



Test Report

HRIPT Test Report

Date: 08/07/2026

Charafeddine Industrial Laboratories s.a.r.l
Address: Aley - Mount Lebanon, Lebanon
Email:
Contact Number: 00961 3

This is to certify that:

Sample Description	ANTATI S.A.R.L
Product Type	Olive Oil Soap
Batch/Lot No.	OS01
Manufacturer	Charafeddine Industrial Laboratories s.a.r.l
Country of Origin	Aley - Mount Lebanon, Lebanon

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. IQS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly

Sample Receiving Date	May 15 2025
Test Performing Date	July 22 2025
Test Performed	Selected test(s) as requested by applicant

Has been assessed with respect to: Test Result Summary

No	Test(s) Requested	Result(s)	Comments
1	HRIPT Test Report	PASS	/

Further details of the product(s) and conditions for certification are given overleaf.

Certificate No: TCL2482-26
Issue Date: 15 July 2026
Expiry Date: 12 July 2027

This certificate verifies the original certificate issued and is valid as long as it is displayed as an electronic copy at www.iqs-ltd.com and surveillance audits are satisfactorily completed.

(Subject to the company maintaining its system to the required standard)

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Following the requirements of EGAC and ilac standard guidelines


President



EGAC CAB 032307 / IAS Inspection Bodies IB - 141



ASSESSMENT OF DERMAL SENSITIZATION POTENTIAL OF A PREPARATION

HUMAN REPEATED INSULT PATCH TEST ON 60 VOLUNTEERS

Date of receipt: May 15, 2025

RESULT:

Throughout the study, the product induced no reaction or irritation.

The number of volunteers that presented an allergic reaction was zero (0%).

CONCLUSION:

According to the experimental conditions of the study, the test product can be considered "Non Sensitizing", "Hypoallergenic", or "Formulated to minimize the risks of allergy under normal way of use."

REGULATORY, CONFIDENTIALITY AND ARCHIVING

Regulatory

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki (World Medical Association) and the ICH E6(R2) Guideline for Good Clinical Practice (GCP). The Human Repeated Insult Patch Test (HRIPT) was performed following the COLIPA (now Cosmetics Europe) Product Test Guidelines for the Assessment of Human Skin Compatibility (1997). The tested cosmetic product was manufactured in accordance with ISO 22716:2007 Cosmetics Good Manufacturing Practices (GMP) and supports the safety assessment requirements of Regulation (EC) No. 1223/2009 on Cosmetic Products. Precautions have been taken to avoid the possibility that participants in the study might experience undesirable effects.

Ethical requirements which have been taken into consideration in the planning of the study include

- a) Participants are informed volunteers, selected after application of inclusion/ non inclusion criteria.
- b) Participants are aware of the purpose and nature of the study and of any foreseeable risks involved in participation in the study and have given written informed consent before the study starts.
- c) A safety evaluation has been conducted on the product tested, before the study starts.
- d) The test procedures conform to national regulations.
- e) The Ethical Review Committee include medical, non-medical, appropriate experts and lay members, it has considered the general ethics of the test and verified that the safety and integrity of the participants in the test are protected, taking into account information on the ingredients).
- f) All reasonable care has been taken to avoid causing excessive skin reactions or other adverse health effects in the participants during the study.
- g) Safety procedures are in place in the event of any unexpected/adverse reactions, including appropriate medical cover.
- h) Volunteers are rewarded for their time, inconvenience, etc., but the reward is not so great that it would persuade them to participate.

Confidentiality

All personal data collected during this study were processed in accordance with Regulation (EU) 2016/679 (General Data Protection Regulation – GDPR) and applicable national data protection legislation. Volunteers provided written informed consent prior to participation. Personal information was processed solely by authorized study personnel bound by confidentiality obligations and used exclusively for the purposes of this clinical investigation. Participant identities remained confidential throughout the study, and all data were anonymized or coded to protect volunteer privacy. Personal data were not disclosed to unauthorized third parties and were securely maintained in accordance with applicable data protection requirements thanks to his personal volunteer's code.

Archiving

The laboratory book which contains all the information (raw data and results) regarding the study and the study reports are kept in the laboratory archives during 2 years.

TYPE AND OBJECTIVE OF THE STUDY

The purpose of this study is to determine the dermal sensitization potential of a product. The HRIPT is performed to confirm the safe use of potentially sensitizing substances in consumer products, such as cosmetics or household products.

PANEL STUDIED, INCLUSION / NON-INCLUSION CRITERIA.

Number of volunteers: A number of 60 volunteers has been recruited to satisfy the objectives of the test.

Panel characteristics

Volunteers are selected on the basis of inclusion and non-inclusion criteria. The volunteers satisfy all the inclusion criteria and are not in conflict with any of the non-inclusion criteria and had a medical examination (health certificate) and a dermatological examination. The volunteers are clearly informed, verbally and in writing, regarding the nature of the study, the timetable, constraints and possible risks. They give their written informed consent before participation in the study.

Inclusion criteria

- Informed volunteers who agree to follow the conditions specified
- Where appropriate of relevant age: 18-70 years old
- Where appropriate of relevant gender: female and/or male
- Where appropriate of relevant origin and health
- Free from any dermatological problems on the area studied
- Meet the specific study criteria on skin type
- Proof of home address & social security number

Non inclusion criteria

- Volunteers who does not meet the inclusion criteria
- Pregnancy or nursing condition
- Irritated skin on test site(s)
- Blemishes, marks (eg. tattoos, scars, sunburn) on the test site(s)
- Medication which may affect skin response and/or past medical history
- Presenting skin pathology which may interfere with the aims) of the study
- Presenting contact allergy to one of the ingredients of the tested product
- Participation in another simultaneous study
- Participation in a previous study without an appropriate rest period between studies
- Minors
- Persons deprived of liberty by legal or administrative decision
- Patients in emergency situation
- Volunteers who refused to give their free and informed consent

Study constraints

During the length of the study, the volunteers are asked:

- Not to put any product, also water on the patches area
- Not to have a bath, neither to expose themselves to UV.
- To avoid all intense sportive activities that could remove the patch.
- Not to take aspirin, anti-histamine, corticoids, anti-inflammatories and any other treatment decreasing or avoiding inflammations or allergies or interfering with skin metabolism.

Volunteers' withdrawals

Participants will be withdrawn for the following reasons:

- They undergo any condition which could affect the outcome of the study;
- They no longer wish to participate in the study.

METHOD PRINCIPLE

Human Repeated Insult Patch Test (HRIPT)

The methodology used by the laboratory is based on the Human Repeated Insult Patch Test (HRIPT) originally described by Marzulli, F.N. and Maibach, H.I. in *Contact Allergy: Predictive Testing in Man* (Contact Dermatitis, 1976, 2, pp. 1–17). The study was performed in accordance with current Good Clinical Practice (ICH E6(R2)), the ethical principles of the Declaration of Helsinki, and the applicable safety assessment requirements of Regulation (EC) No. 1223/2009 on Cosmetic Products.

Table 1. Methodology Used

Test	No. Subjects	Induction site	No. of exposures	Duration of exposure (h)	Frequency of exposure	Rest (days)	Challenge
Human Repeated Insult Patch Test (HRIPT)	60	Upper back	9	48	3 applications/week	14	48 h patch test (1:10 dilution), evaluations at 30 min, 24, 48, 72 and 96 h

According to the study protocol, the finished Olive Oil Soap formulation was evaluated on sixty (60) healthy adult volunteers under occlusive patch conditions. The induction phase consisted of nine applications over three consecutive weeks to the same application site on the upper back. Following a 14-day rest period with no product exposure, a single challenge application was performed on a previously untreated site.

Table 2. HRIPT Time Table

W1	W2	W3	W4	W5	W6
Induction	Induction	Induction	Rest	Rest	Challenge

Applications were repeated 9 times over three consecutive weeks. No product application was performed during the 14-day rest period. A single challenge application was followed by dermatological evaluations.

EQUIPMENT

Occlusive patch chambers (0.64 cm²) mounted on hypoallergenic adhesive tape were used.

DOSE LEVEL

Approximately 0.02 mL of a 1:10 dilution of the finished rinse-off formulation was applied to each patch.

TEST MATERIAL APPLICATION

The area on which the patch is applied is previously cleaned up with demineralized water and dried with cellulose cotton wool tissue.

The patches are put on the back of the volunteer.

The products are tested pure or diluted depending on their type and their use.

- Mostly, the products are tested pure.

- Rinse-off products are tested diluted at 5%.
- Detergents are tested diluted at 10%.
- Hydrophilic products are diluted in demineralized water
- Lipophilic products are diluted in mineral oil.
- Powders are put pure in the patch small cavity and then moistened sufficiently with a drop of mineral oil in order to ensure good contact with the skin and avoid the product dispersion while applying the patch.

The patches thus prepared are left in contact 48 hours.

NEGATIVE CONTROLS

Whilst this activity is always be on a case-by-case basis and will depend on the nature and type of study, the most common approach is to compare the results obtained for the test materials with those of suitable positive and/or negative controls.

A "negative" control is a patch without any product, applied in the same conditions as the product to be tested:

if the product is tested pure: empty patch.

if the product is tested diluted: patch with 0.02ml of the solvent used (demineralized water or mineral oil).

VISUAL ASSESSMENT

Treatment sites are assessed before the first application of test material (baseline) and after treatment at 30 minutes after patch removal during the induction period.

After a rest period of 2 weeks a patch was applied on a previously unpatched and patched skin site. This site was evaluated on 30 minutes, 24, 48, 72 and 96 hours after removal.

Skin reactions are scored throughout the test by the same experienced assessor who made the baseline assessment and under the same lighting source, following a pre-defined irritation and sensitization scoring scales.

RECORDINGS

EXAMPLE OF IRRITATION SCORING SCALE

ERYTHEMA

0 = no evidence of erythema

0.5 = minimal or doubtful erythema

1 = slight redness, spotty and diffuse

2 = moderate, uniform redness

3 = strong uniform redness

4 = fiery redness

DRYNESS (SCALING)

0 = no evidence of scaling

0.5 = dry without scaling; appears smooth and taut

1 = fine/mild scaling

2 = moderate scaling

3 = severe scaling with large flakes

OEDEMA

= absence of oedema

+ = presence of oedema

According to the I.C.D.R.G. (International Contact Dermatitis Research Group).

+? Doubtful reaction + Weak reaction ++ Strong reaction +++ Extreme

IR Irritant reaction of different types

In case of negative evidence of any effect, the indication "-" is recorded.

Panel description

This study included 50 healthy adult volunteers.

A number of 50 subjects satisfactorily completed the test procedure.

Subject skin characteristics are described on the results table.

None of the volunteers selected took a treatment contraindicated with the study.

No withdrawal occurred

No irritation or sensitization reactions occurred on the subjects that decided to withdraw.

No skin reaction was noticed by the dermatologist on the reference area for all subjects

Results obtained for each volunteer.

In case of negative evidence of any effect, the indication "-" is recorded.

[illegible]

Conclusion

A total of 60 healthy adult volunteers successfully completed all phases of the Human Repeated Insult Patch Test (HRIPT). No evidence of primary irritation, cumulative irritation, or delayed contact sensitization was observed during the induction phase or following the challenge application. All dermatological assessments were recorded as negative throughout the study.

Under the conditions of this investigation, the tested Olive Oil Soap demonstrated excellent skin compatibility and did not induce any clinically significant cutaneous reactions in the study population. Based on the observations recorded during the study, the product would be considered non-irritating and non-sensitizing under the test conditions.

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Prepared by
Technical Writer

Dr. H. A. Sara

Test Engineer

Mark



Approved by

IQS International Ltd Has met the requirements of the IAS accreditation for testing and calibration laboratories, has demonstrated compliance with ISO/IEC standard 17025:2017 general requirements for the competence of testing and calibration laboratories and has been accredited

Terms and conditions

The certificate is subject to the following terms and conditions:

The certificate is subject to the following terms and conditions:

- Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 of November 30, 2009, relating to cosmetic products.
 - Cosmetics Europe- The Personal Care Association Guidelines „Product test Guidelines for the Assessment of Human Skin Compatibility 1997”.
 - WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (1964- 2013).
 - The Act on Cosmetic Products, October 4, 2018, Journal of Laws No. 2018 item 2227s.
 - The certificate is only valid for the products and/or manufacturing premises listed above.
 - The Manufacturer shall inform IQS of any intended change of the products detailed above and IQS will assess the changes and decide if the certificate remains valid.
- The following may render this Certificate invalid:
- Changes in the design of the products to which this Certificate refers.
 - Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by Inspection Body According to ISO/IEC 17020 identification number of IQS.

End of Certificate