

## REFERENCES

**Order** YOUR AGREEMENT  
**Offer :** DR17-01069 Rev 2  
**Received Rouen** 10/03/17  
**Requested by:** Mr Karem Eladwey  
**ClientID:** GENTO ANTI BACTERIAL BAR SOAP 29350  
**Description:** GENCODE : 6282307201760  
**Nature:** Cosmetic product  
**Comments:**

SAUDI INDUSTRIAL DETERGENT CO.  
P.O. Box: 2571,

Dammam  
Saudi Arabia

Rouen 18 / 04 / 2017

REPORT  
RN17-05835.001  
Revision 2

Page 1 / 1

The present document voids and replaces any previously issued document of the same job reference that must be destroyed or returned to the laboratory.

Parameters	Units	Results
Patch test (2) (Méthode sous traitant)	%	enclosed

Results validated electronically by **Marine CHAPELLE**  
Responsable Projet



this validation is an electronical signature realised in conformity with requirements of ISO 17025

(1) Assays subcontracted in a SGS laboratory (2) Assays subcontracted in a partner laboratory  
Abbreviations ME or MO described within the field "parameters" of this report mean "Internal method" (adapting from the reference text if described hereinafter).

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**EVALUATION OF THE ACUTE CUTANEOUS TOLERANCE  
OF A COSMETIC PRODUCT ON ADULT VOLUNTEERS:****24-HOUR SEMI-OCCLUSIVE SINGLE PATCH TEST METHOD  
UNDER DERMATOLOGICAL CONTROL****REPORT**

STUDY REFERENCE	<b>CT-071</b>
PRODUCT	<b>«Gento Antibacterial Bar Soap (RN17-05835.001)»</b>
NUMBER OF SUBJECTS	<b>10</b>
PROMOTER	<b>SIDCO (Saudi Industrial Detergents Company)</b>
SPONSOR	<b>SGS MULTILAB</b>
MONITOR	<b>LISKIN IMMEUBLE FONTENAY AFFAIRSE 91, rue Boucicaut 92260 FONTENAY-AUX-ROSES ☎ : 33 (0)9 70 90 65 17</b>
INVESTIGATOR	<b>Dr Marlena NOWAKOWSKA, dermatologist</b>

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14 pages Document

The following results apply only to the samples subjected to LISKIN and such as they are defined in this document  
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## STUDY SUMMARY

**TITLE:** EVALUATION OF THE ACUTE CUTANEOUS TOLERANCE OF A COSMETIC PRODUCT ON ADULT VOLUNTEERS: 24-HOUR SEMI-OCCLUSIVE SINGLE PATCH TEST UNDER DERMATOLOGICAL CONTROL.

**STUDY REFERENCE:** CT-071

**PRODUCT:** Gento Antibacterial Bar Soap (RN17-05835.001)

**STUDY IMPLEMENTATION:** The study was carried out and all test values recorded by the Clinical Unit PROCOS, localized in Poland; ul. Słowackiego 27/33 lok. 33/34; 01-592 Warsaw.

**INVESTIGATOR:** Dr Marlena NOWAKOWSKA

**PROTOCOL:** 24-HOUR SEMI-OCCLUSIVE SINGLE PATCH TEST

**OBJECTIVE:** Determination of the acute skin tolerance of a cosmetic product (tested 5% diluted with water) by application under semi-occlusive patch over a 24-hour period on adult volunteers.

**SUBJECTS:** 10 healthy volunteers with sensitive skin corresponding to inclusion and non-inclusion criteria defined by LISKIN Group.

**STUDY DATES:** March 27th to 29th, 2017

**STUDY DESIGN:** Monocentric and simple blind study.

### EVALUATION CRITERIA:

- Mean Irritation Index       $M.I.I. = \frac{\text{total cutaneous reactions score}}{\text{number of volunteers}}$

- Analysis:      Classification of the product according to its M.I.I.:

M.I.I.	Classification of the product
$M.I.I. < 0.08$	Non irritating (NI)
$0.08 \leq M.I.I. < 0.16$	Very slightly irritating (VSI)
$0.16 \leq M.I.I. < 0.56$	Slightly irritating (SI)
$0.56 \leq M.I.I. < 1$	Moderately irritating (MI)
$1.00 \leq M.I.I. < 1.60$	Irritating (I)
$M.I.I. \geq 1.60$	Very Irritating (VI)

### RESULTS:

Product	M.I.I. at 30'	M.I.I. at 24h
Gento Antibacterial Bar Soap (RN17-05835.001)	0.00	0.00

### CONCLUSION:

Under these study conditions, the product «Gento Antibacterial Bar Soap (RN17-05835.001)» is classified **NON IRRITATING** at the 30 minute and 24 hour readings, according to the M.I.I. calculation.

## 1. QUALITY ASSURANCE

The study described has been conducted according to the Good Clinical Practice Guidelines from FDA (FR of 8/08/1978 Part V - Decree n°77N-0278), EEC (Directives n°91/507 and III 3976/88 of 11/07/1990) and to the Ministry of Health of the French Republic.

The study has been conducted according to Standard Operating Procedures and study protocol defined by the sponsor. All study events recorded during the study are reported.

Controls on data veracity and protocol conformity have been performed and confirmed by persons participating to the study (APPENDIX I).

This report is a translation of an original report written in French.

## 2. CERTIFICATE OF CONFORMITY

I am aware that the study CT-071 has been conducted according to the «**Quality Assurance**» described before.

**There was no event which may have affected the data quality or integrity.**



\_\_\_\_\_  
Mme Charlotte OEHMICHEN  
Technical Director

April 11<sup>th</sup>, 2017

\_\_\_\_\_  
date

### **3. EXPERIMENTAL PROTOCOL**

The study was done according to the operational mode referenced "Single patch test".

#### **3.1. STUDY'S AIM**

Determination of the acute skin tolerance of a cosmetic product (tested 5% diluted with water) by application under semi-occlusive patch over a 24-hour period on adult volunteers.

#### **3.2. VOLUNTEERS**

##### **3.2.1. Inclusion criteria**

- subjects having given their informed, written consent,
- no previous experience of intolerance or allergic reactions to cosmetic products,
- phototype I to III,
- subjects from 18 to 65 years old.

##### **3.2.2. Non-inclusion Criteria**

- Pregnant, nursing women or women planning to be pregnant during the study,
- cutaneous pathology on experiment zone (psoriasis, eczema, vitiligo, pityriasis versicolor, acne, etc...),
- oral medical treatment:
  - anti-histamines, antibiotics, systemic anti-inflammatory drugs < 1 week,
  - cough-suppressants, corticoids < 4 weeks,
  - retinoid, immunosuppressive drugs, anti-cancer drugs during < 6 months,
- volunteers who started, stopped or changed hormonal treatment (including contraceptive pills) < 5 weeks,
- volunteers whose back skin has been exposed to the sun or to UV rays < 1 month,
- volunteers with very irritative skin,
- volunteers presenting an important pilosity of the back, freckles, beauty spots or a tattoo on the back,
- subjects struck down by a serious disease,
- excessive alcohol or tobacco use.

##### **3.2.3. Included volunteers characteristics**

- 10 subjects were included in the study,
- 8 women and 2 men, with sensitive skin,
- subjects from 22 to 63 years old (average age: 41 years).

##### **3.2.4. Exit of included subject**

The subjects have the right to leave the test whenever they want for whatever reason. The premature stop can be due to multiple reasons:

- no respect of the schedule of the visits by the subject,
- undesirable events (including the intercurrent diseases),
- protocol violations and deviations,
- exit after subject acceptance withdrawal.

### 3.3. STUDIED PRODUCT

The product supplied by SGS MULTILAB Group has the following specifications:

Product denomination	Product presentation	Study code	N° Ech. SGS MULTILAB
Gento Antibacterial Bar Soap (RN17-05835.001)	yellow bar soap	HA	RN17-05835.001

Delivery date: March 20th, 2017.

A tested product sample is stored at ambient T°C and protected from the light, in LISKIN office, for 3 months after the study end. After this period and without promoter contrary opinion, the product is destroyed.

### 3.4. METHOD

#### 3.4.1. Instruments, dose, duration

The tested product was applied under the following conditions:

Product HA	Gento Antibacterial Bar Soap (RN17-05835.001)
Area	Scapular area on the back
Type of Patch test	Bande de Webril® (4cm <sup>2</sup> ) Semi-occlusive
Dose	50 µl
Condition of application	5% diluted with water
Application duration	24 hours
Control	Patch without product
Restrictions	During the patch application period, volunteers are asked to not apply any product including water, nor to expose to UV on the treated zone.

#### 3.4.2. Readings

The macroscopic skin examinations were carried out under the same conditions, specifically the lighting (with "daylight" lamps), 30 minutes after removal. If there was no local skin reaction at the 24-hour reading after patch removal, the study was finished. Nevertheless, each volunteer was asked to confirm that there was no reaction the day after. If the volunteer had a visible reaction, he had to return to the center and readings were done until cutaneous reactions reversibility.

The irritation grade of treated zones was done by comparing it to the negative control (without product), according to the following scale:

Score	Quotation	CRITERIA : description			
		ERYTHEMA «E»	OEDEMA «O»	DRYNESS «S»	VESICLES «V»
0	Absent	Normal appearance	Normal appearance	Normal appearance	Normal appearance
0.5	Very slight	Barely perceptible: quite pink coloration of one part of the tested area			
1	Slight	Slight erythema (quite pinked coloration of the complete tested area or rather visible on one part of the tested area)	Slight oedema (palpable and visible)	Light desquamation frosted look	Vesicles more palpable than visible
2	Obvious	Obvious erythema (clear erythema covering all of the tested area)	Obvious oedema with or without papule(s) or vesicle(s)	Obvious Desquamation, Scale look	Vesicles visible
3	Important	Important erythema (severe erythema covering all the tested area or erythema diffusing outside the tested area)	Important oedema (extended area outside the tested area) with or without vesicle(s) or blister(s)	Importante Desquamation, cracking	Overflowing Vesicles of the zone tested or bubbles

### 3.4.3. Results interpretation

Analysis and interpretation were carried out according to the results obtained in experimental conditions at each reading.

Their description was completed by calculation of the acute irritation index (M.I.I.) at each reading according to the following formula:

$$\text{M.I.I.} = \frac{\text{total score of reactions}}{\text{number of subjects}}$$

This obtained global M.I.I. is used to arbitrarily classify the studied cosmetic product according to the following scale:

M.I.I.	Class
M.I.I. < 0,08	<b>Non irritating (NI)</b>
0,08 ≤ M.I.I. < 0,16	<b>Very slightly irritating (VSI)</b>
0,16 ≤ M.I.I. < 0,56	<b>Slightly irritating (SI)</b>
0,56 ≤ M.I.I. < 1,00	<b>Moderately irritating (MI)</b>
1,00 ≤ M.I.I. < 1,60	<b>Irritating (I)</b>
M.I.I. ≥ 1,60	<b>Very Irritating (VI)</b>

Individual values and the product class were taken into account to write a suitable conclusion under the study conditions (24-hour single patch test under semi-occlusion).

#### \* Bibliography references :

- « *Les essais cliniques en dermatologie* », *Thérapie*, 1991, Tome 46, pages 183 à 187
- « *Dermato-allergologie de contact* », G. DUCOMBS, Editions MASSON, 1988 pages 13 à 16 ; 36-37
- « *Dermatotoxicology Methods: The laboratory worker's VADEMECUM* »; N. MARZULLI – H. MAIBACH. Ed. Taylor & Francis, 1998.

#### 4. RESULTS

The individual reading results at each experimental time are presented in APPENDIX II.

The readings at 30 minutes and 24 hours after patch removal, produced following M.I.I. values:

M.I.I.	30 minutes	24 hours
	0.00	0.00
Class	non irritating	non irritating

#### 5. CONCLUSION

Under these study conditions, we can conclude that the product "Gento Antibacterial Bar Soap (RN17-05835.001)", tested under dermatological control and locally applied 5% diluted with water under semi-occlusive patch for 24 hours, on the sensitive skin of 10 adult volunteers, is classified **NON IRRITATING** at the 30 minute and 24 hour readings, according to the M.I.I. calculation.

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## **APPENDIX I**

### **AUTHENTICATION PAGE**



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**ORYGINAŁ**

**KARTA AUTENTYCZNOŚCI REZULTATÓW**  
**FICHE D'AUTHENTIFICATION DES RESULTATS**  
**AUTHENTICATION PAGE**

**CT-071**

PTS - Patch Test Simple

Według posiadanych przeze mnie informacji, badanie było przeprowadzone zgodnie PROTOKOŁEM oraz KARTĄ PARAMETRÓW TESTU.

*A ma connaissance l'étude a été conduite en accord avec le PROTOCOLE et la FICHE DES PARAMETRES D'ETUDE.*

*To my knowledge the study has been conducted according to the PROTOCOL and STUDY PARAMETERS PAGE.*

**Mgr inż. Barbara WAŁEJKO**

Odpowiedzialna za badania

*Responsable d'unité*

*Unit Manager*

podpis / signature

2017-03-31

data / date

**Dr Marlena NOWAKOWSKA**

Lekarz dermatolog

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*Dermatologist*

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## **APPENDIX II**

### **SUBJECTS CHARACTERISTICS**

### **RESULTS TABLE**

## SUBJECTS CHARACTERISTICS

Subject N°	Code of subject	Age	Sex	Phototype	Skin type
1	GRZRO	52	M	II	S
2	SASHE	63	F	II	S
3	BIAAL	44	F	II	S
4	WOZJA	22	F	II	S
5	JECSL	43	M	II	S
6	ROZNA	29	F	II	S
7	BIEMA	43	F	II	S
8	SLOJO	28	F	II	S
9	SZUEW	30	F	II	S
10	PECKA	59	F	II	S
Middle age		41			

F = Female  
M = Male  
N = Normal  
S = Sensitive

## RESULTS TABLE

Subject N°	READING 30 minutes after patch removal						READING 24 hours after patch removal					
	C		HA				C		HA			
	E	O	E	O	S	V	E	O	E	O	S	V
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0
<b>M.I.I.</b>	0,00		0.00				0,00		0.00			

C = Control  
**HA**= Gento Antibacterial Bar Soap (RN17-05835.001)  
E = Erythema  
O = Oedema  
S = Dryness  
V = Vesicles

## **APPENDIX III**

### **RESUME DE L'ETUDE**

# RÉSUMÉ DE L'ÉTUDE

**TITRE:** ETUDE DE LA TOLERANCE CUTANEE AIGUE D'UN PRODUIT COSMETIQUE CHEZ LE VOLONTAIRE ADULTE : PATCH TEST 24 HEURES SEMI-OCCLUSIF SOUS CONTRÔLE DERMATOLOGIQUE.

**REFERENCE DE L'ETUDE :** CT-071

**PRODUIT :** Gento Antibacterial Bar Soap (RN17-05835.001)

**REALISATEUR DE L'ETUDE :** L'étude a été réalisée et les valeurs numériques saisies par l'Unité Clinique PROCOS, localisée en Pologne ; ul. Słowackiego 27/33 lok. 33/34 ; 01-592 Varsovie.

**INVESTIGATEUR :** Dr Marlena NOWAKOWSKA

**PROTOCOLE :** PATCH-TEST SEMI-OCCLUSIF 24 HEURES

**OBJECTIF DE L'ETUDE :** Déterminer le potentiel irritant primaire d'un produit cosmétique (testé dilué à 5% dans l'eau) après application unique sous pansement semi-occlusif pendant 24 heures chez le volontaire adulte.

**SUJETS :** 10 volontaires sains à peau sensible correspondant aux critères d'inclusion et de non-inclusion déterminés par LISKIN.

**PERIODE DE L'ETUDE :** 27/03/17-29/03/17

**PLAN EXPERIMENTAL :** Etude monocentrique en simple aveugle.

## CRITERES D'EVALUATION :

- Indice d'Irritation Moyen :  $I.I.M. = \frac{\text{score total des réactions}}{\text{nombre total de volontaires}}$

- Méthodes d'analyse : Classement du produit en fonction de son I.I.M. :

Valeur d'I.I.M.	Classement du produit
$I.I.M. < 0,08$	Non irritant (NI)
$0,08 \leq I.I.M. < 0,16$	Très légèrement irritant (TLI)
$0,16 \leq I.I.M. < 0,56$	Légèrement irritant (LI)
$0,56 \leq I.I.M. < 1$	Moyennement irritant (MI)
$1,00 \leq I.I.M. < 1,60$	Irritant (I)
$I.I.M. \geq 1,60$	Très Irritant (I)

## RESULTATS :

Dénomination du produit	I.I.M. à 30'	I.I.M. à 24h
Gento Antibacterial Bar Soap (RN17-05835.001)	0,00	0,00

## CONCLUSION :

Dans les conditions expérimentales retenues, le produit «Gento Antibacterial Bar Soap (RN17-05835.001)» s'est révélé **NON IRRITANT**, selon la cotation de l'I.I.M.