

**TEST RUN  
PATCH TEST FOR COSMETICS**

**1- REPORT IDENTIFICATION**

Report Code: PATCH009/17  
Customer: LABORATORIO ANAYCO S.L.  
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**2- OBJETIVE AND PRINCIPLES STUDY**

To determine the skin compatibility of the following product:

Sample 1	
<b>Product Name</b>	Massage oil Santa Sita
<b>Batch</b>	16-1
<b>Aquimisa Sample Number</b>	17_141175

This product has been tested on 11 volunteers who meet certain criteria (Item 5). The results have been visually evaluated in the skin after applying the product once through Patch test.

**3- PLANNING**

STAR DATE: February 6, 2017  
 COMPLETION DATE: February 10, 2017

#### 4- VOLUNTEER INFORMATION CONCERNING

<b>Number of volunteers enrolled</b>	11
<b>Number of volunteers completing study</b>	11
<b>Ages</b>	24-51
<b>Sex</b>	Men and women
<b>Skin Type</b>	Normal skin

All volunteers met the criteria established in section 5.

#### 5- STANDARD FOR EXCLUSION FROM STUDY

The inclusion criteria defined in the protocol to follow were:

- Allergy to colophony or Nickel.
- Marks skin in the area of application of the product that may influence the evaluation of the study or may produce skin reactions (pigmentation, areas with excessive hair, scars, areas with excessive freckles and / or moles, sunburn ... ) .
- Allergies or reactions to the tested cosmetic products.
- Hypersensitive skin.
- Atopic skin.
- Reactions or eczema that have not completely disappeared, scars or pigmentation in the application area prior to the study product.
- Reaction to medicine.
- Treatment containing corticosteroids and it was applied in the treatment area during the 8 days before the start of the study.
- Treatment containing vitamin A or derivatives during the 3 months previous to this research.
- No bathing at home, at the pool or in the sea in a Turkish Sauna during the study.
- Intensely or regularly practice sport whose momentary interruption may pose a problem.
- Intense sun exposure (directly or UV rays) during the study.
- Intense sun exposure during the months prior to the study.
- Treatment with photosensitizing agents such as psoralen (PUVA ) or (UVA ) , and not having carried out the months prior to the study .
- Pregnancy or lactation .

## 6- ANALYTICAL METHOD

Conditions of study	
Area of product application	Upper back
Patch data	Brand: Finn Chambers AQUA®
	Batch: 1616GEN
	Date of Expiry: 2018/12/31
	Features: aluminum wells of 8 mm filter paper coated on transparent and impermeable flexible polyurethane. Capacity of 20 uL
Amount	To complete well: 20 µL
Contact time	<b>48 hours ± 2 hours</b>
Reading area	15 – 30 minutes after removing the patch
Reading late response (#)	<b>96 hours</b>

(#) At 96 hours after the collation of the patch (first 48 hours without the patch)

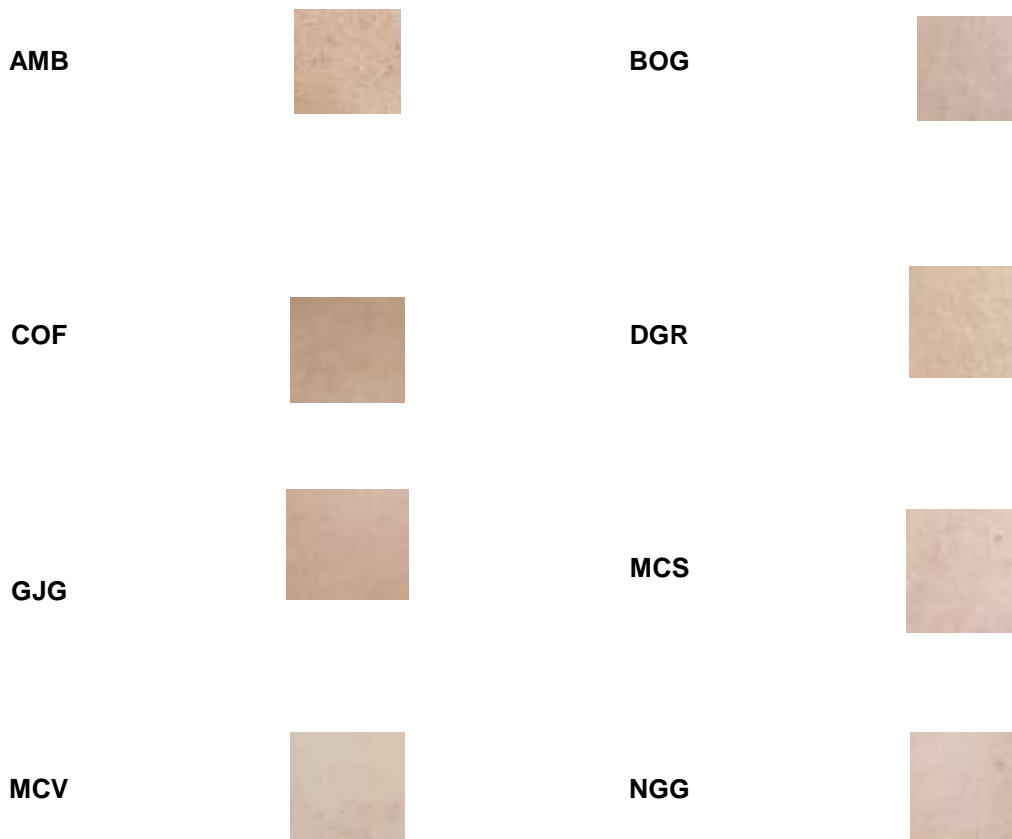
## 7- RESULTS

<i>VOLUNTEER</i>	<i>PLACE OF PATH AREA</i>	<i>READING TO 48 HOURS ± 2 HOURS</i>	<i>READING TO 96 HOURS ± 2 HOURS</i>
AMB	Upper left back	-	-
BOG	Upper left back	-	-
COF	Upper left back	-	-
DGR	Upper right back	-	-
GJG	Upper left back	-	-
MCS	Upper left back	-	-
MCV	Upper left back	-	-
NGG	Upper left back	-	-
VAA	Upper left back	-	-
VIC	Upper left back	-	-
VPG	Upper left back	-	-

Coding establecida by ICDRG (International Contact Dermatitis Research Group) and by EECDRG (European Environmental and Contact Dermatitis Group):

+?	Doubtful reaction, there is only erythema
+	Erythema, infiltration, papules may
++	Eritema, infiltración, pápula y vesícula
+++	Erythema, infiltration, papules and vesicle
-	Negative reaction
RI	Irritant reaction

**Pictures of the results at 96 hours:**



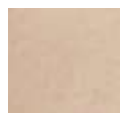
**VAA**



**VIC**



**VPG**



## 8- CONCLUSIONS

None of the participants in the trial have been presented reaction at 48 hours after patch removal or reaction at 96 hours.

**Therefore taking into account the results obtained in the experimental conditions, through Patch test, in the product:**

- Name: Massage oil Santa Sita
- Batch: 16-1
- N° aquimisa: 17\_141175

**The application on the upper back of the skin, under patch for 48 hours, in adult volunteers with normal skin, can be classified as VERY GOOD SKIN COMPATIBILITY.**

**8.1- SIGNED AND DATA**

**Technician: Raquel López Magaña (Degree in Pharmacy)**

Declares that this study was carried out under his responsibility and results presented reflect the completeness of the study.

**Signed:**



February 15, 2017

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