

PRODUCT INFORMATION FILE*

RégimA

Target Cellulite Contouring
Complex

Prepared: April 2019
(Label and 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: Target Cellulite Silhouette Contouring Complex

Product type	Cream
Form	Emulsion
Colour	Off white
Pack size	200ml and 100ml
Pack type	Chubby chunky airless tube
Dispenser type	NA
Part of a set	No
Manufacturer code	CCC 003
Normal use	<p>Directions: AM or PM: cleanse the body of any cream and oil, except SpaZone O₂- Purifying Serum if undertaking a combined treatment. If the body is warm following a bath or shower this aids penetration.</p> <p>Massage briskly a layer of Complex to all areas prone to cellulite, thighs, buttocks, abdomen and inner knees. Then very gently ensure areas of lymph drainage (where toxins are eliminated) are covered, targeting mainly behind the knees, groin, armpits, up to the neck. Leave treatment on. One may apply Slimming Sculpting Solution to target areas over the top.</p>

Pictures of the Item: On following page

Container label

Target Cellulite Silhouette Contouring Complex – 200ml



Carton label

Target Cellulite Silhouette Contouring Complex – 200ml



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 the following:

- That it targets cellulite, facilitates progressive elimination of oedema (fluid retention), stimulates microcirculation by vaso-dilatation and decongestion. Sacred Locus breaks down fat storage, limits formation of new fat cells. Natural biopolymer has a tensor, lifting, anti-winkle effect, smoothing and visibly elasticizing, improving contour, plus the look and feel of lack lustre skin.

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

Target Cellulite Silhouette Contouring Complex base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Prunus Amygdalus Dulcis Oil	11.40612	12	8007-69-0/ 90320-37-9	291-063-5	Skin Conditioning/ Emollient	Textron Tecnica (CJP Chemicals)	Sweet Almond Oil
	Tocopherol	0.00588		54-28-4 (gamma)/ 16698-35-4 (beta)/ 10191-41-0 (DL)/ 119-13-1/ 1406-18-4/ 1406-66-2/ 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			
	Olus Oil	0.588		68956-68-3	273-313-5			
2	Water (Aqua)	5	5	7732-18-5	231-791-2	Solvent	In House	Deionised Water
3	Cetearyl Olivate	5	5	85116-80-9	285-532-3	Emulsifying	Textron Tecnica (CJP Chemicals)	Olivem® 1000
	Sorbitan Olivate	2.5		92202-01-2/ 223706-40-9	296-033-5			
4	Water (Aqua)	3.5875	5	7732-18-5	231-791-2	Solvent / Humectant/ Masking/ Skin Conditioning/ Viscosity Controlling/	Silab (Meganede)	Remoduline™
	Butylene Glycol	1.25		107-88-0	203-529-7			
	Citrus Aurantium Amara Flower Extract	0.1125		72968-50-4/ 68916-04-1	277-143-2			
	Phenoxyethanol	0.025		122-99-6	204-589-7			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Ethylhexylglycerin	0.025		70445-33-9	408-080-2	Refreshing/ Preservative		
5	Shea Butter Glycerides	5	5	68424-61-3/ 194043-92-0	270-312-1	Emulsifying/ Emulsion Stabilising/ Skin conditioning/ Surfactant/ Viscosity Controlling	Olcea (Savannah Fine Chemicals)	Olcea® Creamy Shea
6	Butylene Glycol	2	4	107-88-0	203-529-7	Humectant/ Masking/ Skin Conditioning/ Solvent/ Viscosity Controlling	Silab (Meganede)	Pro-Sveltyl® OP
	Water (Aqua)	1.966		7732-18-5	231-791-2			
	Nelumbo Nucifera Leaf extract	0.34		85085-51-4	285-379-2			
7	Hydrogenated Olive Oil	2.07	3	68334-28-1/ 226993-75-5	269-820-6	Skin Conditioning/ Viscosity Controlling/ Masking/ Perfuming	Textron Tecnica (CJP Chemicals)	Oliwax
	Olea Europaea Fruit Oil	0.633		8001-25-0	232-277-0			
	Olea Europaea Oil Unsaponifiables	0.297		8001-25-0/ 156798-12-8	232-277-0			
8	Olea Europaea Fruit Oil	2	2	8001-25-0	232-277-0	Masking/ Perfuming/ Skin Conditioning	Textron Tecnica (CJP Chemicals)	Olive Oil Extra Virgin
9	Glycerin	2	2	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
	Phenoxyethanol	0.9	1	122-99-6	204-589-7			Verstatil® PC

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
11	Caprylyl Glycol	0.1		1117-86-8	214-254-7	Preservative/ Humectant/ Skin Conditioning/ Emollient	Dr. Straetmans (Meganede)	
12	Water (Aqua)	0.05	1	7732-18-5	231-791-2	Solvent / Skin Conditioning/ Skin Protecting	Silab (Meganede)	Filmexel ®
	Kappaphycus alvarezii extract	0.475		1220882-73-4	310-127-6			
	Caesalpinia spinosa fruit extract	0.475		39300-88-4	254-409-6			
13	Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract)	1	1	93686-22-7	297-672-2	Perfuming	FD Copeland (CJP Chemicals)	Bergamot Oil
14	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 ® T Plus
15	Tocopherol	0.1	0.1	54-28-4 (gamma)/ 16698-35-4 (beta)/ 10191-41-0 (DL)/ 119-13-1/ 1406-18-4/	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	DSM Nutritional Products (Chempure)	dl- α - Tocopherol

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
				1406-66-2/ 2074-53-5 (DL)/ 59-02-9 (D)/ 7616-22-0				
16	Water (Aqua)	51.6	51.6	7732-18-5	231-791-2	Solvent	In House	Deionised Water

CAS/EC not assigned

Ingredient order for the label: Water (Aqua), Prunus Amygdalus Dulcis Oil, Shea butter Glycerides, Butylene Glycol, Olea Europaea Fruit Oil, Cetearyl Olivate, Sorbitan Olivate, Hydrogenated Olive Oil, Glycerin, Persea Gratissima Oil, Citrus Bergamia Peel Oil Expressed, Phenoxyethanol, Olus Oil, Caesalpinia Spinosa fruit Extract, Kappaphycus alvarezii extract, Nelumbo Nucifera Leaf extract, Xanthan Gum, Olea Europaea Oil Unsaponifiables, Limonene, Citrus Aurantium Amara Flower Extract, Tocopherol, Linalool, Caprylyl Glycol, Citral, Ethylhexylglycerin, Linalyl Acetate, Alpha-Pinene.

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*

INCI (EU) Name	CAS number	EC number	Concentration % w/w	Comment
Limonene	5989-27-5	227-813-5	0.2735	Annex III/88*
Linalyl Acetate	115-95-7	204-116-4	0.5379	Low to medium risk allergen as outlined by the SCCS Opinion on fragrance allergens 2*
Linalool	78-70-6	201-134-4	0.1005	Annex III/84*
Citral	5392-40-5	226-394-6	0.0301	Annex III/70*
Alpha -Pinene	80-56-8	201-291-9	0.029	Medium risk allergen as outlined by the SCCS Opinion on fragrance allergens 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 subject to the restrictions laid down, page 128.

2* SCCS Opinion on Fragrance allergens in cosmetic products, 15th plenary meeting, June 2012, Section 7, Table 7-1, page 47.

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 mixture
3 organoleptic properties (colour, odour, whenever relevant)	Off white colour, smooth consistency with characteristic odour (Bergamot Oil perfuming agent)
4 pH (Initial result at 25°C)	6.01
5 viscosity (Initial result at 25°C)	30,000 cPs
6 thermal stability (glass bottle)	40°C for 12 weeks
7 Specific gravity (Initial result at 25°C)	0.951 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 jars confirmed stability at 25°C (room temperature) for 12 weeks. Additional testing was performed at 5°C, 40°C and 50°C.

Stability testing at 5°C

During testing at 5°C an increase in viscosity was noted from week 1 to week 2 and in week 8 and week 12, the increase was noted to be 21%, 33%, 32% respectively.

Stability testing at 40°C

During testing at 40°C a change in appearance was noted in week 4; the product appeared slightly darker, this continued until week 12. Additionally, a decrease in pH was noted as 16%, 24%, 39% and 39% in weeks 2 to 12 respectively. A decrease in viscosity was noted from week 1 to 8 with the decrease being 94%, 63%, 47% and 20% respectively, an 40% increase was then noted in week 12.

The appearance of the cream was noted as slightly darker from week 4 through to week 12. It was determined that a warning be placed on the product indicating users to keep in a cool place

Stability testing at 50°C

Accelerated stability testing performed at 50°C indicated a significant change in the physical parameters outlined in the test from week 1, where a decrease in the pH was noted to be 20%, 27%, 38%, 46% and 47% from week 1 to 12 respectively. A decrease in viscosity was noted in week 1 and 4; 52% and 40% respectively.

From week 4; the creams appearance was noted as 'slightly darker' in comparison to the initial observation of off white, this change in appearance was noted through to week 12 where the consistency was also noted to be lumpy. Additionally, from week 8 the characteristic odour appeared stronger and this was continued through to week 12 of testing. A warning will be put in place for the user to keep in a cool dark place.

With normal storage and the consumer complying with additional warnings placed on the packaging, it is not expected that the product will deviate from specifications outlined. The stability report is presented in Appendix 4.

The Accelerated Aging Rate (AAR) was calculated to estimate the shelf life of the product. The AAR is calculated using the following equation;

$Q_{10}^A = ((\text{Accelerated Aging Temp.} - \text{Ambient Temp.})/10)$ where Q₁₀ is the Accelerated Aging Factor with an industry standard of 2.

$$\therefore AAR = 2^A ((50 - 25)/10) = 5.66$$

The study was performed over 12 weeks, 84 days, therefore $84 \times 5.66 =$ approximately 475 days using the Accelerated Aging scenario. This has confirmed the shelf life of 6 months which has been assigned to this product.

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 *Chubby Chunky Airless Containers* are made from 100ml; Low density polyethylene (LDPE) and AS/PP and 200ml; Polypropylene (PP) and Low-density polyethylene (LDPE). The pump in the 100ml is made from. 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

Target Cellulite Silhouette Contouring Complex is a product designed to moisturise the skin. It is a leave-on cream that in normal circumstances will be used twice daily on the entire body, mainly the thighs, buttocks, abdomen, inner knees, groin and arm pits.

A.6 Exposure to the Cosmetic Product

Site of application	Entire body (excluding the head)
Surface area of application (cm ²)	15,670
Volume of product applied (mg)	7,820*
Frequency of application/use per day	2.28/day**
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 applied daily Relative daily exposure of 130.33 mg/kg bw/day based on a 60kg adult
Dermal absorption information	None
other	NA

*Volume of product applied = 7.82g (7820 mg). This volume of application was determined as follows; Skin Care, Body Lotion, estimated daily amount applied; 7.82g. This figure has been extracted from adapted from SCCS Notes for Guidance for the testing of Cosmetic Ingredients and their safety Evaluation, 9th Revision, Section 4.2, Table 2, page 79.

**Frequency of application for Target Cellulite Silhouette Contouring Complex = 2.28/day. The frequency of application has been adapted from the following; Skincare, Body Lotion frequency of application of 2.28/day. This figure has been extracted from SCCS Notes for Guidance for the testing of Cosmetic Ingredients and their safety Evaluation, 9th Revision, Section 4.2, Table 1, page 76.

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)
Prunus Amygdalus Dulcis Oil 8007-69-0	11.40612	130.33	1	14.87
Shea Butter Glycerides 68424-61-3	5	130.33	1	6.52
Butylene Glycol 107-88-0	3.25	130.33	1	4.24
Olea Europaea Fruit Oil 8001-25-0	2.633	130.33	1	3.432
Cetearyl Olivate 85116-80-9	2.5	130.33	1	3.258
Sorbitan Olivate 92202-01-2	2.5	130.33	1	3.258
Hydrogenated Olive Oil 68334-28-1	2.07	130.33	1	2.698
Glycerin 56-81-5	2	130.33	1	2.607
Persea Gratissima Oil 8024-32-6	2	130.33	1	2.607
Citrus bergamia peel oil expressed 93686-22-7	1	130.33	1	1.303
Phenoxyethanol 122-99-6	0.925	130.33	1	1.206
Olus Oil 68956-68-3	0.588	130.33	1	0.766
Caesalpinia spinosa fruit extract 39300-88-4	0.475	130.33	1	0.619
Kappaphycus alvarezii extract 1220882-73-4	0.475	130.33	1	0.619

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)
Nelumbo Nucifera Leaf extract 85085-51-4	0.34	130.33	1	0.443
Xanthan Gum 11138-66-2	0.3	130.33	1	0.391
Olea Europaea Oil Unsaponifiables 8001-25-0	0.297	130.33	1	0.387
Citrus Aurantium Amara Flower Extract 5989-27-5	0.1125	130.33	1	0.147
Tocopherol 54-28-4	0.10588	130.33	1	0.138
Caprylyl Glycol 1117-86-8	0.1	130.33	1	0.130
Ethylhexylglycerin 70445-33-9	0.025	130.33	1	0.033

100% dermal absorption is used as Target Cellulite Silhouette Contouring Complex 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
Prunus Amygdalus Dulcis Oil 8007-69-0	A									2014 CIR Compendium. For use up to 77%, Final amended report 03/11 available from CIR; JACT 2(5):85-99, 1983; re-review IJT 24 (S1):98-101, 2005.
Shea Butter Glycerides 68424-61-3	A									For use up to 6.5%, Final report 09/12/2017 available from CIR
Butylene Glycol 107-88-0	A									2014 CIR Compendium. For use up to 89%, JACT 4(5):223-48, 1985 confirmed 02/04 IJT 25 (S2), 2006.
Olea Europaea Fruit Oil 8001-25-0	A									2014 CIR Compendium. For use up to 100%, final report 03/11 available from CIR.
Cetearyl Olivate 85116-80-9	A									2014 CIR Compendium. For use up to 3%; Safe for use in cosmetics when formulated to be non-irritating, Final report 03/2013 available from CIR.
Sorbitan Olivate 92202-01-2	A									2014 CIR Compendium. For use up to 7.5%, IJT 21 (S1):93-112,2002.
Hydrogenated Olive Oil 68334-28-1	A									2014 CIR Compendium. For use up to 12%, Final report 03/11 available from CIR.
Glycerin 56-81-5	A									Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin.
Persea Gratissima Oil 8024-32-6	A									2014 CIR Compendium. For use up to 98%, final amended report 03/11 available from CIR; JEPT 4(4):93-103, 1980 (original) re-review IJT 22(S1):1-35, 2003.
Citrus Bergamia Peel Oil Expressed	B									Supplier IFRA certificate of conformity supplied and presented in Appendix 3. Maximum allowable concentration in product is 19.91% (Category 4C – Body creams), actual concentration in Target Cellulite Silhouette Contouring Complex is 1%. All allergen components are declared in Section A.1. fragrance allergen table. It was determined that <i>Citrus Bergamia Peel Oil Expressed</i> is expected to be safe for use in Target Cellulite Silhouette Contouring Complex.
Phenoxyethanol 122-99-6	A									2014 CIR Compendium. For use up to 1%, JACT 9(2):259-77,1990.

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	Comment	
Olus Oil 68956-68-3	A		A read across was performed to Vegetable Oil as Olus Oil is an expressed oil of vegetable origin that primarily consists of triglycerides of fatty acids. 2014 CIR Compendium. For use up to 31%, Final report 03/11 available from CIR.								
Caesalpinia spinosa fruit extract 39300-88-4	A		A read across was performed on Caesalpinia spinosa fruit extract to Caesalpinia Spinosa gum. Caesalpinia Spinosa fruit Gum for use up to 0.5%, Final report 03/12 available from CIR. Caesalpinia spinosa fruit extract is present in Target Cellulite Silhouette Contouring Complex at a level of 0.475%, it is therefore expected to be safe for use in the product formulation.								
Kappaphycus alvarezii extract 1220882-73-4	#		A secondary assessment was performed on Kappaphycus alvarezii extract where the proprietary ingredient sulphated galactan; Carrageenan was evaluated. Carrageenan is isolated from red seaweeds with molecular weights of between 200,000 and 400,000, with dermal penetration evaluated as being limited due to the large size of the molecule. Carrageenan is GRAS by the US FDA under the Code of Federal Regulations (21 CFR 182.7255) and is also approved as food additive ingredient. Carrageenan has also been considered safe for food use with no ADI and Considered acceptable for use topically. It is therefore expected to be safe for use in Target Cellulite Silhouette Contouring Complex. Secondary assessment is presented in Appendix 4.								
Nelumbo Nucifera Leaf extract 85085-51-4			Limited publicly available information is available on Nelumbo Nucifera Leaf extract; therefore, a secondary assessment was performed on Nelumbo Nucifera Leaf extract to determine its safety. The assessment showed that the commercially recommended oral dose of Nelumbo Nucifera Leaf extract ranged from 1,000 – 3,000 mg daily. The relative daily exposure was calculated to range from 16.6mg/kg bw/day to 50 mg/kg bw/day, this equated to 38-115 times less than the level present in Target Cellulite Silhouette Contouring Complex (0.433 mg/kg bw/day), which in addition, is applied dermally where absorption is expected to be less than the oral route. It was determined that Nelumbo Nucifera Leaf extract is expected to be safe for use as formulated. The secondary assessment for Nelumbo Nucifera Leaf extract is present in Appendix 4. RegimA has provided additional information on Pro-Sveltyl® from Silab; the report and assessment are presented in Appendix 4.								
Xanthan Gum 11138-66-2	A		2014 CIR Compendium. For use up to 6%, Final report 09/12 available from CIR.								

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 Oil Unsaponifiables 8001-25-0	A		2014 CIR Compendium. For use up to 3%, Final report 03/11 available from CIR.							

<p>Citrus Aurantium Amara Flower Extract 72968-50-4</p>	<p>For use up to 0.0325% in leave on formulations. Final report 12/06/2016 available from CIR website.</p> <p>Citrus Aurantium Amara (Bitter Orange) Flower Extract is present in Target Cellulite Silhouette Contouring Complex at 0.1125%. Citrus Aurantium Amara (Bitter Orange) Flower Extract was found to be non-irritating in human subjects during dermal irritation studies when leave on formulations were comprised of up to 0.001%. HRIPT of Citrus Aurantium Amara (Bitter Orange) Flower Extract at concentrations of up to 0.0225% were found not to be not sensitizing. Citrus Aurantium Amara (Bitter Orange) Flower Extract is safe for use when formulated to be non-irritating and non-sensitizing. A read across to Citrus Aurantium Amara (Bitter Orange) flower Oil was also performed to determine its dermal sensitization potential. Tests performed on Citrus Aurantium Amara (Bitter Orange) flower Oil found it not to be sensitizing at 4% in petrolatum; Final report 12/06/2016 available from CIR.</p> <p>Additionally, a Toxtree assessment was performed to determine the safety of Citrus Aurantium Amara Flower Extract, the assessment utilised the Cramer Rules and Revised Cramer Decision Tree along with a QSAR Skin Irritation/Skin Corrosion assessment.</p> <p>The results indicated a Low (Class I) classification in both the Cramer Rules and Revised Cramer Decision Tree, a Low (Class II) classification using the Cramer Rules describes a substance of simple chemical structure with known metabolic pathways and innocuous end products which suggest a low order of oral toxicity. The Threshold of Toxicological Concern has been established as 1,800 µg/day - 30µg/kg bw/day. The Revised Cramer Decision Tree Low (Class I) classification describes a substance with simple chemical structures and for which efficient modes of metabolism exist which suggests a low order of oral toxicity, the 5th percentile NOEL was established as 3.0 mg/kg bw/day with a human exposure threshold of 1.8 mg/person/day. A QSAR Skin Irritation/Skin Corrosion assessment indicated an unknown result.</p> <p>Citrus Aurantium Amara (Bitter Orange) Flower Extract is present in formulation at 0.147 mg/kg bw/day, lower than that outlined in the above assessments, it was therefore determined to be safe for use when used as directed.</p> <p>Bitter orange is regulated by the Food and Drug Administration (FDA). Although <i>C. aurantium</i> is listed in its Poisonous Plants Database, <i>C. aurantium</i> orange oil extract, peel, flowers, and leaf are listed in the food additive database, an inventory often referred to as "Everything" Added to Food in the United States</p>
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		<p>(EAFUS). Additionally, bitter orange peel, oil, oleoresins, and extracts are Generally Recognized as Safe (GRAS) as a direct additive to food. Citrus Aurantium Amara Flower Extract NTP Toxicological Literature Review</p> <p>As Citrus Aurantium Amara (Bitter Orange) Flower Extract is present at a higher percentage to that outlined in the CIR Compendium a warning will be placed on the label to direct the consumer to stop use if irritation occurs. It is not expected to cause irritation when used as directed.</p>
Tocopherol 54-28-4	A	2014 CIR Compendium. For use <= 5%. IJT 21(S3):51-116, 2002; Final report 03/2014 available from CIR.
Caprylyl Glycol 1117-86-8	A	2014 CIR Compendium. For use up to 5%, IJT 31 (S2):147-168, 2012.
Ethylhexylglycerin 70445-33-9	A	For use up to 8%, IJT 32(Suppl. 3):5-21, 2013

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

^b all possible routes of exposure should be considered

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

Food item, hazard and exposure data not required.

Fragrances:

Target Cellulite Silhouette Contouring Complex contains a fragrance called Bergamot Oil. The fragrance allergens are presented in Section A.1. with the IFRA certificate and certificate of conformity presented in Appendix 3.

A.9 Undesirable Effects and Serious Undesirable Effects

No undesirable effects are anticipated based on the product being used as directed on the body twice daily. The areas of the body that Target cellulite Silhouette Contouring Complex is targeted towards includes thighs, buttocks, abdomen, inner knees, behind knees, groin, armpits, up to neck.

A.10 Information on the Cosmetic Product

Target Cellulite Silhouette Contouring Complex was released in September 2017. Over the period September 2017 to April 2019 760 units have been sold and there have been no adverse reactions reported to RégimA.

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 Target Cellulite Silhouette Contouring Complex will cause damage to human health when used as directed.

It is therefore concluded that Target Cellulite Silhouette Contouring Complex can be placed on the market in the EU as a face and body serum.

Review of human data on the product

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

B.2 Label Warnings and Instructions for Use

Directions for use are given on the product label and outer packaging of both the 100ml and 200 ml packaging, this is presented in Appendix 4.

Directions

Target Cellulite Silhouette Contouring Complex 100ml: AM or PM: Cleanse the body of any cream and oil. If the body is warm following a bath or shower this aids penetration. Massage briskly a layer of Complex to all areas prone to cellulite, thighs, buttocks, abdomen and inner knees. Then very gently areas of lymph drainage (where toxins are eliminated) are covered, targeting mainly behind knees, groin, armpits, up to neck. Leave treatment on.

Target Cellulite Silhouette contouring Complex 200ml: To be used as part of a RégimA in-salon treatment.

Cleanse the body of cream and oil, except SpaZone O₂ Purifyer Serum if undertaking a combined treatment. Ensure the body is warm as this will aid penetration.

Massage briskly a layer of Complex to all areas prone to cellulite, thighs, buttocks, abdomen and inner knees. Then very gently ensure areas of lymph drainage are

covered, targeting mainly behind knees, groin, armpits, up to neck. Leave treatment on. One may apply Slimming Sculpting Solution to target areas over the top.

Warnings:

Target Cellulite Silhouette Contouring Complex 100ml

'MUST NOT be combined with any other product range'

'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'

'If irritation occurs, discontinue use'

Target Cellulite Silhouette contouring Complex 200ml:

'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'

'MUST NOT be combined with any other product range'

'If irritation occurs, discontinue use'

B.3 Reasoning

This product contains many ingredients with a positive reputation for their skin moisturising properties and with good local tolerance when used as directed. 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



After analysing 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/>

METHOD OF MANUFACTURE / GMP CERTIFICATION



PROOF OF EFFECT CLAIMED

This product claims to *target cellulite, facilitates progressive elimination of oedema (fluid retention), stimulates microcirculation by vaso-dilatation and decongestion. Sacred Locus breaks down fat storage, limits formation of new fat cells. Natural biopolymer has a tensor, lifting, anti-wrinkle effect, smoothing and visibly elasticizing, improving contour, plus the look and feel of lack lustre skin.*

RégimA have provided a report from the manufacturers Silab (Meganede) on the active ingredient Pro-Sveltyl® an ingredient that claims anti-cellulite and draining properties. The product Pro-Sveltyl® contains the active ingredient named *Nelumbo nucifera* which is better known as Sacred Lotus. The Pro-Sveltyl® properties include;

- *In Vivo* (Human) studies have demonstrated the anti-cellulitis action, the draining effect and the slenderizing properties of Pro-Sveltyl®. The test was performed at 4% versus a placebo where it was found that Pro-Sveltyl® significantly reduced skin surface irregularities which resulted from the presence of cellulitis, drains zones of edema and reduces the circumference of the thighs, abdomen and hips.
- Reducing fat storage by activating lipolysis and boosting the synthesis of SIRT-1
- Limits adipose tissue inflammation by stimulating the expression of adiponectin
- Preserving fibrous architecture by inhibiting the activity of adipocyte MMP-2 and MMP-9
- *In Vitro* studies have shown its effects on fat storage, adipose tissue inflammation and on fibrous matrix of adipose tissue.

These properties have been confirmed by *In vitro* and *In vivo* (Human studies), this report is presented 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



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-Methylionone	127-51-5	A	A	A
Amyl Cinnamal	122-40-7	A	A	A
Amylcinnamyl Alcohol	101-85-9	A	A	A
Anise Alcohol	105-13-5	A	A	A
Benzyl Alcohol	100-51-6	A	A	A
Benzyl Benzoate	120-51-4	A	A	A
Benzyl Cinnamate	103-41-3	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	3.00	0.01	3.01
Citronellol	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-53-0	A	A	A
Evernia Furfuraceae (Tree Moss) Extract	90028-67-4	A	A	A
Evernia Prunastri (Oak Moss) Extract	90028-68-5	A	A	A
Famesol	4602-84-0	A	A	A
Geraniol	106-24-1	A	A	A
Hexyl Cinnamal	101-86-0	A	A	A
Hydoxycitronellal	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.



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 (incl. 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 cleaners, 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. liquitabs), 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-cartrige systems) Odoured Distilled Water (that can be added to steam irons), Machine Dishwash Detergent and Deodorizers Deodorizers/Maskers 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

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.