77, 1990								
Caprylyl Glycol 1117-86-8	A	Safe when used up to 5%, Safety assessment of 1,2-glycols as used in cosmetics, International Journal of Toxicology 31 (S2), 1475-1685, 2012								
Xanthan Gum 11138-66-2	A	2014 CIR Compendium safe up to 6%, Safety Assessment of Microbial Polysaccharide Gums as Use in Cosmetics, Final Report, CIR, October, 2012								
Decarboxy Carnosine HCl 57022-38-5	A	A natural peptide, Included in Health Canada drug and health products as a skin conditioning agent with no restrictions, Product Data Sheet reports not irritant skin or eye, (tested in vitro), tested in vivo volunteers well tolerated to 1.5% concentration.								

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
T-butyl alcohol 75-65-0	A	Safe for use up to 0.5% IJT 24(2):1-20, 2005, (Amended) JACT 8(4):627-41, 1989 (Original Report)								
Prunus Persica (Peach) Leaf Extract 84012-34-0	##	Prunus Persica (Peach) Kernel Oil- is safe up to 22%, 2014 CIR Compendium; Final Report Plant-Derived Fatty Acid Oils as Used in Cosmetics, 03/2011. Read-across to the Kernel oil for the leaf extract considered appropriate when considering the low concentration in the product, strictly in-salon use and historical safe use based on experience of this product.								
Hypericum Perforatum Extract 84082-80-4	A	Acute toxicity studies using rats, guinea pigs and mice indicate that the extract is relatively non-toxic, mixtures containing the extract and oil were not irritants or sensitizers in animals and produced minimal/no ocular irritation in rabbits and was not irritating in clinical studies. Also, hypericum perforatum extract is used in over 50 cosmetic foundations across a wide range of product types, International Journal of Toxicology 20(S2): 31-39, 2001. As there is no data available on the efficacy and safety of the extract in children and adolescents, use below the age of 18 is not recommended. The use of Hypericum has been documented for a long period and beside the risk of increased photosensitivity of the treated skin (the label will contain a suitable warning, see Section B.2 of this PIF) no concerns are known. The risk has been deemed an acceptable level for traditional herbal medicinal products, Assessment Report on Hypericum Perforatum L., Herba, Doc. Ref.: EMA/HMPC/101303/2008.								
Centella Asiatica Extract 84696-21-9	C	-	Non- irritant	Non-irritant	Safe at 0.024% inclusion rate	Not genotoxic	10	9.60x10- 6	1.04x106	NOAEL based on reproduction toxicity effects in male rats
Ascorbic Acid 50-81-7	A	2014 CIR Compendium, safe when used up to 10%, International Journal of Toxicology 24(2): 51-111, 2005								
Pyrus Malus (Apple) Fruit Extract 85251-63-4	A	Safe (concentration of use not reported) CIR Compendium, 2014, Food item GRAS								
Rubus Idaeus (Raspberry) Fruit Extract	##	Rubus Idaeus (Raspberry) Seed Oil- is safe up to 5%, 2014 CIR Compendium. In addition, raspberries are food items and raspberry leaf is a well-known herb that has been used orally for decades against various ailments according to handbooks and articles. Raspberry leaf preparations are generally recognized as safe. In mice an oral								

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
84929-76-0		dose of extract equivalent to 10% of body weight of dried raspberry leaves was considered non-toxic. Neither the chemical composition nor the long-term widespread use in the European Union suggest that there is a high risk associated with the use of raspberry leaf preparations, Reference: EMA/HMPC/44209/2012.								

^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 The reference Where hazard ID A or B is reported, the maximum allowed usage concentration should be stated.

^b all possible routes of exposure should be considered

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

Food item, hazard and exposure data not required.

other; read-across to information on related ingredient as presented

Fragrances:

Zone 50 Power Peel Natural Exfoliating Gel - Advanced Masque does not contain a fragrance.

A.9 Undesirable Effects and Serious Undesirable Effects

A letter describing in-salon use of this product and its immediate effects is included in Appendix 4 and described here.

‘On application of the Power Peel Masque there may be a tingling, itching sensation. The tingling is alleviated by the application of Laser Azu-Gel, which is massaged around the face. There is rarely erythema, unless the skin is dehydrated or there are extensive solar keratosis. Over the next few days following the in-Rooms application there may be slight flaking or peeling of the skin which subsides quickly and the patient applies Scar Forte Serum and day protection as desired. The patients tolerate these treatments extremely well, are very happy with the results and attend the Rooms regularly for these Power Peel Masques.

No undesirable effects are anticipated based on the product being used in-salon as directed on the face once every 4-6 weeks.

A.10 Information on the Cosmetic Product

RégimA Zone is an award winning company based in South Africa whose awards include:

- Professional Beauty Best Training Industry Award concurrently in 2013 and 2014.
- Best Supplier of Skin Care in the Industry 2015
- Best Product Range 2015 in South Africa’ and the ‘Best New Product 2015’ by the Pharmaceutical and Cosmetic Review Magazine for the Innovation, Formulation, Packaging, Marketing and Regulations categories.

RégimA has a very strong reputation for both the efficacy and consumer acceptability for their skin care products which are sold only to doctors, salons and spas.

Zone 50 Power Peel NE Gel- Advanced Masque was released in 2013. Over the period October 2014 to May 2016, 1388 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

Ingredients no. 1 (a mixture containing Lactic Acid), 2 (Malic Acid) and 4 (Citric Acid) and declare up to 24.5%, 22.5% and 5% alpha hydroxyl acid (AHA) content respectively, which would equate to a maximum of 52% content in the formulated product which has a pH of 1.03. According to the criteria on the FDA web-site about the use of AHAs in cosmetic products, they can be used safely when the following is the case: (<http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm107940.htm>)

- The AHA concentration is 10 percent or less.
- The final product has a pH of 3.5 or greater.
- The final product is formulated in such a way that it protects the skin from increased sun sensitivity or its package directions tell consumers to use daily protection from the sun.

In this product the concentration of AHA is greater than 10 percent and the pH is less than 3.5. Consequently the product is for strictly in-salon use by professional therapists who have been trained according to the RegimA training scheme. Additionally the product insert and labelling contain the advice to use daily protection from the sun.

When used according to the label and product insert directions, it is not expected that Zone 50 Power Peel Natural Exfoliating Gel - Advanced Masque will cause lasting damage to human health. This is supported by a letter from Richard J Van Der Poel MB ChB FRCS (Edin.) Plastic and Reconstructive Surgeon who has supervised the use of this product in-salon in South Africa (see below).

It is therefore concluded that Zone 50 Power Peel NE Gel - Advanced Masque can be placed on the market in the EU as an exfoliating masque, under the condition **that it is only to be applied in-salon by a RegimA trained professional skin care therapist.**

Review of human data on the product

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

Statement of tolerability

The product has been used under the guidance of a plastic and reconstructive surgeon, Richard J Van Der Poel, whose patients have tolerated the 50% AHA formulation without lasting adverse irritating effects being reported.

Richard J Van Der Poel reports ‘On application of the Power Peel Masque there may be a tingling, itching sensation. The tingling is alleviated by the application of Laser Azu-Gel, which is massaged around the face. There is rarely erythema, unless the skin is dehydrated or there are extensive solar keratosis. The Power Peel Gel is then thoroughly cleansed with RégimA Derma Zest Cleansing + Toning Gel ensuring all masque has been removed. Following cleansing Scar Forte Serum and a RégimA product containing sun protection is always applied.

Over the next few days following the in-Rooms application there may be slight flaking or peeling of the skin which subsides quickly and the patient applies Scar Forte Serum and day protection as desired.

The patients tolerate these treatments extremely well, are very happy with the results and attend the Rooms regularly for these Power Peel Masques.

I feel that these products and treatments offer safe, continuity of care at home and in-Rooms for my patients pre and post-op.’ The statement is included in Appendix 4.

B.2 Label Warnings and Instructions for Use

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

Directions for use: In-salon: Cleanse with RegimA products. Apply 2 pump depressions to the face, avoiding the eye area and neck. Allow 10 to 15 minutes before removing by cleansing thoroughly with RegimA cleanser. This is an in-salon masque applied as part of a RegimA facial ideally every 4-6 weeks. Follow with RegimA home care products, which must include a product containing sun protection.

Label warnings:

‘Not for retail. Strictly in-salon Masque for use by a RegimA trained professional skin care therapist.

‘All skin types- except sensitive’

‘Must always be followed by a RegimA product containing UVA and UVB protection’.

‘Keep out of reach of children’.

‘Protect from temperatures above 25°C’.

‘Suitable for adults only’.

B.3 Reasoning

This product contains many ingredients with a positive reputation for its exfoliating properties. There are no reasons to anticipate tolerance problems with intermittent 4-6 week use. Supporting evidence has been given by Richard J Van Der Poel, plastic and reconstructive surgeon, who has used this product as an in-salon treatment. Clients have tolerated the 50% AHA formulation without lasting adverse irritating effects being reported.

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

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

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

A handwritten signature in dark ink, reading "Shirley H", enclosed within a thin rectangular border.

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


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Certification Manager
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Page 1 of 1







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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.