

# PRODUCT INFORMATION FILE\*

RégimA

Zone ‘Acne Attack’ Pro-  
Masque

Prepared: June 2017  
(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 .....	12
A.3 Microbiological Quality .....	13
A.4 Impurities, traces, information about the packaging material .....	13
A.5 Normal and reasonably foreseeable use .....	13
A.6 Exposure to the Cosmetic Product.....	13
A.7 Exposure to the Substances .....	14
A.8 Toxicological Profile of the Substances .....	16
A.9 Undesirable Effects and Serious Undesirable Effects .....	21
A.10 Information on the Cosmetic Product.....	21
B: Part Cosmetic Product Safety Assessment .....	22
B.1 Assessment Conclusion .....	22
B.2 Label Warnings and Instructions for Use .....	22
B.3 Reasoning .....	24
B.4 Assessors Credentials and Approval of Part B .....	24
List of References .....	25
METHOD OF MANUFACTURE / GMP CERTIFICATION.....	26
PROOF OF EFFECT CLAIMED .....	27
ANIMAL TESTING STATEMENT .....	27
Appendix 1: Safety Data Sheets or Ingredient Specifications .....	28
Appendix 2: Microbial Challenge Test .....	29
Appendix 3: Certificates of Allergen Content.....	30
Appendix 4: Miscellaneous.....	31

## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

**Product Name:** Zone 'Acne Attack' Pro-Masque

Product type	Masque to help congested skins
Form	Cream
Colour	Off white
Pack size	50ml
Pack type	WO Jar
Dispenser type	N/A
Part of a set	No
Manufacturer code	AAP 003
Normal use	<b>In-salon use only.</b> Cleanse face and neck with RegimA Cleanser. Apply a pea size amount of 'Acne Attack' Pro-Masque, using fingertips, to face, and neck if also problematic, avoiding eye area. Do not steam whilst Masque is in place. Leave for 5 to 10 minutes maximum then cleanse thoroughly to remove the Masque.

**Pictures of the Item: On following page**

## Container label

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

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

**Ingredients**

Aqua (Water), Salicylic Acid, Lactic Acid, Hydrogenated Polydecene, Butylene Glycol, Propylene Glycol, Panthenol, C14-22 Alcohols, Polyacrylate Crosspolymer-6, Stearic Acid, Nasturtium Officinale Extract, Arctium Lappa Root Extract, Salvia Officinalis (Sage) Leaf Extract, Citrus Medica Limonum (Lemon) Fruit Extract, Hedera Helix (Ivy) Extract, Saponaria Officinalis Extract, Spiraea Ulmaria Flower Extract, Phenoxyethanol, C12-20 Alkyl Glucoside, Xanthan Gum, Caprylyl Glycol



**REPAIRING - PROBLEM SKINS**

**Directions for use:**

**IN-SALON TREATMENT:** Cleanse face and neck with RégimA. Apply 'Acne Attack' Pro Masque to face and neck if affected, using fingertips, avoiding eye area. Do not steam whilst Masque is in place. Leave for 10 to 15 minutes maximum then cleanse thoroughly to remove the Masque.

Ask client to do the 'lick test', licking around their mouth to ensure the skin is completely cleansed. Follow with appropriate RégimA serums and creams.

Always apply a RégimA day product containing sun protection.

**MUST NOT be combined with any other product range**



**RégimA™**  
**International Skin Treatments**  
 50 Van Buuren Road, Bedfordview, 2008  
 Gauteng, South Africa  
[www.regima.zone](http://www.regima.zone)  
 Manufactured In South Africa

EU - RP CSH-Europe: The Greenway, Ardilaun Court, St. Stephen's Green, Dublin 2, Ireland  
 UK - RP CSH-UK: Pentlands Science Park, Penicuik, Nr Edinburgh, EH26 0PZ, UK  
 US - FDA - 1007858

**RÉGIMÀ IS AGAINST ANIMAL TESTING**

**STRICTLY IN-SALON MASQUE**  
**FOR USE BY A RÉGIMÀ TRAINED PROFESSIONAL**  
**SKIN CARE THERAPIST**

**KEEP OUT OF REACH OF CHILDREN**

**50ml e 1.69floz**

## 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 safely help congested, problematic skins. Selected botanicals, work synergistically providing particular benefits for oily problem skins.

# **COSMETIC PRODUCT SAFETY REPORT**

## **Part A: Cosmetic Product Safety Information**

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



**Zone 'Acne Attack' Pro-Masque base formula**

No	Raw Ingredient (INCI Name)	%	% (w/w)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Salicylic Acid	30	30	69-72-7	200-712-3	Keratolytic/ Masking/ Preservative/ Skin Conditioning	Salicylates & Chemicals (Fourchem)	Salicylic Acid 99%
2	Lactic Acid	10.8	12	79-33-4/ 50-21-5	201-196-2/ 200-018-0	Buffering/ Skin	Merck KGaA	L(+)-Lactic Acid, PURAC®
	Aqua (Water)	1.2		7732-18-5	231-791-2	Conditioning/ Humectant		
3	Hydrogenated Polydecene	10	10	68037-01-4	500-183-1	Emollient/ Masking/ Perfuming/ Skin Conditioning	BP (Lipo Chemicals)	Silkflo 364 NF
4	Butylene Glycol	5	5	107-88-0	203-529-7	Humectant/ Masking/ Skin Conditioning/ Solvent/ Viscosity Controlling	Various	Butylene Glycol
5	Aqua (Water)	2.475	5	7732-18-5	231-791-2	Skin Conditioning/ Humectant/ Solvent/ Viscosity Controlling	Greentech (Natchem)	Meadowswe et Medulat
	Propylene Glycol	2.47		57-55-6	200-338-0			
	Spiraea Ulmaria Flower Extract	0.055		84775-57-5	283-886-3			



No	Raw Ingredient (INCI Name)	%	% (w/w)	CAS	EC	Function	Supplier (Agent)	Tradename
6	Butylene Glycol	2.625	5	107-88-0	203-529-7	Solvent/ Skin Conditioning/ Astringent/ Soothing/ Tonic/ Antimicrobial Cleansing/ Perfuming	Greentech (Natchem)	Phytelene Complex EGX 247 BG
	Aqua (Water)	2.345		7732-18-5	231-791-2			
	Nasturtium Officinale Extract	0.01065		84775-70-2	283-899-4			
	Arctium Lappa Root Extract	0.002175		84012-13-5	281-658-8			
	Salvia Officinalis (Sage) Leaf Extract	0.002175		84082-79-1	282-			
	Citrus Limon (Lemon) Fruit Extract	0.01065		84929-31-7	284-515-8			
	Hedera Helix (Ivy) Extract	0.002175		84082-54-2	282-000-2			
	Saponaria Officinalis Extract	0.002175		84775-97-3	283-921-2			
7	C14-22 Alcohols	1.9875	2.5	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	Emulsion Stabilising/ Emulsifying/ Surfactant	Seppic (Sharon Bolel Chemical Marketing)	Montanov L
	C12-20 Alkyl Glucoside	0.5						
	Aqua (Water)	0.0075		7732-18-5	231-791-2			
	Glucose	0.005		50-99-7	200-075-1			

No	Raw Ingredient (INCI Name)	%	% (w/w)	CAS	EC	Function	Supplier (Agent)	Tradename
8	Panthenol	2	2	81-13-0	201 327 3	Skin Conditioning	DSM Nutritional Products (Chempure)	D-Panthenol
9	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		#	#			
10	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			
11	Myristic Acid	0.004	1	544-63-8	208-875-2	Cleansing/ Emulsifying/ Perfuming/ Emulsion Stabilising/ Masking/ Refatting/ Surfactant/ Opacifying/ Surfactant	Various	Stearic Acid
	Palmitic Acid	0.543		57-10-3	200-312-9			
	Stearic Acid	0.449		57-11-4	200-313-4			
	Arachidic Acid	0.004		506-30-9	208-031-3			

No	Raw Ingredient (INCI Name)	%	% (w/w)	CAS	EC	Function	Supplier (Agent)	Tradename
12	Xanthan Gum	0.3	0.3	11138-66-2	234-394-2	Binding/ Emulsifying/ Emulsion Stabilising/ Gel forming/ Skin Conditioning/ Surfactant/ Viscosity Controlling	CP Kelco (Tranarc)	Keltrol CG-T
13	Aqua (Water)	23.7	23.7	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

# not assigned

Ingredient order for the label: Salicylic Acid, Aqua (Water), Lactic Acid, Hydrogenated Polydecene, Butylene Glycol, Propylene Glycol, Panthenol, C14-22 Alcohols, Polyacrylate Crosspolymer-6, **Phenoxyethanol, Palmitic Acid, Caprylyl Glycol, C12-20 Alkyl Glucoside, Stearic Acid, Xanthan Gum, T-Butyl Alcohol, Spiraea Ulmaria Flower Extract, Citrus Limon (Lemon) Fruit Extract, Nasturtium Officinale Extract, Glucose, Arachidic Acid, Myristic Acid, Arctium Lappa Root Extract, Hedera Helix (Ivy) Extract, Salvia Officinalis (Sage) Leaf Extract, Saponaria Officinalis 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 ‘Acne Attack’ Pro-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	Cream
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Cream
3 organoleptic properties (colour, odour, whenever relevant)	Characteristic odour
4 pH (at 25°C)	2.08
5 viscosity (at 25°C)	44000 cPs
6 thermal stability (glass bottle)	Stable for 12 weeks at 25°C
7 Specific gravity	0.987 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 25°C for 12 weeks although an increase in pH of around 20% was noted at 40°C at week 8 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 WO jar is made from poly methyl methacrylate. The inner jar is made of polypropylene with a polyethylene lining and LDPE disc. The inner cap consists of polypropylene and the outer cap of acrylonitrile-butadiene-styrene. 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’ is a product designed to safely help congested, problematic skins. 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 program (see Appendix 4). It is used every 4-6 weeks in the salon only on the face and the neck (if also problematic), avoiding the eye area.

### **A.6 Exposure to the Cosmetic Product**

Site of application	Face and neck (if problematic)
Surface area of application (cm <sup>2</sup> )	565 cm <sup>2</sup>
Volume of product applied (ml)	0.25 ml (pea sized amount)
Frequency of application/use per day	1 application/4weeks (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)	0.25 ml exposure per 4-6 weeks Estimated exposure based on 60 kg adult= 4.17 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/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Salicylic Acid 69-72-7	30	4.17	1	1.25
Lactic Acid 79-33-4	10.8	4.17	1	0.45
Hydrogenated Polydecene 68037-01-4	10	4.17	1	0.42
Butylene Glycol 107-88-0	7.625	4.17	1	0.32
Propylene Glycol 57-55-6	2.47	4.17	1	0.10
Panthenol 81-13-0	2	4.17	1	0.083
C14-22 Alcohols 67762-30-5	1.9875	4.17	1	0.083
Polyacrylate Crosspolymer-6 # <sup>1</sup>	1.9	4.17	1	0.079
Phenoxyethanol 122-99-6	0.975	4.17	1	0.041
Palmitic Acid 57-10-3	0.543	4.17	1	0.023
Caprylyl Glycol 1117-86-8	0.525	4.17	1	0.022
C12-20 Alkyl Glucoside 67762-30-5	0.5	4.17	1	0.021
Stearic Acid 57-11-4	0.449	4.17	1	0.019
Xanthan Gum 11138-66-2	0.3	4.17	1	0.013
T-Butyl Alcohol 75-65-0	0.08	4.17	1	0.0033
Spiraea Ulmaria Flower Extract 84775-57-5	0.055	4.17	1	0.0023
Citrus Limon (Lemon) Fruit Extract	0.01065	4.17	1	0.00044

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
84929-31-7				
Nasturtium Officinale Extract 84775-70-2	0.01065	4.17	1	0.00044
Glucose 50-99-7	0.005	4.17	1	0.00021
Arachidic Acid 506-30-9	0.004	4.17	1	0.00017
Myristic Acid 544-63-8	0.004	4.17	1	0.00017
Arctium Lappa Root Extract 84012-13-5	0.002175	4.17	1	0.000091
Hedera Helix (Ivy) Extract 84082-54-2	0.002175	4.17	1	0.000091
Salvia Officinalis (Sage) Leaf Extract 84082-79-1	0.002175	4.17	1	0.000091
Saponaria Officinalis Extract 84775-97-3	0.002175	4.17	1	0.000091

# 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.

<sup>#1</sup> Not assigned



## A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Salicylic Acid 69-72-7	A	2014 CIR Compendium, safe when formulated to avoid irritation and to avoid increasing sun sensitivity, or when increased sun sensitivity would be expected, directions for use include the daily use of sun protection. The label for this product states that sun protection (UVA and UVB) must always be used following use of this Masque. IJT 22(3):1-108. Safe use of this product is supported by human usage information and strictly in-salon use by RegimA trained professionals (see Section A.10 and B.1).								
Lactic Acid 79-33-4	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 <sup>1</sup> ; International Journal of Toxicology 17(S1): 1-242, 1998 Safe use in this product is supported by human usage information (see section A.10 and B.1)								
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
Butylene Glycol 107-88-0	A	Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006								
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. <i>et al.</i> , International Journal of Toxicology 31(S 2), 2012								
Panthenol 81-13-0	A	Safe up to 25%, JAQCT 6(1): 139-62, 2006								
C14-22 Alcohols	## <sup>1</sup>	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								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
67762-30-5		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 under half of the worst case % presented in the CIR compendium, therefore it is not expected that any of the other C- alcohols would at a % unsafe for use, especially considering there is a mix of 9 alcohols in 2.385%.								
Polyacrylate Crosspolymer-6 # <sup>1</sup>	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 revere 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
Phenoxyethanol	B	2014 CIR Compendium safe up to 1%, JACT 9(2):259-77, 1990								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
122-99-6										
Palmitic Acid 57-10-3	A	2015 CIR Compendium, safe for use up to 25%, JACT 6(3):321-401, 1987 confirmed 06/05								
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								
C12-20 Alkyl Glucoside 67762-30-5	A	Safe for use in cosmetics when formulated to be non-irritating; International Journal of Toxicology 32 (S3): 22-48, 2013								
Stearic Acid 57-11-4	A	2014 CIR compendium, safe at use over 50%, JACT 6(3):321-401, 1987 confirmed 06/05 IJT 25(S2),2006								
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								
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)								
Spiraea Ulmaria Flower Extract 84775-57-5	A	Meadowsweet, also known as Dropwort ( <i>Filipendula ulmaria</i> ): <a href="https://www.globalherbalsupplies.com/herb_information/meadowsweet.htm">https://www.globalherbalsupplies.com/herb_information/meadowsweet.htm</a> Used as a herbal medicine at up to 6g for tea preparation, considered not harmful systemically bearing in mind 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 not a concern in a product intended as a peel for in-salon use by trained professionals.								
Citrus Limon (Lemon) Fruit Extract 84929-31-7	#	Annex II/358 R1, Furocoumarines (e.g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. Restriction does not apply as this ingredient is a natural essence; GRAS								
Nasturtium Officinale Extract	#	Watercress is a food item and systemic toxicity is acceptable. The supplier notes it is non-irritant and in consideration of its food item status, it can be assumed that watercress is safe when applied dermally.								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
84775-70-2										
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.								
Arachidic Acid 506-30-9	A	Arachidic acid is a saturated long-chain fatty acid with a 20-carbon backbone. It is found naturally as a minor component of peanut oil and is formed by the hydrogenation of arachidonic acid: <a href="https://pubchem.ncbi.nlm.nih.gov/compound/Arachidic_acid#section=Top">https://pubchem.ncbi.nlm.nih.gov/compound/Arachidic_acid#section=Top</a> Hence a read across to arachidonic acid is deemed appropriate. The 2014 CIR Compendium considers that the safety of this ingredient has not yet been documented and substantiated for cosmetic use until data is generated. However, considering that Arachidic acid makes up about 1.93% of peanut oil (see Appendix 4), a commonly ingested food item, compared to 0.0004% arachidic acid in the formulation for this product, systemic safety can be assumed. The 2014 CIR Compendium also states that in a 24 h single patch test, a formulation containing 0.04% Arachidonic Acid was not a skin irritant (this is 100 time greater than the concentration in this formulation) and on this basis, it is considered acceptable for topical use in this product.								
Myristic Acid 544-63-8	A	2014 CIR Compendium, safe for use up to 50%, JACT 6(3):321-401, 1987 confirmed 06/05 IJT 25(S2), 2006; IJT 29 (S3): 162-186, 2010								
Arctium Lappa Root Extract 84012-13-5	## <sup>1</sup>	2014 CIR Compendium, Arctium Lappa <b>Seed Oil</b> is expected as safe for use in product categories and concentrations comparable to others in these groups. Assessment report on Arctium lappa L., radix, EMA/HMPC/246764/2009; a carcinogenicity study showed rats treated with a diet containing 33% of roots of Arctium lappa L. for 120 days had no tumours detected in any animal. Other in vivo focused on other parts of the plant, however the available data does not point to any serious concern with respect to safety. Preparations of Arctium lappa root can be considered as safe.								
Hedera Helix (Ivy) Extract	A	Used as oral medicinal use as expectorant. GRAS for topical use with warning regarding discontinue use if irritation or itching occurs.								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
84082-54-2		<a href="http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-HMPC_assessment_report/2012/01/WC500120648.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-HMPC_assessment_report/2012/01/WC500120648.pdf</a>								
Salvia Officinalis (Sage) Leaf Extract 84082-79-1	A	Traditional use has shown that sage leaf can be recognised as safe when used in recommended dosages (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.								

<sup>a</sup> 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.

<sup>b</sup> all possible routes of exposure should be considered

<sup>c</sup> A MoS of greater than 100 is considered to represent safe use

# Food item, hazard and exposure data not required.

##<sup>1</sup> other; read-across to information on components

**Fragrances:**

Zone 'Acne Attack' Pro-Masque 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 and neck every 4-6 weeks.

**A.10 Information on the Cosmetic Product**

Zone 'Acne Attack' Pro-Masque was released in 2016. Over the period June 2016 to December 2016, 2563 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’ Pro Masque will cause damage to human health when used as directed.

It is therefore concluded that Zone ‘Acne Attack’ Pro Masque can be placed on the market in the EU as an in-salon use masque to help congested skins.

#### 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).

IN-SALON: Cleanse face and neck with RegimA Cleanser. Apply a pea size amount of ‘Acne Attack’ Pro-Masque, using fingertips, to face, and neck if also problematic, avoiding eye area. Do not steam whilst Masque is in place. Leave for 5 to 10 minutes maximum then cleanse thoroughly to remove the Masque.

Warnings:

‘Do not apply to damaged/open skin’.

‘May sting and itch on application’.

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

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

‘Suitable for adults only- keep out of reach of children’.



‘Store below 25°C in a cool dry place. Protect from light’.

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their properties to help congested skins properties. There are no reasons to anticipate tolerance problems with intermittent 4-6 week use. The Masque is used in-salon only, by trained staff (see Appendix 4).

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 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, 9<sup>th</sup> 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

  
Pieter Weterings  
Certification Manager  
SGS Belgium NV, Systems and Services Certification  
SGS House - Noordlaan 87 - 2030 Antwerp - Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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](mailto:jax@regima.com)**

**POSTAL ADDRESS: PO BOX 9523 Edenglen 1613**

**PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA**

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### 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.