

PRODUCT INFORMATION FILE*

RégimA Company

Slimming Sculpting Solution
Lift-Firm-Tone-Sculpt

Prepared: March 2019
(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: Slimming Sculpting Solution Lift-Firm-Tone-Sculpt


Product type	Body Cream
Form	Cream
Colour	Off White
Pack size	100ml and 200ml
Pack type	Chubby Chunky Airless Container
Dispenser type	Polypropylene pump
Part of a set	No
Manufacturer code	BSS 002
Normal use	<p>Directions for use:</p> <p>200ml Box To be used as part of a RégimA in-salon treatment.</p> <p>Cleanse the body of cream and oil, except SpaZone O₂-Purifyer Serum and/or Target Cellulite, which may be used in combination.</p> <p>Apply one pump depression per target area such as thighs, inner knees, abdomen, upper arms. Gently massage a thin layer of cream solution to target areas. A cooling sensation may be felt. Therapist may then apply plastic wrap firmly over treated areas and leave for one hour. Plastic wrap is then removed.</p> <p>These SpaZone products are leave on treatments that work synergistically so are not cleansed off until the next morning if possible.</p>

Pictures of the Item: On following page

Container label


Ingredients

Aqua (Water), Cetearyl Olivat (and) Sorbitan Olivat, Shea Butter Glycidides, Olea Europaea (Olive) Fruit Oil, Tropaeolum Majus Flower/Leaf/Stem Extract, Hydrolyzed Celosia Cristata Flower/Seed Extract, Hydrolyzed Prunella Vulgaris Extract, Rosa Canina Fruit Oil, Ribes Nigrum (Black Currant) Seed Oil, Hydrogenated Olive Oil, Olea Europaea (Olive) Fruit Oil, Olea Europaea (Olive) Oil Unsaponifiables, Glycerin, Persea Gratissima (Avocado) Oil, Kappaphycus Alvarezii Extract, Caesalpinia Spinosa Fruit Extract, Tocopherol, Xanthan Gum, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Phenoxyethanol (and) Capryly Glycol




RégimA
International Skin Treatments
50 Van Buuren Road, Bedfordview, 2008
Gauteng, South Africa
www.regima.zone
Manufactured in South Africa

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



RÉGIMÀ IS AGAINST ANIMAL TESTING

RégimA Spa ZONE

SLIMMING SCULPTING SOLUTION

LIFT – FIRM – TONE SLIM – SCULPT

ALL SKIN TYPES

Directions for use:
To be used as part of a RégimA in-salon treatment.

Cleanse the body of cream and oil, except SpaZone O2-Purifyer Serum and/or Target Cellulite, which may be used in combination.

Apply one pump depression per target area, such as thighs, inner knees, abdomen, upper arms. Gently massage a thin layer of Cream Solution to target areas. A cooling sensation may be felt. Therapist may then apply plastic wrap firmly over treated areas and leave for one hour. Plastic wrap is then removed.

These SpaZone products are leave-on treatments that work synergistically, so are not cleansed off, until the next morning if possible.

MUST NOT be combined with any other product range

STRICTLY FOR PROFESSIONAL USE

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

200 ml. e Net 6.7 fl. oz.

REGIMIN ON THE MARKET

Ingredients

Aqua (Water), Cetearyl Olivate (and) Sorbitan Olivate, Shea Butter Glycolates, Olea Europaea (Olive) Fruit Oil, Tocopherol, Argemone Flower Seed Extract, Hydrolyzed Purohitia Virgata Extract, Rose Geranium Fruit Oil, Ribes Nigrum (Black Currant) Seed Oil, Hydrogenated Olive Oil, Olea Europaea (Olive) Fruit Oil, Olea Europaea (Olive) Oil, Unsaponifiables, Glycerin, Ribesida Galactinase (Avoocad) Oil, Kappaphycus Alveolata Extract, Castanea Sativa Fruit Extract, Tocopherol, Xanthan Gum, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Phenylethanol (and) Capryl Glycol

RegimA™
International Skin Treatments

50 Van Buren Road, Inverloch, 3868
Gravelly, South Africa
www.regima.co.za
Manufactured in South Africa

For CPTA (Cosmetology) the Government of South Africa, 50 Van Buren Road, Inverloch, 3868
UK - BP (Cosmetics) Marketing Company Ltd,
Trenton, NJ 08619, USA
US - FDA - 100/7850

RECYCLING IS AN ABSOLUTE ACHIEVEMENT

A synergy of powerful bio-actives has been shown to limit the development of fat masses, particularly in the abdomen and thighs, not forgetting those less than five years old, helping facilitate elimination of fat, stimulating lipolytic activity (breaking down of fat) of adipocytes (fat cells).

A new slenderizing strategy, short and long term, is obtained from the synergy of specific plant polyphenols, providing a dual action, stimulating biological cell functions against mechanical stress, and, by tightening the dermal fibre network, skin regains elasticity and tone, restoring curve contour.

If the body is slenderizing it is important that restoration of skin's natural stretching response is achieved simultaneously. Advanced Natural Technology is the key to successful body sculpting, ingredient synergy offering - Lifting - Firming - Toning - Slenderizing - Sculpting. All in one magical treatment.

With continued treatments one can experience a decrease in oedema (fluid retention), thigh and abdominal circumference, dermal tightening, helping regain elasticity and tone.

RégimA™
SKIN TREATMENTS

RégimA™
SpaZONE

**SLIMMING
SCULPTING
SOLUTION**

LIFT - FIRM - TONE
SLIM - SCULPT

200 ml. e Net 6.7 fl. oz.

ALL SKIN TYPES

Directions for use:

To be used as part of a RégimA in-salon treatment.

Cleanse the body of cream and oil, except Spazone C2-Purifier Serum and/or Target Cellulite, which may be used in combination.

Apply one pump depression per target area, such as thighs, inner knees, abdomen, upper arms. Gently massage a thin layer of Cream Solution to target areas. A cooling sensation may be felt, therapist may then apply plastic wrap firmly over treated areas and leave for one hour. Plastic wrap is then removed.

These Spazone products are leave-on treatments that work synergistically, so are not cleaned off, until the next treatment if possible.

MUST NOT be combined with any other product (except

STRICTLY FOR PROFESSIONAL USE

UNLESS CONTAINER CAP IS REMOVED TOP AS THE SMALL WINDOW REVEALS INCHES

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 limit the development of fat masses, particularly in the abdomen and thighs and to firm the upper arms. It helps to facilitate the elimination of fat, stimulating lipolytic activity (breaking down of fat) of adipocytes (fat cells).

Provides a dual action mechanism by tightening the dermal fiber network, allowing the skin to regain elasticity and tone, restoring curve contour.

It has been described that with continued treatments the consumer can experience a decrease in oedema (fluid retention), thigh and abdominal circumference, dermal tightening, helping regain elasticity and tone.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Slimming Sculpting Solution Lift Firm Tone Sculpt base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Cetearyl Olivat	2.5	5	85116-80-9	285-532-3	Emulsifying	Textron Tecnica (CJP Chemicals)	Olivem® 1000
	Sorbitan Olivat	2.5		223706-40-9/ 92202-01-2	296-0335-5			
2	Shea butter Glycerides	5	5	194043-92-0/ 68424-61-3	270-312-0			
3	Olea Europaea Fruit Oil	5	5	8001-25-0	232-277-0	Masking/ Perfuming/ Skin Conditioning	Textron Tecnica (CJP Chemicals)	Olive Oil Extra Virgin
4	Water (Aqua)	3.38	4	7732-18-5	231-791-2	Solvent/ Skin Conditioning/ Abrasive/ Bulking	Silab (Meganede)	Coheliss™
	Pentylene Glycol	0.4		5343-92-0	226-285-3			
	Secale Cereale Seed Extract	0.22		90106-48-2	290-271-3			
5	Water (Aqua)	3.464	4	7732-18-5	231-791-2	Solvent/ Skin Conditioning/ Skin Protecting	Silab (Meganede)	BioSculptine® s GR
	Pentylene Glycol	0.4		5343-92-0	226-285-3			
	Hydrolyzed Celosia Cristata Flower/Seed Extract	0.1088		669066-11-9	613-997-8			
	Hydrolyzed Prunella Vulgaris Extract	0.0272		90105-92-3	290-211-6			
6	Rosa Canina Fruit Oil	3	3	84603-93-0/ 84696-47-9	238-652-0	Emollient/ Skin Conditioning	Seatons (Croda)	Seatons Rosehip Oil Ref-LQ-(JL)
7	Ribes Nigrum Seed Oil	3	3	68606-81-5/ 97676-19-2	271-749-0	Emollient	Textron Tecnica (CJP Chemicals)	Blackcurrent Seed Oil
8	Hydrogenated Olive Oil	1.95	3	226993-75-5/ 68334-28-1	269-820-6/	Skin Conditioning/ Viscosity Controlling/		Oliwax®

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Olea Europaea Fruit Oil	0.825		8001-25-0	232-277-0	Masking/ Perfuming	Textron Tecnica (CJP Chemicals)	
	Olea Europaea Oil Unsaponifiables	0.225		8001-25-0/ 798-12-8	232-277-0			
9	Glycerin	3	3	56-81-5	200-289-5	Humectant/ Perfuming/ Skin Protecting/ Viscosity Controlling	Various	Refined Glycerine
10	Persea Gratissima Oil	2	2	8024-32-6	232-428-0	Skin Conditioning	Textron Tecnica (CJP Chemicals)	Cold Pressed refined Avocado Oil
11	Phenoxyethanol	0.9	1	122-99-6	204-589-7	Preservative/ Emollient/ Humectant/ Skin Conditioning	Dr. Strartmans (Meganede)	Verstatil® PC
	Caprylyl Glycol	0.1		117-86-8	214-254-7			
12	Water (Aqua)	0.05	1	7732-18-5	231-791-2	Solvent/ Skin Conditioning	Silab (Meganede)	Filmixel®
	Kappaphycus Alvarezii extract	0.475		1220882-73- 4	310-127-6			
	Caesalpinia Spinosa Fruit pod extract	0.475		39300-88-4	254-409-6			
13	D-Limonene	0.2735	1	5989-27-5	227-813-5	Perfuming/ Masking/ Antifoaming	FD Copeland (CJP Chemicals)	Bergamot Oil
	Linalyl Acetate	0.5379		115-95-7	204-116-4			
	Linalool	0.1005		78-70-6	201-134-4			
	Citral	0.0301		5392-40-5	226-394-6			
	Gamma-Terpinene	0.029		99-85-4	202-794-6			
	Pinene	0.029		80-56-8	201-291-9			
14	Xanthan Gum	0.25	0.25	11138-66-2	234-394-2	Binding/ Emulsifying/ Smulsion Stabilising/	CP Kelco (Tranarc)	Keltrol T-Plus

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
						Gel Forming/ Skin Conditioning/ Surfactant/ Viscosity Controlling		
15	Tocopherol	0.1	0.1	54-28-4 (gamma)/ 166698-35-4 (beta)/ 10191-41- 0(DL)/ 119-13-1/ 1406-18-4/ 14066-66-2/ 2074-53- 5(DL)/ 59-02-9(D)/ 7616-22-0	200-201-5/ 240-747-1/ 233-466-0/ 204-299-0/ 215-798-8/ 218-197-9/ 200-412-2	Antioxidant/ Masking/ Skin Conditioning	DL- α - Tocopherol	DSM nutritional products (Chempure)
16	Water (Aqua)	59.65	59.65	7732-185	231-791-2	Solvent	In House	Deionised water

not assigned

Ingredient order for the label: Water (Aqua), Olea Europaea Fruit Oil, Shea Butter Glycerides, Glycerin, Ribes Nigrum Seed Oil, Rosa Canina Fruit Oil, Cetearyl Olivatate, Sorbitan Olivatate, Persea Gratissima Oil, Hydrogenated Olive Oil, Citrus bergamia peel Oil expressed, **Phenoxyethanol, Pentylene Glycol, Caesalpinia Spinosa Fruit Pod extract, Kappaphycus Alvarezii Extract, Limonene, Xanthan Gum, Olea Europaea Oil Unsaponifiables, Secale Cereale Seed Extract, Hydrolyzed Celosia Cristata Flower/Seed Extract, Linalool, Caprylyl Glycol, Tocopherol, Citral, Hydrolyzed Prunella Vulgaris Extract, Alpha-Pinene, Linalyl Acetate.** 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>	<i>Reference</i>
Alpha -pinene	80-56-8	201-291-9	0.029	SCCS opinion on Fragrance allergens in cosmetic products, medium risk allergen *
Linalyl Acetate	115-95-7	204-116-4	0.5379	SCCS opinion on Fragrance allergens in cosmetic products, low risk allergen *
Citral	5392-40-5	226-394-6	0.0301	Annex III/70 2*
Limonene	5989-27-5	227-813-5	0.2795	Annex III/88 2*
Linalool	78-70-6	201-134-4	0.1005	Annex III/84 2*

The restrictions of the fragrance allergens relate to the following sources:

* SCCS Opinion on Fragrance allergens in cosmetic products, SCCS/1459/11.

2* Regulation (EC) No. 1223/2009 of the European parliament and of the council of 30 November 2009 on cosmetic products, Annex III List of substances which cosmetic products must not contain except to the restrictions laid down, L342/128.

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 ...)	w/o
3 organoleptic properties (colour, odour, whenever relevant)	Off white cream, characteristic Bergamot odour
4 pH (at 25°C)	4.43
5 viscosity (at 25°C)	19,000 cPs
6 thermal stability (glass bottle)	40°C for 12 weeks
7 Specific gravity (at 25°C)	0.961/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 jars has confirmed stability at 25°C for 12 weeks. During the test period the viscosity had significantly increased by 21%.

Additional testing was performed at 5°C, 40°C and 50°C over a 12 week period.

5°C Stability testing

During stability testing at 5°C at the week 12 time point the appearance of the product was described as having oily globules. An 44% increase in viscosity was also noted.

40°C Stability testing

Accelerated stability testing at 40°C showed changes in the product appearance at week 12 where it was noted as having 'oily globules'. Additionally, in week 12, the odour was noted to have changed where it was described as 'slightly stronger base odour' and the pH had dropped by 21%.

50°C Stability testing

A slight yellowish appearance change was noted from week 2 to 8 when the product was tested at 50°C, with the appearance noted as separating on week 12.

The pH had notably changed in week 2 where there was a 14% drop, this decrease continued through to week 12 where there was a 29% decrease. Additionally during viscosity testing there was a change noted from week 1 there was a 43% increase additional changes were noted in week 4, 8 and 12 where the changes were 49%, 20% and 40% respectively

A label warning is in place to store Slimming Sculpting Solution-Lift-Firm-Tone-Sculpt at a temperature of 25°C, with this it is not expected to affect the stability of the product as formulated.

A.3 Microbiological Quality

A PET test has been performed according to USP method 38 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 Airless Chubby Chunky Containers used in the 100ml slimming sculpting solution are made from Polypropylene and Low-density Polyethylene (LDPE), the pump is LDPE. The Airless Chubby Chunky Containers used in the 200ml slimming sculpting solution are made from Polypropylene with the pump being made from LDPE and High-density Polyethylene (HDPE). The components of the packaging material and suitability of use criteria are included 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

Slimming Sculpting Solution Lift-Firm-Tone-Sculpt is a product designed to limit the development of fat masses, helping facilitate the elimination of fat, stimulating lipolytic activity (breaking down of fat) of adipocytes (fat cells) . It is a leave-on product that in normal circumstances will be used once daily on the thighs, inner knees, abdomen and upper arms.

A.6 Exposure to the Cosmetic Product

Site of application	Total body area (Area body -Area head female)
Surface area of application (cm ²)	15670*
Volume of product applied (mg)	7820**
Frequency of application/use per day	Once daily
Target population	Adults
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	7.82g used once daily on a 60kg person, Relative Daily Exposure has been calculated as 130.33 mg/kg bw/day

Dermal absorption information	None
other	NA

* Surface area of application has been established as 15670cm², taking worst case scenario of RégimA Slimming Sculpting Solution Lift-Firm-Tone-Sculpt being applied to the entire body during one treatment session. Area body – Area head female = 15670cm². Table 1; Mean exposed skin surface area per product type and frequency of application per product type, Section 4-2, page 76, SCCS Notes of guidance for the testing of cosmetic ingredients and their Safety Evaluation, 9th revision.

** Volume of product applied = 7820mg; taken as worst case scenario of application of product to the entire body. Volume of product applied has been extracted from Skin Care, *Body lotion*, Table 2: Estimated daily exposure levels for different cosmetic product types according to Cosmetics Europe Data, SCCS Notes of Guidance for the testing of Cosmetic Ingredients and their Safety evaluation, 9th revision.

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)
Olea Europaea Fruit Oil 8001-25-0	5.825	130.33	1	7.5917
Shea butter Glycerides 194043-92-0	5	130.33	1	6.5165
Glycerin 56-81-5	3	130.33	1	3.9099
Ribes Nigrum Seed Oil 68606-81-5	3	130.33	1	3.9099
Rosa Canina Fruit Oil 84603-93-0	3	130.33	1	3.9099
Cetearyl Olivatate 85116-80-9	2.5	130.33	1	3.2583
Sorbitan Olivatate 223706-40-9	2.5	130.33	1	3.2583
Persea Gratissima Oil 8024-32-6	2	130.33	1	2.6066
Hydrogenated Olive Oil 226993-75-5	1.95	130.33	1	2.5414
Citrus bergamia peel oil expressed 93686-22-7	1	130.33	1	1.3033

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
Phenoxyethanol 122-99-6	0.9	130.33	1	1.1730
Pentylene Glycol 5343-92-0	0.8	130.33	1	1.0426
Caesalpinia Spinosa Fruit pod extract 39300-88-4	0.475	130.33	1	0.6191
Kappaphycus Alvarezii extract 1220882-73-4	0.475	130.33	1	0.6191
Xanthan Gum 11138-66-2	0.25	130.33	1	0.3258
Olea Europaea Oil Unsaponifiables 8001-25-0	0.225	130.33	1	0.2932
Secale Cereale Seed Extract 90106-48-2	0.22	130.33	1	0.2867
Hydrolyzed Celosia Cristata Flower/Seed Extract 669066-11-9	0.1088	130.33	1	0.142
Caprylyl Glycol 117-86-8	0.1	130.33	1	0.130
Tocopherol 54-28-4	0.1	130.33	1	0.130
Hydrolyzed Prunella Vulgaris Extract 90105-92-3	0.0272	130.33	1	0.0354

[#] No dermal absorption data is available, 100% dermal absorption assumed as it is a leave on product.

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
Olea Europaea Fruit Oil 8001-25-0	A	2014 CIR Compendium. For use up to 100%, Final report 03/11 available from CIR. Present in the current formulation at 5.825% and is therefore considered safe for use.								
Shea butter Glycerides 194043-92-0	A	For use up to 6.5%, Final report 09/12/2017 available from CIR. Present in the current formulation at 5% and is therefore considered safe for use.								
Glycerin 56-81-5	A	Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin.								
Ribes Nigrum Seed Oil 68606-81-5	A	2014 CIR Compendium. For use up to 0.3%, Final report 03/11 available from CIR. Ribes Nigrum Seed Oil is present in Slimming Sculpting Solution-Lift-Firm-Tone-Sculpt at 3%. A dermal irritation and sensitization study was performed using a skin cream containing 0.2% Ribes Nigrum (Blackcurrant) oil was evaluated with 106 participants in a HRIPT with an occlusive patch. The test indicated that it was not a dermal irritant or a sensitizer. Ribes Nigrum at 0.25% was formulated in a cream (type not specified) which was evaluated on 119 participants to determine Primary cutaneous irritation the results showed no primary irritation . <i>Ribes Nigrum</i> (Blackcurrant) <i>seed oil</i> is also a food item; GRAS, it is therefore considered safe for use in Slimming Sculpting Solution-Lift-Firm-Tone-Sculpt.								
Rosa Canina Fruit Oil 84603-93-0	A	2014 CIR Compendium. For use up to 19%, final report 03/11 available from CIR. Present in the current formulation at 3% and is therefore considered safe for use.								
Cetearyl Olivatate 85116-80-9	A	2014 CIR Compendium. For use up to 3% and when formulated to be non-irritating, Final report 03/2013 available from CIR. Present in the current formulation at 2.5% and is therefore considered safe for use.								
Sorbitan Olivatate 223706-40-9	A	2014 CIR Compendium. For use up to 7.5%, IJT 21(S1):93-112, 2002. Present in the current formulation at 2.5% and is therefore considered safe for use.								

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
Persea Gratissima Oil 8024-32-6	A	2014 CIR Compendium. For use up to 89%, Final amended report 03/11 available from CIR; JEPT 4(4):93-103, 1980 (original) re-review IJT 22(S1) :1-35, 2003. Present in the current formulation at 2% and is therefore considered safe for use.								
Hydrogenated Olive Oil 226993-75-5	A	2014 CIR Compendium. For use up to 12%, Final report 03/11 available from CIR. Present in the current formulation at 1.95% and is therefore considered safe for use.								
Phenoxyethanol 122-99-6	A	2014 CIR Compendium. For use up to 1%, JACT 9(2):259-77,1990. Present in the current formulation at 0.9% and is therefore considered safe for use.								
Pentylene Glycol 5343-92-0	A	2014 CIR Compendium. For use up to 5%, IJT 31 (S2):147-168, 2012. Present in the current formulation at 0.8% and is therefore considered safe for use.								
Caesalpinia Spinosa Fruit pod extract 39300-88-4	##	<p>A secondary assessment was performed on Caesalpinia Spinosa Fruit Pod extract. A recommended dose was established as 1-5%; where 5% was used as the worst case scenario dose. Caesalpinia Spinosa Fruit Pod extract is present in Slimming Sculpting Solution lift-Firm-Tone-Sculpt at 0.475%, 10.5 times lower than that of the worst case dose outlined. A read across to Caesalpinia Spinosa gum was performed due to the gum being derived from the dried, gummy exudate of <i>Caesalpinia Spinosa leuminosae</i>. Caesalpinia Spinosa gum has been approved for use as a food ingredient with no specific ADI for man established. 2014 CIR Compendium has outlined a use concentration of 0.5% for Caesalpinia Spinosa gum (Final report 03/12 available from CIR). It's present in the current formulation at 0.475% and is therefore considered safe for use..</p> <p>Caesalpinia Spinosa Fruit pod extract is not expected to cause any adverse outcome effects in Slimming Sculpting Solution lift-Firm-Tone-Sculpt as formulated when used as directed.</p>								
Kappaphycus Alvarezii extract 1220882-73-4	##	<p>A secondary assessment was performed on Kappaphycus Alvarezii extract. A read across was performed to Carrageenan as the primary component of Kappaphycus Alvarezii is sulfonated galactans known as Carrageenan. Carrageenan is GRAS the US FDA and is an approved food additive. The WHO JECFA report established confirmed that carrageenan is safe for food use and concluded that it is not necessary to specify an ADI. The carrageenan molecule is a large molecule</p>								

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
		with average molecular weights of 200,000-400,000 leading to a low dermal absorption potential and therefore reducing the risk of a systemic effect. It was therefore concluded that the presence of Kappaphycus Alvarezii extract in Slimming Sculpting Solution Lift-Firm-Tone-Sculpt at 0.475% is not expected to cause an adverse outcome effect when used as directed.								
Xanthan Gum 11138-66-2	A	2014 CIR Compendium. For use up to 6%, Final report 09/12 available from CIR. Present in the current formulation at 0.25% and is therefore considered safe for use.								
Olea Europaea Oil Unsaponifiables 8001-25-0	A	2014 CIR Compendium. For use up to 3%, Final report 03/11 available from CIR. Present in the current formulation at 0.225% and is therefore considered safe for use.								
Secale Cereale Seed Extract 90106-48-2	A	The common name for <i>Secale Cereale Seed Extract</i> is Rye Seed Extract. Rye seeds are a common food ingredient with no safety concerns associated with it. It was determined that <i>Secale Cereale Seed Extract</i> is not expected to cause any adverse outcomes when used as directed, at 0.22% (0.0092 mg/kg bw/day).								
Hydrolyzed Celosia Cristata Flower/Seed Extract 669066-11-9	##	A secondary assessment of Hydrolyzed Celosia Cristata Flower/Seed Extract has been performed. It has been used in traditional medical for the purposes of headaches, ulcers and eye inflammation. Limited toxicological data is available however an oral administration study where a methanol extract of <i>Celosia Cristata</i> was administered in feed at doses of between 1000-4000 mg/kg which equated to 150-600 mg/kg bw/day with a conversion factor was applied. Hydrolyzed Celosia Cristata Flower/Seed Extract is present in Slimming Sculpting Lift-Firm-Tone-Slim-Sculpt at 0.142 mg/kg bw/day; 1056 –4225 times lower than the doses previously outlined. Hydrolyzed Celosia Cristata Flower/Seed Extract is a component of Silab [®] product marketed as Biosculptine, the combined safety has been examined and was confirmed as both non-irritating in cutaneous irritation tests <i>in vivo</i> on human volunteers and non-sensitizing following evaluation in human volunteers using the Marzulli-Maibach method, these studies are outlined in the Biosculptine leaflet in Appendix 4. It is therefore concluded that Hydrolyzed Celosia Cristata Flower/Seed								

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 is not expected to cause any adverse outcomes when used as directed, in Slimming Sculpting Lift-Firm-Tone-Slim-Sculpt as formulated.								
Caprylyl Glycol 117-86-8	A	2014 CIR Compendium. For use up to 5%, IJT 31 (S2):147-168, 2012. Present in the current formulation at 0.1% and is therefore considered safe for use.								
Tocopherol 54-28-4	A	2014 CIR Compendium. For use ≤5%, IJT 21(S3):51-116, 2002; Final report 03/2014 available from CIR. Present in the current formulation at 0.1% and is therefore considered safe for use.								
Hydrolyzed Prunella Vulgaris Extract 90105-92-3	##	A secondary assessment has been performed on Hydrolysed Prunella Vulgaris extract. Limited toxicological data was available with a dose range of 0.75g to 30g established via oral administration and topical application. Hydrolysed Prunella Vulgaris extract is present in Slimming Sculpting Solution Lift-Firm-Tone-Sculpt at 0.0354 mg/kg bw/day. The systemic exposure was calculated to be 12.5 mg/kg bw/day and 500mg/kg bw/day based on a 60kg human which equated to 353 and 14124 times greater than that outlined in formulation for 0.75g (750mg) and 30g (30,000mg) respectively. Prunella Vulgaris is a common Chinese herbal medicine that is used to treat a range of illnesses that include high blood pressure. Prunella Vulgaris has been listed on the FDA Poisonous Plant Database, it was also found that small doses of Prunella Vulgaris is considered safe. <i>Hydrolyzed Prunella Vulgaris Extract</i> is a component of Silab [®] product marketed as Biosculptine, the combined safety has been stated as non-irritating in cutaneous irritation tests when used between 2 and 4% in human volunteers. Along with the irritation potential being evaluated the sensitizing potential was evaluated and resulted in a non-sensitizing affirmation following its evaluation <i>in vivo</i> on human volunteers using the Marzulli-Maibach method, this is presented in the Biosculptine leaflet presented in Appendix 4. As hydrolyzed Prunella Vulgaris is present in Slimming Sculpting Solution Lift-Firm-Tone-Sculpt at a low level (0.0272%) and considering the available safety information, it is not expected that there would be adverse effects and it is expected to be safe for use when used as directed.								

^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.

Secondary assessment performed and report presented in Appendix 4.

Fragrances:

Slimming Sculpting Solution Lift-Firm-Tone-Sculpt contains the fragrance Citrus Bergima Peel Oil expressed, known as Bergamot Oil. The IFRA certificate is presented in Appendix 3 and fragrance allergen composition is outlined in Section A.1.

A.9 Undesirable Effects and Serious Undesirable Effects

No undesirable effects are anticipated based on the product being used as directed on the total body area, once daily.

A.10 Information on the Cosmetic Product

Slimming Sculpting Solution Lift-Firm-Tone-Sculpt was released in July 2017. Over the period July 2017 to October 2018 , 346 units have been sold and there have been no adverse reactions reported to RégimA Company.

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 Slimming Sculpting Solution Lift-Firm-Tone-Sculpt will cause damage to human health when used as directed.

It is therefore concluded that Slimming Sculpting Solution Lift-Firm-Tone-Sculpt can be placed on the market in the EU as a body cream.

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 label and (Appendix 4).

Directions:

100ml Box

Cleanse the body of cream and oil, except SpaZone Target Cellulite, which may be used in combination.

Apply one pump depression per target area, such as thighs, inner knees, abdomen, upper arms. Gently massage a thin layer of cream solution to target areas. A cooling sensation may be felt.

These SpaZone products are leave-on treatments that work synergistically, so do not cleanse off until the next morning if possible.

200ml Box

To be used as part of a RégimA in-salon treatment.

Cleanse the body of cream and oil, except SpaZone O₂-Purifyer Serum and/or Target Cellulite, which may be used in combination.

Apply one pump depression per target area such as thighs, inner knees, abdomen, upper arms. Gently massage a thin layer of cream solution to target areas. A cooling sensation may be felt. Therapist may then apply plastic wrap firmly over treated areas and leave for one hour. Plastic wrap is then removed.

These SpaZone products are leave on treatments that work synergistically so are not cleansed off until the next morning if possible.

A IBPN technology® label is attached to packaging indicating that RégimA hold the license to utilize Silab's Interpenetrating biopolymer Network in their cosmetics. The certificate stating this is presented in Appendix 4.

Warnings:

100ml

'Must not be combined with any other product range'

'A cooling sensation may be felt'

'Airless Container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in the label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'If irritation occurs, discontinue use'

200ml

'To be used as part of RégimA in-salon treatment'

'Must not be combined with any other product range'

'A cooling sensation may be felt'

'Strictly for professional use'

'Airless Container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in the label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'If irritation occurs, discontinue use'

B.3 Reasoning

This product contains many ingredients with a positive reputation for their body lotion 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, MSB

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

A handwritten signature in dark ink, appearing to read 'Shirley H', with a long horizontal flourish extending to the right.

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 body lotion.

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/>



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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Prime Product Manufacturing (Pty) Ltd

Main Site: Necsa Site, Building VB5, Elias Motsoaledi Street Ext (Church Street West), R104 Pelindaba, Madibeng Municipality, North West
has been registered by Intertek as conforming to the requirements of:

ISO 22716:2007

The management system is applicable to:

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

Certificate Number:
0072927-00

Initial Certification Date:
07 March 2018

Date of Certification Decision:
07 March 2018

Issuing Date:
07 March 2018

Valid Until:
06 March 2021



**Certificate
Mark**
coming soon



Calin Moldovean
President, Business Assurance



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.



PROOF OF EFFECT CLAIMED

This product claims to limit the development of fat masses, particularly in the abdomen and thighs, firm upper arms, helping facilitate elimination of fat, stimulating lipolytic activity (breaking down of fat) of adipocytes (fat cells).

A new slenderizing strategy, short and long term, is obtained from the synergy of specific plant polyphenols, providing a dual action mechanical stress and by tightening the dermal fiber network. Skin regains elasticity and tone, restoring curve contour.

With continued treatments one can experience a decrease in oedema (fluid retention), thigh and abdominal circumference, dermal tightening, helping regain elasticity and tone.

The claims relating to Slimming Sculpting Solution -Lift-Firm-Tone-Sculpt are substantiated by supplemented data supplied by Silab. RégimA is a licensed user of Silab products which include Biosculptine®, Coheliss and Filmexel where through *In Vitro* and human *In Vivo* testing have shown to substantiate the results claimed.

The additional information on Silab® ingredients are located in Appendix 4.

ANIMAL TESTING STATEMENT

To the best of our knowledge, the manufacturer and his suppliers have not carried out or commissioned any animal testing for the purpose of developing new cosmetic products.

The statement below is a confirmation of the company policy:

RégimA Skin Treatments

CK92/05371/23

VAT No. 4590131043

Tel: 011 615 2869 or 011 622 7827

Fax: 011 616 8008

Cell: 0836537020

e-mail: jax@regima.com

POSTAL ADDRESS: PO BOX 9523 Edenglen 1613

PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA

Animal Testing Compliance Statement

This letter is to serve as testimony as to the practice of animal testing, and confirm that RégimA Skin Treatments has not, nor will not engage in any practice that involves animal testing in any form.

RégimA Skin Treatments hereby confirms neither the manufacturer nor RégimA Skin Treatments itself have commissioned or carried out any form of animal testing during the course of product development. This applies to any and all activities performed as part of the development process, including, but not restricted to: R&D, stability testing, safety and toxicology assessments, suitability studies or any other facet related to the product's development.

Appendix 1: Safety Data Sheets or Ingredient Specifications

Safety data sheets and technical data sheets for the ingredients are maintained electronically with the PIF by the Responsible Person. They are available on request.

Appendix 2: Microbial Challenge Test

A microbial challenge test is maintained electronically with the PIF by the Responsible Person. It is available on request.

Appendix 3: Certificates of Allergen Content



IFRA Conformity Certificate

Compound Name : BERGAMOT OIL {BOL-BE01}

Code Number : RCP-76695

We certify that the above compound is in compliance with the standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA-47th amendment, published June 2013), provided it is used at a maximum concentration level of:

IFRA category (*)	Maximum level of use (%)(w/w) (**)
1A 1B (***)	1.33 (***)
2	1.66
3A	6.64
3B	6.64
3C	6.64
3D	6.64
4A	19.91
4B	19.91
4C	19.91
4D	19.91
5	9.96
6 (***)	33.19 (***)
7A	3.32
7B	3.32
8A	46.47
8B	46.47
9A	100.00
9B	100.00
9C	100.00
10A	82.97
10B	82.97
11A	100.00
11B	100.00

(*) See annex for definition of IFRA categories

(**) Usage limit N/A = Not Applicable; no IFRA restrictions

(***) IFRA would recommend that any material used to impart perfume or flavour in products intended for human ingestion should consist of ingredients that are in compliance with appropriate regulations for foods and food flavourings

For other kinds of application or use at higher concentrations, a new safety evaluation may be needed; please contact F.D. Copeland and Sons Ltd.

The IFRA Standards regarding restrictions are based on safety assessments by the Panel of Experts of the RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS (RIFM) and are enforced by the IFRA Scientific Committee.

Evaluation of individual Fragrance ingredients is made according to the safety standards contained in the relevant section of the IFRA Code of Practice.

It is the ultimate responsibility of our customer to ensure the safety of the final product (containing this fragrance) by further testing if need be.

The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued. It is your responsibility to ensure that the usage of the fragrance ingredients and the levels of such usage are permitted at all times according to the relevant laws and regulations

ANNEX: Definition of IFRA categories

Finished Product Types	IFRA category
Lip products of all types (solid and liquid lipsticks, balms, clear or coloured, lipwax, etc.) Toys	1A (**)
Waxes for mechanical hair removal	1B
Deodorant and Antiperspirant Products of all types (pump spray, aerosol spray, stick, roll-on, under-arm and body, etc.) Fragranced Bracelets	2
Hydroalcoholic Products applied to recently shaved skin - EdT	3A
Hydroalcoholic Products applied to recently shaved skin- Fine fragrance	3B
Eye Products of all types (eye shadow, mascara, eyeliner, eye make-up, etc.) including eye care Men's Facial Creams and Balms; Baby Creams, Lotions, Oils; Body Paint for Children	3C
Tampons	3D
EdT: Hydroalcoholic Products applied to unshaved skin, Ingredients of Perfume Kits, Scent Pads, Foil Packs, Scent Strips for Hydroalcoholic Products	4A
Hydroalcoholic Products applied to unshaved skin - Fine fragrance	4B
Hair styling aids sprays of all types (pumps, aerosol sprays etc.), Hair Deodorant Body Creams, Oils, Lotions, Fragrancing Creams of all types (except baby creams, lotions and oils) Fragrance Compounds for Cosmetic Kits, Foot Care Products, Body Paint for Adults	4C
Fragrancing cream	4D
Women's Facial Creams/Facial Make-up, Hand Cream, Facial Masks Hand Sanitisers, Wipes or Refreshing Tissues for Face, Neck, Hands, Body Baby Powder and Talc Hair Permanent and Other Hair Chemical Treatments (e.g. relaxers) but not hair dyes, Dry Shampoo or Waterless Shampoo	5
Mouthwash, including Breath Sprays, Toothpaste	6 (**)
Intimate Wipes, Baby Wipes	7A
Insect Repellent (intended to be applied to the skin)	7B
Make-up Removers of all types (not including face cleansers) Hair Styling Aids Non-Spray of all types (mousse, gels, leave-in conditioners, etc.) Nail Care, Powders and talcs (not including baby powders and talcs)	8A
Hair Dyes	8B
Shampoos of all types (including baby shampoos), Conditioner (Rinse-Off), Face Cleansers of all types (washes, gels, scrubs, etc.), Liquid Soap, Bar Soap (Toilet Soap), Depilatory(not including waxes for mechanical hair removal), Shaving Creams of all types (stick, gels, foams, etc.) Body Washes of all types (including baby washes) and Shower Gels of all types Bath Gels, Foams, Mousses, Salts, Oils and other products added to bathwater	9A
Feminine Hygiene – pads, liners, Toilet Paper Wheat bags	9B
Other* Aerosols (ind. air freshener sprays and air freshener pump sprays, but not deodorants / antiperspirants, hair styling aids spray and animal sprays) Facial Tissues, Napkins, Paper Towels	9C
Handwash Laundry Detergents of all types including concentrates Machine Wash Laundry Detergents (liquids, powders, tablets etc.) including laundry bleaches and concentrates Fabric Softeners of all types including fabric softener sheets, Hand Dishwashing Detergent including concentrates Hard Surface Cleaners of all types (bathroom and kitchen cleansers, furniture polish etc.) Other Household Cleaning Products (fabric cleaners, soft surface cleaners, carpet cleaners etc.) Dry Cleaning Kits, Shampoo for pets	10A
Diapers, Toilet Seat Wipes	10B
All non-skin contact including: Air Fresheners and Fragrancing of all types (concentrated aerosol air fresheners, plug-ins, solid substrate, membrane delivery, ambient, electrical...) excluding aerosol products, Liquid refills for air fresheners (cartridge systems), Scent delivery system using a dry air technology that releases a fragrance without sprays, aerosols or heated oils (technology of nebulization), Air delivery systems Candles, Joss Sticks, Incense, Air freshening crystals, Fragranced lamp ring, Scent pack, Machine Only Laundry Detergent (e.g. liquid tabs), Toilet Blocks, Insecticides (mosquito coil, paper, electrical, for clothing etc.) excluding aerosols Fuels, Paints, Floor wax, Plastic articles (excluding toys)	11A
All incidental skin contact including: Pot pourri, powders, fragrancing sachets, incense, Reed diffusers, Liquid refills for airfresheners (non-cartridge systems) Odoured Distilled Water (that can be added to steam irons), Machine Dishwash Detergent and Deodorizers Deodorizers/Masks not intended for skin contact (e.g. fabric drying machine deodorizers, carpet powders) Treated Textiles (e.g. starch sprays, fabric treated with fragrances after wash, deodorizers for textiles or fabrics, tights with moisturizers) Infused socks, Scratch and sniff (sampling technology) Shoe Polishes, Cat litter, Animal Sprays (all types)	11B

(**) This IFRA certificate does not include a GRAS-FEMA conformity check



Allergen Analysis

Compound Name : BERGAMOT OIL {BOL-BE01}

Code Number : RCP-76695

flavour ingredient	CAS No.	Concentration present as a percentage (%) or 'A' for absent in flavour		
		Added as such	From natural & other sources	Total
alpha-iso-Methylanone	127-51-5	A	A	A
Amyl Cinnamal	122-40-7	A	A	A
Amylcinnamyl Alcohol	101-85-9	A	A	A
Anise Alcohol	105-11-5	A	A	A
Benzyl Alcohol	100-51-6	A	A	A
Benzyl Benzoate	120-51-4	A	A	A
Benzyl Cinnamate	101-41-3	A	A	A
Benzyl Salicylate	118-58-1	A	A	A
Butylphenyl Methylpropional (Lilial)	80-54-6	A	A	A
Cinnamal	104-55-2	A	A	A
Cinnamyl Alcohol	104-54-1	A	A	A
Citral	5392-40-5	1.00	0.01	1.01
Citronellal	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-53-0	A	A	A
Evernia Furfuracea (Tree Moss) Extract	90028-67-4	A	A	A
Evernia Prunastri (Oak Moss) Extract	90028-68-5	A	A	A
Farnesol	4602-84-0	A	A	A
Geraniol	106-24-1	A	A	A
Hexyl Cinnamal	101-86-0	A	A	A
Hydroxycitronellal	107-75-5	A	A	A
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (Lyral)	31906-04-4	A	A	A
Isoeugenol	97-54-1	A	A	A
Limonene	5989-27-5	A	27.35	27.35
Linalool	78-70-6	10.00	0.05	10.05
Methyl 2-Octynoate	111-12-6	A	A	A

The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued. We will not therefore accept liability for misuse of this data resulting in damage or loss.

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.