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## SUBJECTIVE EVALUATION OF THE SLIMMING AND ANTI-CELLULITE EFFICACY OF AN INSTITUTE CARE

<b>Report (version 1):</b>	<b>#12E1681, September 21, 2012</b>
<b>Price proposal:</b>	<b>#12E1681-2</b>
<b>Products:</b>	<b>1- Detox de base 2- Active Slim Gel 3- Active Slim Crème 4- Ultra Slim Effect</b>
<b>Forms:</b>	<b>1- Orange Gel 2- Blue Gel 3- Pinkish beige emulsion 4- Red Gel</b>
<b>Application zone:</b>	<b>Body</b>
<b>Sponsor:</b>	<b>PROVENCE COSMETICS 118 Allée Renoir 13600 La Ciotat FRANCE</b>
<b>Study monitor:</b>	<b>Mr VERGNOLLE</b>
<b>Investigation site:</b>	<b>DERMSCAN France</b>
<b>Project Manager / Assistant:</b>	<b>Mrs Anne VIOLA / Carine KURDIAN <a href="mailto:avi@dermscan.com">avi@dermscan.com</a> / <a href="mailto:cku@dermscan.com">cku@dermscan.com</a></b>

ISO 9001: 2008 certified, DERMSCAN is authorized as a clinical testing center by the French Ministry of Health and the AFSSAPS and benefits from a governmental Research Tax Credit from the French Ministry of Research.

**Document: 2/2**  
(document including 26 pages)

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**CERTIFICAT DE CONTROLE QUALITE****QUALITY INSPECTION STATEMENT**

PRM03-F-001\_V2



Numéro de l'étude clinique / <i>Clinical study number</i> :	12E1681
Date de début de l'étude / <i>Study start date</i> :	August 6, 2012
Date de fin de l'étude / <i>Study completion date</i> :	August 10, 2012

L'étude référencée ci-dessus a été conduite conformément aux règles des Bonnes Pratiques Cliniques (BPC-ICH) et aux procédures opératoires standardisées de DERMSCAN.

*The study listed above was conducted in conformance with Good Clinical Practice (GCP-ICH) and DERMSCAN standard operating procedures.*

La personne habilitée à exercer le contrôle qualité final atteste du respect des règles et des procédures nommées ci-dessus.

*The Quality inspection Auditor testifies to the respect of the rules, the standards and procedures listed above.*

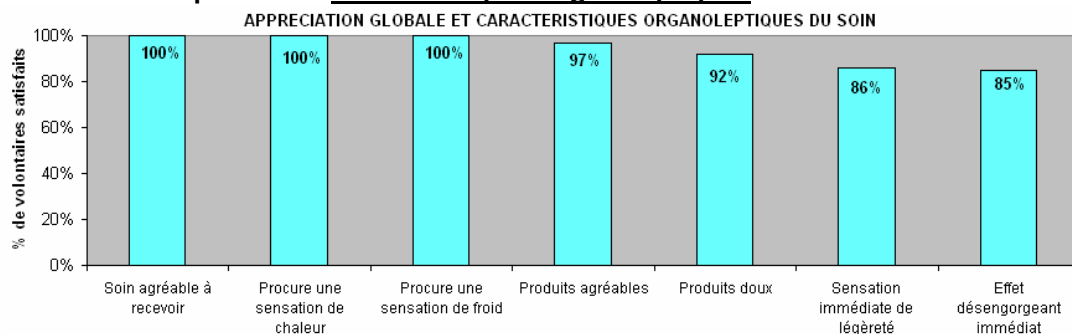
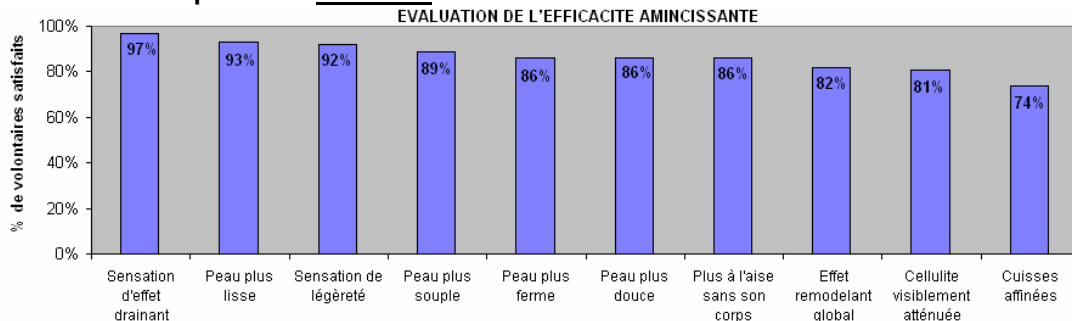
Nom / <i>Last name</i> :	JANIAUT
Prénom / <i>First name</i> :	Fabienne
Date / <i>Date</i> :	September 21, 2012
Signature / <i>Signature</i> :	

## RESUME DU RAPPORT D'ETUDE N°12E1681

	<b>Promoteur : PROVENCE COSMETICS</b>  <b>Adresse :</b> 118 allée Renoir 13600 LA CIOTAT FRANCE	<b>Investigateur : DERMSCAN</b>  <b>Adresse :</b> Domaine Scientifique de la Doua Bâtiment CEI 2 56, boulevard Niels Bohr 69623 Villeurbanne Cedex - FRANCE	
<b>Titre de l'étude</b>	<b>EVALUATION SUBJECTIVE DE L'EFFICACITE AMINCISSANTE ET ANTI-CELLULITE D'UN SOIN INSTITUT</b>		
<b>Produits</b>	<b>Références :</b> 1- Detox de base 2- Active Slim Gel 3- Active Slim Crème 4- Ultra Slim Effect	<b>Formes galéniques :</b> 1- Gel Orange 2- Gel Bleu 3- Emulsion beige rosé 4- Gel Rouge	
<b>Dates de l'étude</b>	Du 6 au 10 août 2012.		
<b>Objectif</b>	Evaluer subjectivement les caractéristiques organoleptiques et l'efficacité du soin étudié.		
<b>Plan expérimental</b>	Etude en ouvert et en intra-individuel.		
<b>Critère d'évaluation</b>	Evaluation subjective avec un questionnaire.	<b>Cinétique</b>	J0t0, J0timm.
		<b>Méthodologie</b>	Avant / Après.
		<b>Zone d'application</b>	Corps.
		<b>Fréquence d'application</b>	Un soin unique réalisé par une esthéticienne.
<b>Population étudiée</b>	Nombre de volontaires analysés : 27		
	Age moyen : 41±3 ans (entre 20 et 63 ans).		
	<u>Critères principaux d'inclusion :</u>		
	<ul style="list-style-type: none"><li>• Sexe : féminin.</li><li>• Age: plus de 18 ans.</li><li>• Volontaire ayant un Indice de Masse Corporelle (IMC) (poids/taille<sup>2</sup>) compris entre 23 et 27.</li><li>• Capitons visibles au niveau des cuisses.</li><li>• Surcharge graisseuse au niveau du ventre, des hanches et des cuisses.</li></ul>		

**Résultats -  
Conclusion**

**Dans les conditions expérimentales de l'étude, sur une population en léger surpoids, immédiatement après la fin du soin corps, les produits ont été appréciés par une majorité des volontaires :**

✓ **pour leurs caractéristiques organoleptiques**✓ **pour leur efficacité**

✓ **93% des volontaires ont trouvé la durée du soin idéale et tous ont estimé qu'il répondait aux attentes.**

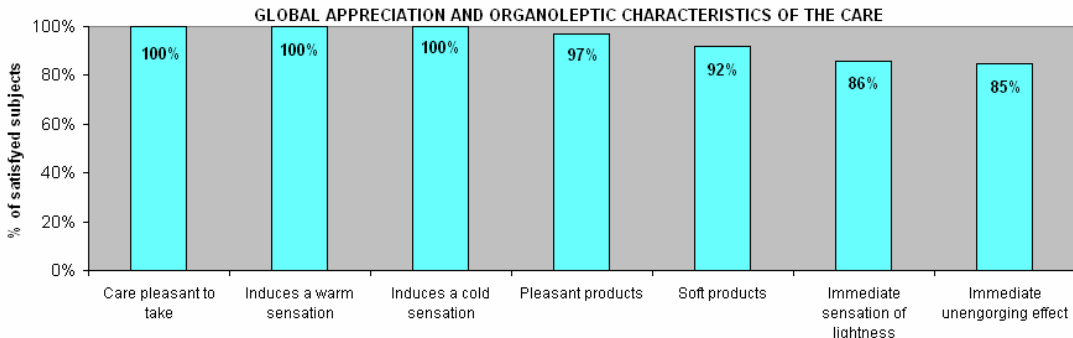
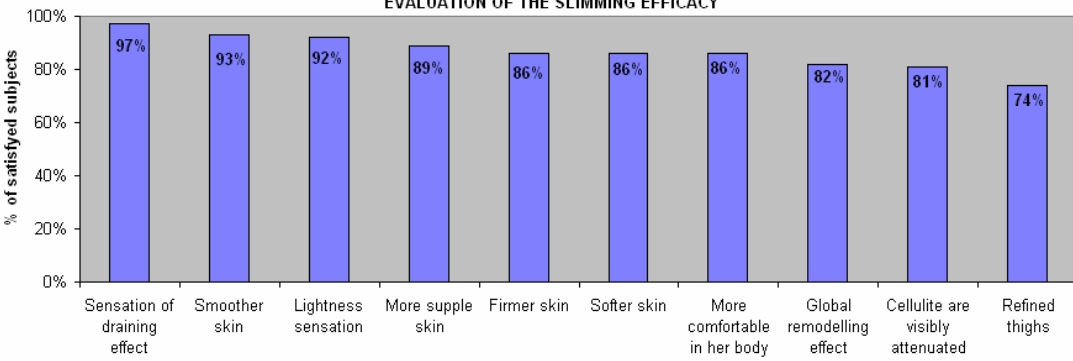

**Carine KURDIAN**  
Assistante Chef de Projets

**Date**  
21 septembre 2012

**Signature**

## SUMMARY OF THE STUDY REPORT #12E1681

	<b>Sponsor:    PROVENCE COSMETICS</b>		<b>Investigator:   DERMSCAN</b>	
	<b>Address:</b> 118 allée Renoir 13600 LA CIOTAT FRANCE		<b>Address:</b> Domaine Scientifique de la Doua Bâtiment CEI 2 56, boulevard Niels Bohr 69623 Villeurbanne Cedex - FRANCE	
<b>Study Title</b>	<b>SUBJECTIVE EVALUATION OF THE SLIMMING AND ANTI-CELLULITE EFFICACY OF AN INSTITUTE CARE</b>			
<b>Products</b>	<b>References:</b> 1- Detox de base 2- Active Slim Gel 3- Active Slim Crème 4- Ultra Slim Effect		<b>Galenic forms:</b> 1- Orange Gel 2- Blue Gel 3- Pinkish beige Emulsion 4- Red Gel	
<b>Study dates</b>	From August 6 to 10, 2012.			
<b>Objective</b>	To subjectively evaluate the organoleptic properties and the efficacy of the studied care.			
<b>Experimental plan</b>	Open and intra-individual study.			
<b>Assessment criterion</b>	Subjective evaluation with a questionnaire.	<b>Kinetics</b>	D0t0-D0timm.	
		<b>Methodology</b>	Before / After.	
		<b>Application zone</b>	Body.	
		<b>Application frequency</b>	Single care realized by a beautician.	
<b>Studied population</b>	Number of subjects analysed: 27			
	Average age: 41±3 years (between 20 and 63).			
	<u>Main inclusion criteria:</u> <ul style="list-style-type: none"><li>• Sex: female.</li><li>• Age: more than 18 years old.</li><li>• Subject with a Body Mass Index (BMI= weight/height²) ranging between 23 and 27.</li><li>• Visible fat nodes on thighs.</li><li>• Fat overload on stomach, hips and thighs.</li></ul>			

Results - Conclusion	<p>Under these study conditions, in a slight overweight population, immediately after the end of the body care, products <u>satisfied the majority of the subjects</u> :</p> <p>✓ for their <u>organoleptic characteristics</u></p> <p>GLOBAL APPRECIATION AND ORGANOLEPTIC CHARACTERISTICS OF THE CARE</p>  <table><tr><th>Characteristic</th><th>% of satisfied subjects</th></tr><tr><td>Care pleasant to take</td><td>100%</td></tr><tr><td>Induces a warm sensation</td><td>100%</td></tr><tr><td>Induces a cold sensation</td><td>100%</td></tr><tr><td>Pleasant products</td><td>97%</td></tr><tr><td>Soft products</td><td>92%</td></tr><tr><td>Immediate sensation of lightness</td><td>86%</td></tr><tr><td>Immediate unengorging effect</td><td>85%</td></tr></table> <p>✓ for their <u>efficacy</u></p> <p>EVALUATION OF THE SLIMMING EFFICACY</p>  <table><tr><th>Characteristic</th><th>% of satisfied subjects</th></tr><tr><td>Sensation of draining effect</td><td>97%</td></tr><tr><td>Smoother skin</td><td>93%</td></tr><tr><td>Lightness sensation</td><td>92%</td></tr><tr><td>More supple skin</td><td>89%</td></tr><tr><td>Firmer skin</td><td>86%</td></tr><tr><td>Softer skin</td><td>86%</td></tr><tr><td>More comfortable in her body</td><td>86%</td></tr><tr><td>Global remodelling effect</td><td>82%</td></tr><tr><td>Cellulite are visibly attenuated</td><td>81%</td></tr><tr><td>Refined thighs</td><td>74%</td></tr></table> <p>✓ <u>93% of the subjects found ideal the care duration and all felt that it corresponded to the expectations.</u></p>			Characteristic	% of satisfied subjects	Care pleasant to take	100%	Induces a warm sensation	100%	Induces a cold sensation	100%	Pleasant products	97%	Soft products	92%	Immediate sensation of lightness	86%	Immediate unengorging effect	85%	Characteristic	% of satisfied subjects	Sensation of draining effect	97%	Smoother skin	93%	Lightness sensation	92%	More supple skin	89%	Firmer skin	86%	Softer skin	86%	More comfortable in her body	86%	Global remodelling effect	82%	Cellulite are visibly attenuated	81%	Refined thighs	74%
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## 1. AIM

The objective of this study was to evaluate the subjective appreciation of the organoleptic characteristics and the efficacy of "BIOSLIMMING" care after a single application.

## 2. METHODS

### 2.1. Trial period

Beginning of the study:	August 6, 2012.
End of the study:	August 10, 2012.
First results by e-mail:	August 29, 2012.

### 2.2. Experimental plan

This was an open and intra-individual study; each subject was her own control.

### 2.3. Assessment criterion

Analysis of the subjects' answers to a subjective evaluation questionnaire.

### 2.4. Principle

A subjective evaluation questionnaire, prepared by the clinical trial center and submitted to the sponsor, was filled in by the subjects after the end of the care to subjectively evaluate the organoleptic characteristics of the studied products and their global efficacy.

### 2.5. Method pertinence

Answers given by the subjects to a subjective evaluation questionnaire are used to evaluate the characteristics and the efficacy of the studied products. These subjective criteria give, in particular, accurate information regarding products appreciation.

### 2.6. Subject selection

#### 2.6.1. Number of subjects

The study was done on 25 subjects minimum, at sponsor's request.

### 2.6.2. Inclusion criteria

General criteria
Healthy subject.
Subject having given her informed, written consent.
Cooperative subject, aware of the necessity and duration of controls so that perfect adhesion to the protocol established by the clinical trial center could have been expected.
Specific criteria
Sex: female.
Age: more than 18 years old.
Subject with a Body Mass Index (BMI= weight/height <sup>2</sup> ) ranging between 23 and 27.
Visible fat nodes on thighs.
Fat overload on stomach, hips and thighs.

### 2.6.3. Non-inclusion criteria

Pregnant or nursing woman or woman planning to get pregnant during the study.
Cutaneous pathology on the studied zone (eczema, etc).
Woman having changed, started or stopped any hormonal treatment for less than 1.5 month.
Use of topical or systemic treatment liable to interfere with the study of the product efficacy or tolerance.
Treatment acting on the subcutaneous lipids (slimming...) or stop of this type of treatment for less than one month
Subject having undergone a surgery under general anaesthesia in the month before the beginning of the study.

### 2.6.4. Compliance assessment

If the protocol was not respected and if the deviation was minor, the technician or the investigator warned the subject of the importance of respecting the prescribed protocol. If the subject persisted or if the deviation was major, the subject was declared non-compliant. In this case, the subject was removed from the study for non-compliance.

The single application of the care was done, at the laboratory, by the beautician of the sponsor.

### 2.6.5. Restrictions during the study

No use of dermopharmaceutical or cosmetic products other than the studied product was authorized on the body during the study.  
Only the usual cleansing product(s) were authorized on the body in the morning of the study.

## 2.7. Operational aspect

### 2.7.1. Trial schedule

#### ***Pre-inclusion visit***

- Subjects came to the laboratory without having applied any product to the body since the previous evening (except the morning wash).
- They read, signed and dated the information sheet (instructions on the product use and restrictions related to the study) and informed consent forms in duplicate. These documents were also signed and dated by the person who conducted the informed consent discussion. The subjects received a copy.
- Verification of inclusion and non-inclusion criteria by the technician.
  - Body Mass Index (BMI= weight/height<sup>2</sup>) ranging between 23 and 27 (**cf Appendix 9.1**).
  - Presence of fat nodes and of a local fat overload on stomach, hips and thighs.

#### ***On D0t0***

- Subjects returned to the laboratory without having applied any product to the body since the previous evening (except the morning wash).
- Realization of the care by the sponsor's beautician.

#### ***On D0timm***

- The subjects answered the subjective evaluation questionnaire.

### 2.7.2. Adverse Events/Serious Adverse Events

During the study, the following rules were applied:

#### *2.7.2.1. Definitions*

An Adverse Event (AE) is defined as any noxious symptom, temporarily linked to the use of a study product, occurring in a subject taking part in a clinical trial, whether or not this symptom is related to the studied product(s).

An adverse reaction is defined as any noxious and unexpected reaction that might be related to the studied product(s).

All adverse events judged, by the investigator, as being possibly, probably or certainly related to the studied product are considered as adverse reactions.

A Serious Adverse Event (SAE) is defined as an adverse event or effect that:

- results in death (note: death is the outcome, not the event),
- is life threatening,
- requires in-patient hospitalization (at least one night) or prolongation of existing hospitalization (does not include hospitalization scheduled before the inclusion),
- results in persistent or significant disability or incapacity,
- is a congenital anomaly/birth defect,
- is considered like by the investigator.

The severity/intensity of adverse events can be graded on a three-point scale:

- **Mild** or *Grade 1*: discomfort noted, but does not disturb normal daily activities.
- **Moderate** or *Grade 2*: discomfort sufficient to reduce or affect normal daily activities.
- **Severe** or *Grade 3*: inability to work or have normal daily activities.

#### *2.7.2.2. Documentation*

All concomitant treatments are reported in the CRF and the study report.

All Adverse Events likely to be related to the studied product (adverse reactions) are reported in the CRF and the study report.

All Serious Adverse Events are reported in the CRF and the study report.

#### *2.7.2.3. Notification*

The investigator declares to the sponsor, by fax or e-mail, the occurrence of adverse reactions according to their severity and their unexpectedness (according to the investigator's advice).

All Serious Adverse Events are transmitted by e-mail to the sponsor without delay, at the latest 24 hours after knowledge of their occurrence.

A SAE declaration form signed by a physician is sent, within 48 hours, by fax or e-mail with acknowledgement of receipt.

#### *2.7.2.4. Follow-up*

When an adverse event likely to be linked to the studied product or the protocol persists at the end of the study, the Investigator ensures that the subject is followed up until total resolution of the event or stabilization of the symptoms without releasing the Sponsor of any obligation or responsibility.

#### *2.7.2.5. Occurrence of pregnancy*

The occurrence of a pregnancy (reported or diagnosed) after inclusion in the study is considered as an intercurrent event not related to the studied products or the protocol and induces the immediate dropping out of the subject.

A follow-up will be done according to the current internal procedures up to the end of the pregnancy or to its interruption.

#### *2.7.2.6. Premature termination of the study*

##### **◆ Study exit conditions**

\* In compliance with the Helsinki Declaration (1964) and its successive updates and with the French law 2004-806 dated August 9, 2004 concerning public health <sup>(ref: 1 to 3 in §8.1)</sup>, subjects have the right to exit from the study at any time and for any motive.

\* The investigator can also interrupt the subject participation in the study prematurely in the case of a disease occurrence, a pregnancy or the occurrence of an adverse reaction.

\* The sponsor can demand that any subject be excluded from the study for major infringements to the protocol, for administrative reasons or any other motive.

Nevertheless, premature removal of a high percentage of subjects from the study can make the study difficult or impossible to interpret. Consequently, any premature exit without valid motives should be avoided as much as possible and is carefully documented in the case report form, the final report and, if necessary, in the Adverse Event form.

Every premature exit must be classified under one of the following headings:

- presence of a non-inclusion criteria,
- Adverse Event occurrence,
- Serious Adverse Event occurrence,
- withdrawal of consent,
- untraceable panelist,
- appearance of non-inclusion criteria,
- non-adherence to the protocol,
- other reason.

#### ◆ Replacement conditions

No replacement is foreseen as 10% additional subjects are planned to be included in the study.

### 2.7.3. Collection and validation of data

According to the law "informatique et libertés" (ref: 4 in §8.1), an identification code was attributed to each subject on purpose to keep his identity confidential. This code consists of: the first three letters of the subject's name and the first two letters of her first name.

The personnel in charge of the study (technician, physician,...) added data to subject case report form and to a computerized data base.

Data were validated by DermScan's Project Manager.

### 2.7.4. Audit and trial monitoring visit

An audit and/or trial monitoring visit might be carried out at the sponsor's request or by the appropriate regulatory authority. The aim of the monitoring visit is to verify that the study is conducted according to the determined protocol and current regulations.

### 2.7.5. Quality management

In order to ensure the conformity of the clinical trials to the study sponsor's requirement, DERMSCAN has implemented a quality management system which has been certified ISO 9001: 2008 by AFNOR certification.

This quality assurance system includes Good Clinical Practices (GCP) and regulation requirements.

Each study report is the subject of a quality inspection by a member of the DERMSCAN Proofreading Committee. The proofreader is chosen because he is not involved in the audited study. The inspection of the study report allows confirming that the results reflect exactly the study raw data.

A certificate of quality inspection, signed by the person who checked the report is enclosed in each study report to certify that the study report reflects the study raw data and fulfils any standard and regulatory requirements.

**2.8. Studied products****2.8.1. Confidentiality procedure**

The totality of the products, were brought by the sponsor at the laboratory for the beginning of the study.

**2.8.2. Storage**

Not applicable

**2.8.3. References**

- 1- Detox de base.
- 2- Active Slim Gel.
- 3- Active Slim Crème.
- 4- Ultra Slim Effect

**2.8.4. Aspects**

- 1- Orange Gel
- 2- Blue Gel
- 3- Pinkish beige Emulsion
- 4- Red Gel

**2.8.5. Labeling**

Example of labeling of each product by the clinical trial center and translation:

DERMSCAN Etude n°	DERMSCAN Study #
N° vol : .....	Subject#:.....
En cas d'urgence : n° tél.....	Emergency telephone number: .....
N°DermScan : .....	DermScan ref.:.....
Conservation : .....	Conservation: .....
A tenir hors de portée et de la vue des enfants. A utiliser sous stricte surveillance médicale pour essai clinique.	Keep out of reach and sight of children. To be used only under strict medical supervision for clinical trial.

**2.8.6. Application frequency**

A single care was realized at the laboratory.

**2.8.7. Application sites and method**

Application sites: to the body.

Application method: according the protocol of the sponsor.

**2.8.8. Products issue**

Not applicable. The single care was done by the sponsor's beautician.

**2.8.9. Products future**

As far as possible, one sample of the studied products is kept by the laboratory for a period of one year after its receipt.

At the sponsor request, the used and not used products were brought back.

**2.9. Archivage**

Data will be securely archived digitally and on paper for ten years from the date of dispatch of the final report.

Paper documents relating to this study are stored maximum during one year at DermScan before to be transmitted for archiving to the company LOCARCHIVES (Parc industriel de la plaine de l'Ain – Allée des cèdres – 01150 SAINT-VULBAS – FRANCE).

At the end of this period of ten years, the study archives will be destroyed unless otherwise stipulated in writing by the sponsor.

**3. STUDY FOLLOW-UP****3.1. Population**

	Number of subjects			Reason(s)	
	Included subjects	Subjects who completed the study	Analyzed subjects	Subjects who did not complete the study	Non-analyzed subjects
Questionnaire	28	28	27	/	Subject #17 did not fill in the questionnaire

**3.2. Protocol non-adherences**

Description of the non-adherence	Type of non-adherence (minor / major)	Data kept in the analysis (yes / no)
Subject #01 had a BMI of 29.8 instead of 27 maximum.	minor	yes
Subject #17 had a BMI of 22.4 instead of 23 minimum.	minor	yes

The protocol non-adherences of the subjects #1 and #17 did not invalidate the data obtained for these subjects.

**3.3. Audit / Trial monitoring visit**

Study monitor went from August 8, 2012 to August 10, 2012.



#### 4. SUBJECT CHARACTERISTICS

The table below presents the observations concerning the subjects included in the study.

Subject	Last name	First name	Age	Sex	Skin type	Phototype	Comments	Inclusion date	Care date
1	BAR	SY	47	F	N	II	Minor protocol non-adherence (BMI= 29.8)	August 6, 2012	August 9, 2012
2	OSI	JO	49	F	N	IV	None	August 6, 2012	August 8, 2012
3	LAX	LO	23	F	N	II	None	August 6, 2012	August 7, 2012
4	BOU	SA	40	F	N	IV	None	August 6, 2012	August 8, 2012
5	ALA	CH	44	F	N	IV	None	August 6, 2012	August 7, 2012
6	DES	MI	40	F	N	III	None	August 6, 2012	August 7, 2012
7	MAN	AN	62	F	D	II	None	August 6, 2012	August 9, 2012
8	JOU	EV	20	F	N	II	None	August 6, 2012	August 7, 2012
9	JON	DA	63	F	N	II	None	August 6, 2012	August 8, 2012
10	MER	NE	29	F	N	IV	None	August 6, 2012	August 8, 2012
11	CHO	SO	35	F	N	II	None	August 6, 2012	August 7, 2012
12	CHO	LI	30	F	N	III	None	August 6, 2012	August 8, 2012
13	LIL	CL	37	F	N	IV	None	August 6, 2012	August 7, 2012
14	BEA	AS	40	F	D	II	None	August 6, 2012	August 7, 2012
15	LOF	GA	27	F	D	III	None	August 6, 2012	August 9, 2012
16	KRA	ME	50	F	D	III	None	August 6, 2012	August 8, 2012
17	ELK	JA	27	F	D	IV	Minor protocol non-adherence (BMI= 22.4)	August 6, 2012	August 8, 2012
18	PER	MA	63	F	D	II	None	August 6, 2012	August 9, 2012
19	DES	KR	53	F	D	II	None	August 6, 2012	August 9, 2012
20	KHE	SA	27	F	D	IV	None	August 6, 2012	August 9, 2012
21	BLA	HE	42	F	N	II	None	August 6, 2012	August 9, 2012
22	TUP	NA	60	F	D	III	None	August 6, 2012	August 10, 2012
23	CRO	ME	21	F	D	III	None	August 6, 2012	August 10, 2012
24	VIN	EV	62	F	D	III	None	August 6, 2012	August 10, 2012
25	TAT	ME	21	F	N	III	None	August 6, 2012	August 10, 2012
26	AND	JU	53	F	D	III	None	August 6, 2012	August 10, 2012
27	BOU	NA	32	F	N	IV	None	August 6, 2012	August 10, 2012
28	SZK	IS	45	F	C	II	None	August 6, 2012	August 10, 2012
<b>Mean</b>			<b>41</b>	<b>F</b>	<b>28</b>	<b>N</b>	<b>15</b>	<b>I</b>	<b>0</b>
<b>Median</b>			<b>40</b>	<b>M</b>	<b>0</b>	<b>D</b>	<b>12</b>	<b>II</b>	<b>11</b>
<b>Minimum</b>			<b>20</b>			<b>C</b>	<b>1</b>	<b>III</b>	<b>9</b>
<b>Maximum</b>			<b>63</b>			<b>G</b>	<b>0</b>	<b>IV</b>	<b>8</b>
<b>SEM</b>			<b>3</b>					<b>V</b>	<b>0</b>
<b>CI 95%</b>			<b>5</b>					<b>VI</b>	<b>0</b>

Legend: F: female  
M: male

D: dry skin  
N: normal skin  
C: combination skin  
G: greasy skin

## 5. RESULTS: Subjective evaluation questionnaire

The subjects' answers (in percentage) to the subjective evaluation questionnaire are presented in **Appendix 9.2**.

The synthesis of the answers is presented in the table below.

GLOBAL APPRECIATION AND ORGANOLEPTIC CHARACTERISTICS OF THE CARE	
<b>Pleasant products</b>	<b>97%</b>
completely agree	56%
rather agree	41%
<b>Soft products</b>	<b>92%</b>
completely agree	44%
rather agree	48%
<b>Immediate unengorging effect</b>	<b>85%</b>
completely agree	22%
rather agree	63%
<b>Immediate sensation of lightness</b>	<b>86%</b>
completely agree	30%
rather agree	56%
<b>Care pleasant to take</b>	<b>100%</b>
completely agree	59%
rather agree	41%
<b>Induces a warm sensation (1st phase)</b>	<b>100%</b>
completely agree	96%
rather agree	4%
<b>Induces a cold sensation (2nd phase)</b>	<b>100%</b>
completely agree	93%
rather agree	7%

EVALUATION OF THE SLIMMING EFFICACY	
<b>Sensation of draining effect</b>	<b>97%</b>
completely agree	41%
rather agree	56%
<b>Smoother skin</b>	<b>93%</b>
completely agree	26%
rather agree	67%
<b>More supple skin</b>	<b>89%</b>
completely agree	26%
rather agree	63%
<b>Firmer skin</b>	<b>86%</b>
completely agree	19%
rather agree	67%
<b>Softer skin</b>	<b>86%</b>
completely agree	30%
rather agree	56%
<b>Global remodelling effect</b>	<b>82%</b>
completely agree	30%
rather agree	52%
<b>Refined thighs</b>	<b>74%</b>
completely agree	11%
rather agree	63%
<b>Cellulite are visibly attenuated</b>	<b>81%</b>
completely agree	7%
rather agree	74%
<b>More comfortable in her body</b>	<b>86%</b>
completely agree	30%
rather agree	56%
<b>Lightness sensation</b>	<b>92%</b>
completely agree	33%
rather agree	59%
<b>Pleasant care to take</b>	<b>96%</b>
completely agree	63%
rather agree	33%

YOUR OPINION	
<b>Ideal duration of the care</b>	<b>93%</b>
<b>The care corresponds to the expectations</b>	<b>100%</b>
agree	85%
appreciably	11%
a little	4%

## 6. CONCLUSION

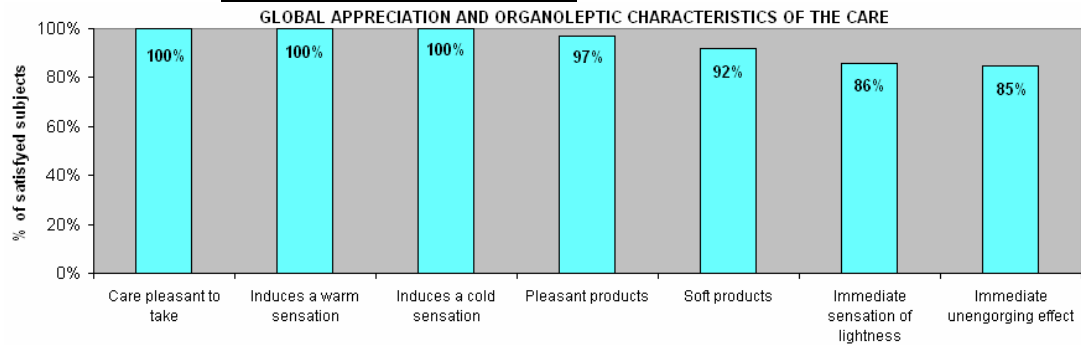
The objective of this study was to evaluate the subjective appreciation of the organoleptic characteristics, and the efficacy of "BIOSLIMMING" care after a single application.

Study conditions:

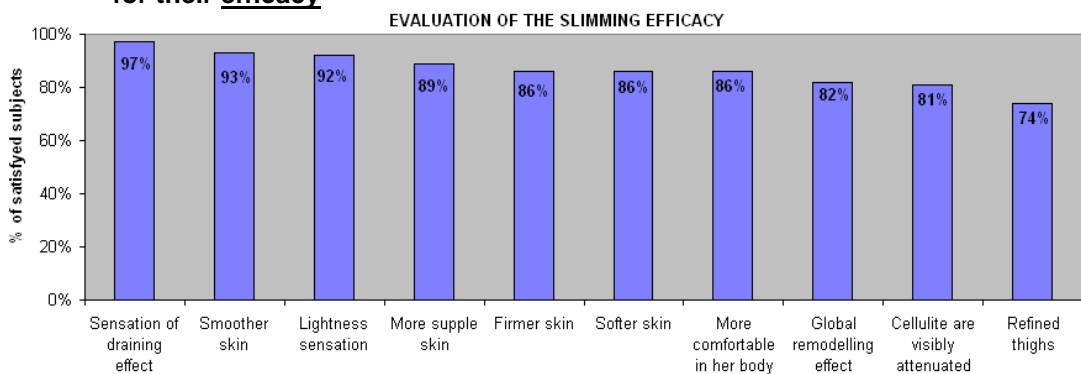
Products	References: 1- Detox de base 2- Active Slim Gel 3- Active Slim Crème 4- Ultra Slim Effect	Galenic forms: 1- Orange Gel 2- Blue Gel 3- Pinkish beige Emulsion 4- Red Gel	
Experimental plan	Open and intra-individual study.		
Assessment criteria	Subjective evaluation with a questionnaire.	Kinetics	D0t0-D0timm.
		Methodology	Before / After.
		Application zone	Body.
		Application frequency	Single care realized by a beautician.
Studied population	Number of subjects analysed: 27		
	Average age: 41±3 years (between 20 and 63).		
	<u>Main inclusion criteria:</u> <ul style="list-style-type: none"><li>Sex: female.</li><li>Age: more than 18 years old.</li><li>Subject with a Body Mass Index (BMI= weight/height²) ranging between 23 and 27.</li><li>Visible fat nodes on thighs.</li><li>Fat overload on stomach, hips and thighs.</li></ul>		

**Under these study conditions, in a slight overweight population, immediately after the end of the body care, products satisfied the majority of the subjects:**

✓ **for their organoleptic characteristics**



✓ **for their efficacy**



✓ **93% of the subjects found ideal the care duration and all felt that it corresponded to the expectations.**

## 7. CERTIFICATION

The study was conducted according to Helsinki Declaration (1964) and its successive updates. Data were obtained using the study protocol, current internal procedures and in the spirit of the note for guidance on Good Clinical Practice CPMP / ICH / 135 / 95, January 1997 <sup>(ref: 1 to 4 in §8.1)</sup>.

Any modifications are the sole responsibility of the author of the modification, whether he/she is acting for the sponsor or independently. Any partial or total reproduction of this study report requires prior written agreement from DERMSCAN.

The on-line publishing, on the Internet, of this study report with the signatures is strictly prohibited.

This study was totally performed under the responsibility of DERMSCAN.

DERMSCAN quality system is certified ISO 9001: 2008.

*All the observations and numerical data collected throughout the study are reported in this document. We certify that these data are in accordance with the obtained results.*

**Date(s) and signature(s) :** September 21, 2012

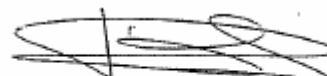
**Names**

**Functions**

**Date(s) and signature(s) :**



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Project Manager Assistant



**Marlène PIRAUD**  
Research Technician

## 8. BIBLIOGRAPHY

### 8.1. Regulatory

1. ICH TOPIC E6/ Note for guidance on Good Clinical Practice- CPMP / ICH / 135 / 95, January 1997.
2. WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI/ Ethical Principles for Medical Research Involving Human Subjects- Helsinki Declaration (1964) and its successive updates.
3. LOI HURIET SERUSCLAT/ CSP Titre II – Recherches Biomédicales- n°88-138 du 20 décembre 1988 modifié par la loi française 2004-806 du 9 août 2004, concernant la santé publique.
4. LOI "INFORMATIQUE ET LIBERTES"/ Loi n°78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés mise à jour par la loi n°2004-801 du 6 août 2004 concernant la protection des personnes pour la déclaration à la CNIL.

### 8.2. Data analysis

1. SOKAL R. R., ROHLF F. J. / Biometry : the principles and practice of statistics in biological research - 3rd edn.W.H. Freeman and company, New York, 1995.

## 9. APPENDICES

9.1. Weight control and Body Mass Index (BMI)

Average variation of the weight (in kg)  
in comparison with the initial state

Subjects	Weight (kg)		$\Delta$ (timr - t0)
	t0	timr	
1	81.0	80.5	-0.5
2	69.0	69.0	0.0
3	67.0	66.0	-1.0
4	60.0	60.0	0.0
5	65.5	65.0	-0.5
6	58.5	58.5	0.0
7	63.0	63.0	0.0
8	69.0	69.0	0.0
9	59.0	59.0	0.0
10	65.0	65.0	0.0
11	61.0	60.0	-1.0
12	60.0	60.0	0.0
13	60.0	60.0	0.0
14	69.0	69.0	0.0
15	65.0	65.0	0.0
16	70.5	70.5	0.0
17	64.0	64.0	0.0
18	65.0	65.0	0.0
19	61.0	61.0	0.0
20	73.5	73.5	0.0
21	65.0	64.5	-0.5
22	62.5	62.5	0.0
23	58.0	58.0	0.0
24	68.5	68.5	0.0
25	68.5	68.5	0.0
26	56.0	56.0	0.0
27	69.0	69.0	0.0
28	71.0	71.0	0.0
Mean	65.2	65.0	-0.1
Median	65.0	65.0	0.0
Minimum	56.0	56.0	-1.0
Maximum	81.0	80.5	0.0
SEM	1.0	1.0	0.1
95% CI	2.1	2.1	0.1

Body Mass Index  
(weight/height<sup>2</sup>)

Subjects	Height	BMI
1	1.7	29.8
2	1.62	26.3
3	1.69	23.5
4	1.57	24.3
5	1.61	25.3
6	1.54	24.7
7	1.57	25.6
8	1.68	24.4
9	1.56	24.2
10	1.66	23.6
11	1.60	23.8
12	1.59	23.7
13	1.61	23.1
14	1.70	23.9
15	1.65	23.9
16	1.65	25.9
17	1.69	22.4
18	1.56	26.7
19	1.62	23.2
20	1.68	26.0
21	1.61	25.1
22	1.59	24.7
23	1.57	23.5
24	1.66	24.9
25	1.62	26.1
26	1.50	24.9
27	1.67	24.7
28	1.65	26.1
Mean	1.6	24.8
Median	1.6	24.7
Minimum	1.5	22.4
Maximum	1.7	29.8
SEM	0.0	0.3
95% CI	0.0	0.6

$\Delta\%$	0%
p=	NA

% of subjects with a weight loss	18%
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## 9.2. Subjective evaluation questionnaire

**Q1 à Q7-Durant le soin, avez-vous ressenti les sensations suivantes ? During the care, did you feel the following sensations?:**

### 1 PRODUITS AGREABLES/ PLEASANT PRODUCTS

Tout à fait d'accord / completely agree 56%	Plutôt d'accord / rather agree 41%	Plutôt pas d'accord / rather disagree 4%	Pas d'accord / disagree 0%
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### 2 PRODUITS DOUX / SOFT PRODUCTS

Tout à fait d'accord / completely agree 44%	Plutôt d'accord / rather agree 48%	Plutôt pas d'accord / rather disagree 7%	Pas d'accord / disagree 0%
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### 3 EFFET DESENGORGEANT IMMEDIAT / IMMEDIATE UNENGORGING EFFECT

Tout à fait d'accord / completely agree 22%	Plutôt d'accord / rather agree 63%	Plutôt pas d'accord / rather disagree 15%	Pas d'accord / disagree 0%
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### 4 SENSATION IMMEDIATE DE LEGERETE / IMMEDIATE SENSATION OF LIGHTNESS

Tout à fait d'accord / completely agree 30%	Plutôt d'accord / rather agree 56%	Plutôt pas d'accord / rather disagree 15%	Pas d'accord / disagree 0%
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### 5 SOIN AGREABLE A RECEVOIR / CARE PLEASANT TO TAKE

Tout à fait d'accord / completely agree 59%	Plutôt d'accord / rather agree 41%	Plutôt pas d'accord / rather disagree 0%	Pas d'accord / disagree 0%
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### 6 LE SOIN PROCURE UNE SENSATION DE CHALEUR (1ere phase) / THE CARE INDUCES A WARM SENSATION (1st phase)

Tout à fait d'accord / completely agree 96%	Plutôt d'accord / rather agree 4%	Plutôt pas d'accord / rather disagree 0%	Pas d'accord / disagree 0%
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### 7 LE SOIN PROCURE UNE SENSATION DE "FROID" (2nde phase) / THE CARE INDUCES A COLD SENSATION (2nd phase)

Tout à fait d'accord / completely agree 93%	Plutôt d'accord / rather agree 7%	Plutôt pas d'accord / rather disagree 0%	Pas d'accord / disagree 0%
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**Q8 à Q18- Après le soin, avez-vous constaté des résultats visibles sur votre silhouette ? After the care, did you notice visible results on the silhouette?**

	Tout à fait d'accord / completely agree	Plutôt d'accord / rather agree	Plutôt pas d'accord / rather disagree	Pas d'accord / disagree
<b>8 EFFET DRAINANT RESENTI</b> <i>DRAINING EFFECT FELT</i>	41%	56%	4%	0%
<b>9 PEAU PLUS LISSE</b> <i>SMOOTHER SKIN</i>	26%	67%	7%	0%
<b>10 PEAU PLUS SOUPLE</b> <i>MORE SUPPLE SKIN</i>	26%	63%	11%	0%
<b>11 PEAU PLUS FERME</b> <i>FIRMER SKIN</i>	19%	67%	15%	0%
<b>12 PEAU PLUS DOUCE</b> <i>SOFTER SKIN</i>	30%	56%	15%	0%
<b>13 EFFET REMODELANT GLOBAL</b> <i>GLOBAL REMODELING EFFECT</i>	30%	52%	19%	0%
<b>14 CUISSES AFFINEES</b> <i>REFINED THIGHS</i>	11%	63%	22%	4%
<b>15 CELLULITE VISIBLEMENT ATTENUÉE</b> <i>CELLULITE VISIBLY ATTENUATED</i>	7%	74%	15%	4%
<b>16 PLUS A L'AISE DANS SON CORPS</b> <i>MORE COMFORTABLE IN HER BODY</i>	30%	56%	11%	4%
<b>17 SENSATION DE LEGERETE</b> <i>LIGHTNESS SENSATION</i>	33%	59%	4%	4%
<b>18 SOIN AGREABLE A RECEVOIR</b> <i>PLEASANT CARE TO TAKE</i>	63%	33%	4%	0%

**19 QUE PENSEZ-VOUS DE LA DUREE DE CE SOIN ? / WHAT DO YOU THINK ABOUT THE DURATION OF THIS CARE?**

4%	trop courte <i>too short</i>	93%	idéale <i>ideal</i>	4%	trop longue <i>too long</i>
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**20 CE SOIN CORRESPOND-IL A VOS ATTENTES ? / DOES THIS CARE CORRESPOND TO YOUR WAITINGS?**

85%	tout à fait / agree	11%	sensiblement / appreciably	4%	un peu / a little	0%	pas du tout / not at all
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**21 IMPRESSION GENERALE SUR LE SOIN / GENERAL IMPRESSION ON THE CARE**

Subjects	Remarks
1	Delighted.
2	Very pleasant, too short to see an effect after only one care.
3	Very positive, pleasant and well explained.
4	Very pleasant, I like it a lot, the products fragrance are relaxing.
5	Very good care, it should be commercialized in France.
6	This care is of quality with very pleasant fragrances.
8	This care is of quality with results.
9	Pleasant care.
10	Very well.
12	Very satisfied, pleasant.
13	Very well.
14	It smells very good.

Subjects	Remarks
15	Very good, surprising effects.
18	Very good.
19	Good products that I could buy.
20	It should be efficient but after several cares.
21	Positive impression.
22	Pleasant to receive, good efficacy.
23	Satisfactory.
24	Good.
25	Good impression.
26	To see the effects, a single care is not enough.
27	Ideal.
28	Pleasant to receive.