The Cosmetic Test Company
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# FINAL CLINICAL STUDY REPORT

# Assessment of the anti-acne potential, the clinical and dermatological tolerance and the acceptability of a cosmetic product after 28 days of application under normal conditions of use - use test under dermatological control

Investigational product:

**ACTIVE WATER SPRAY - ADVANCED WATER S-100**

**Sponsor: ADWATIS SA**
Boucle de Cydalise 1, 2300 La Chaux-de-Fonds, SWITZERLAND.

**IDEA Tests Study number**: 310319
**Date of beginning of the study**: 02/05/2022
**Date of end of the study**: 18/07/2022

**Investigator**: Ioana Silvia SIMIAN

**Version 1 of 29/07/2022**

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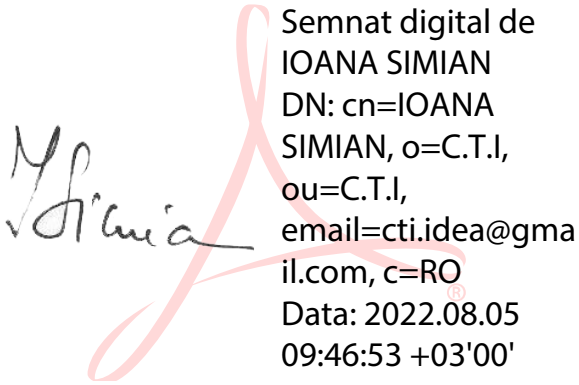
# AUTHENTICITY OF THE RESULTS

The study giving rise to this report was conducted under my responsibility, in accordance with the experimental protocol and in the spirit of Good Clinical Practice. I certify that this report precisely reflects the study conducted as well as the results obtained.

Ioana Silvia SIMIAN, investigator

Dermatologist

Signature / date:




This report was audited by the IDEA Clinic Quality Assurance department. It exactly reflects the study's raw data as well as the application of the applicable procedures.

Signature / date:

# 1. PURPOSE OF THE STUDY

At the request of **ADWATIS SA** company, we have assessed, under dermatological control, the anti-acne potential, the clinical and dermatological tolerance and the acceptability of the product:

**ACTIVE WATER SPRAY - ADVANCED WATER S-100**
Code ID-22/05270

used under normal use conditions recommended by the sponsor, over a period of 28 days. And, in general, we assessed the product's ability to keep the skin in good condition.

The study has been supplemented by the taking of standardised photographs on D1 and D28.

# 2. INVESTIGATIONAL PRODUCT

## 2.1. Characteristics

| | | |
|---|---|---|
| Name | : | ACTIVE WATER SPRAY - ADVANCED WATER S-100 |
| IDEA Tests code | : | ID-22/05270 |
| Batch number | : | 2103 |
| Aspect | : | Liquid |
| Colour | : | Colourless |
| Product type | : | Finished cosmetic product |
| Product class | : | Care |
| Storage conditions | : | +20°C ± 5°C |
| Expiry date | : | 30/03/2023 |
| Packaging | : | Plastic spray |
| Number of received samples | : | 25 |

## 2.2. Instructions for use during the study

Apply twice a day on the face, morning and evening. Spray generously (6-7 sprays) on the face (eyes closed) at a distance of 15-20 cm. Leave on for 20-30 seconds. Wipe off gently. Then repeat the operation (3-4 sprays), let dry or wipe off after 10-15 seconds.

# 3. EXPECTED POPULATION BY PROTOCOL

## 3.1. Number of volunteers to be included

20 volunteers had to be included. Approximately 10% additional volunteers had to be recruited in order to obtain the appropriate number of volunteers at the end of the study.

## 3.2. Inclusion criteria

Volunteers who met the following criteria had to be included:

- healthy volunteers;
- volunteers between 18 and 45 years old;
- volunteers with mixed oily to oily facial skin;
- volunteers with acne grade 2 to 3 on the GEA scale (minimum 33% of grade 3);
- volunteers with normal clinical examination prior to inclusion;
- volunteers without strong allergy;
- volunteers not exhibiting any dermatological lesion on face;
- volunteers with no significant past history of allergy to cosmetics or household products;
- volunteers who have already used a product in the same category as that of the investigational product;
- volunteers who have signed a written free informed express consent;
- if the volunteer was a woman: woman who is not pregnant or not liable to become pregnant, woman who is not breastfeeding;
- volunteers able to understand the requirements of the study.

### 3.3. Non-inclusion criteria

Volunteers who met the following criteria had to be not included:

- volunteers with a general disease incompatible with the study;
- volunteers with active dermatological disease;
- volunteers having received treatment with Isotrétinoïne or an antiacneic oral contraceptive during the last six months;
- volunteers in receipt of anti-inflammatory drugs, corticosteroids, histamine antagonists, or any other treatment reducing or inhibiting inflammatory or allergic reactions; the prohibited medications will be described in the current in-house manual;
- volunteers who has been exposed to U.V. (natural or artificial) during the 3 weeks before the start of the study;
- volunteers being exposed to chlorine in his/her professional environment;
- volunteers in the exclusion period between two studies.

### 3.4. Study imperatives

Throughout the study, each volunteer was asked:

- to attend all of the visits without having applied a hygiene, care and/or makeup product on face;
- not to manipulate facial imperfections (papules, comedones, scales, dead skin);
- not to intentionally or unintentionally expose theirself to UV light (natural or artificial);
- not to change their usual hygiene and cosmetic practices;
- not to use new cosmetic products;
- not to use another cosmetic product in the same class as that of the investigational product;
- to use the investigational product in place of their usual product;
- not to undergo aesthetic or dermatological procedures;
- not to undergo planned surgery;
- not to go to the beautician (for care, hair removal, etc. on face) or to the barber;
- if the volunteer was a woman: to continue using medically acceptable contraception to prevent pregnancy.

### 3.5. Specific study requirements and constraints relative to the Covid-19 epidemic

Taking into account the Covid-19 epidemic specific context, the volunteer was required to:

- inform the investigator of any contamination or the appearance of any symptom suggestive of Covid-19 during the study;
- inform the investigator of any contamination or the appearance of any symptom suggestive of Covid-19 concerning a person with whom he/she has been in contact during the study;
- follow the instructions given by the laboratory with regard to protective measures against Covid-19 detailed in the internal charter of the study Centre. These measures were communicated by phone, email and SMS; and displayed through billboard.

## 4. METHODOLOGY

The study was monocentric, open and comparative between D28 and D1 (cf. specific protocol – study 310319).

### 4.1. Visit on D1

- Inform the volunteer about the study process;
- Collect signed, written, free, informed, express consent from the volunteer;
- Confirm that the inclusion and non-inclusion criteria are met;
- If the volunteer is eligible, allocate him/her an inclusion number in order of arrival into the study;
- Record the clinical examination (face) and treatments currently taken by the volunteer;
- Carry out of counting of acne lesions;
- Take standardized photograph of face (front) with the Fotofinder;
- Give the investigational product and instructions for use;
- Remind the volunteer about the restrictions required by the study, in particular the need to apply the product the day before the next appointment and to attend the visit without having applied product onto the face;
- Arrange a new appointment on D28 with the volunteer.

### 4.2. Visit on D28

- Check that the protocol imperatives have been met;
- Check compliance of the applications;
- Recover the remaining product in its initial packaging;
- Record the clinical examination and treatments possibly taken by the volunteer during the study;
- Carry out of counting of acne lesions;
- Record the possible clinical signs and/or symptoms of the volunteer;
- Note down the volunteer's impressions of the product's cosmetic qualities;
- Take photograph in same conditions as on D1.

## 5. RESULTS AND ANALYSIS

### 5.1. Experimental conditions

Study site : CTI, Str. Iuliu Teodori, nr. 1, Sector 5 - 050496 BUCURESTI - ROMANIA

Study dates

- Beginning : 02/05/2022
- End : 18/07/2022

#### 5.1.1. Population analysed

Number of volunteers included : 25

Number of volunteers analysed : 21

- 13 women and 8 men
- average age of 31 years, between 18 and 45 years
- mixed oily to oily facial skin
- with acne grade 2 to 3 on the GEA scale including 10 volunteers having acne grade 3

#### 5.1.2. Events during the study

| Inclusion number | Event | Description | Deviation | Degree of impact | Decision taken | Comments |
|---|---|---|---|---|---|---|
| 11, 15, 16 and 25 | Study appointment | Failed to appear for their appointment completing the study | Yes | Major | Withdrawal | « Lost to follow-up » |

Samples of the investigational product brought back by the volunteers at the end of the study were quarantined prior to their destruction.

## 5.2. Results - discussion

### 5.2.1. Anti-acne potential (n = 21)

| | Total score | | Comedones and microcysts | | Papulae | | Pustules | | Nodules and cysts | |
|---|---|---|---|---|---|---|---|---|---|---|
| | D1 | D28 | D1 | D28 | D1 | D28 | D1 | D28 | D1 | D28 |
| **Average** | **18.0** | **13.0** | **12.1** | **9.3** | **5.8** | **3.6** | **0.1** | **0.0** | **0.0** | **0.0** |
| Standard deviation | 7.3 | 6.0 | 2.8 | 2.7 | 6.0 | 4.1 | 0.7 | 0.0 | 0.0 | 0.0 |
| Minimum | 7 | 4 | 7 | 4 | 0 | 0 | 0 | 0 | 0 | 0 |
| Maximum | 33 | 29 | 17 | 14 | 16 | 16 | 3 | 0 | 0 | 0 |
| **Percentage of variation (%)** | **-** | **-28.2** | **-** | **-22.8** | **-** | **-37.7** | **-** | **NA** | **-** | **NA** |
| p value Significance* | - | **p < 0.000 (S)** | - | **p < 0.000 (S)** | - | **p = 0.010 (S)** | - | **NA** | - | **NA** |

* Wilcoxon test for paired data:
S : Significant ($p \leq 0.05$)
NA : Not Applicable: the percentages of variation are reported only from 10 volunteers who presented acne lesions of this type on D1 and/ or Dend.

Data analysis showed a statistically significant decreased in the total score of acne lesions, comedones and microcysts and papulae on D28 compared to D1.

### 5.2.2. Clinical and dermatological tolerance

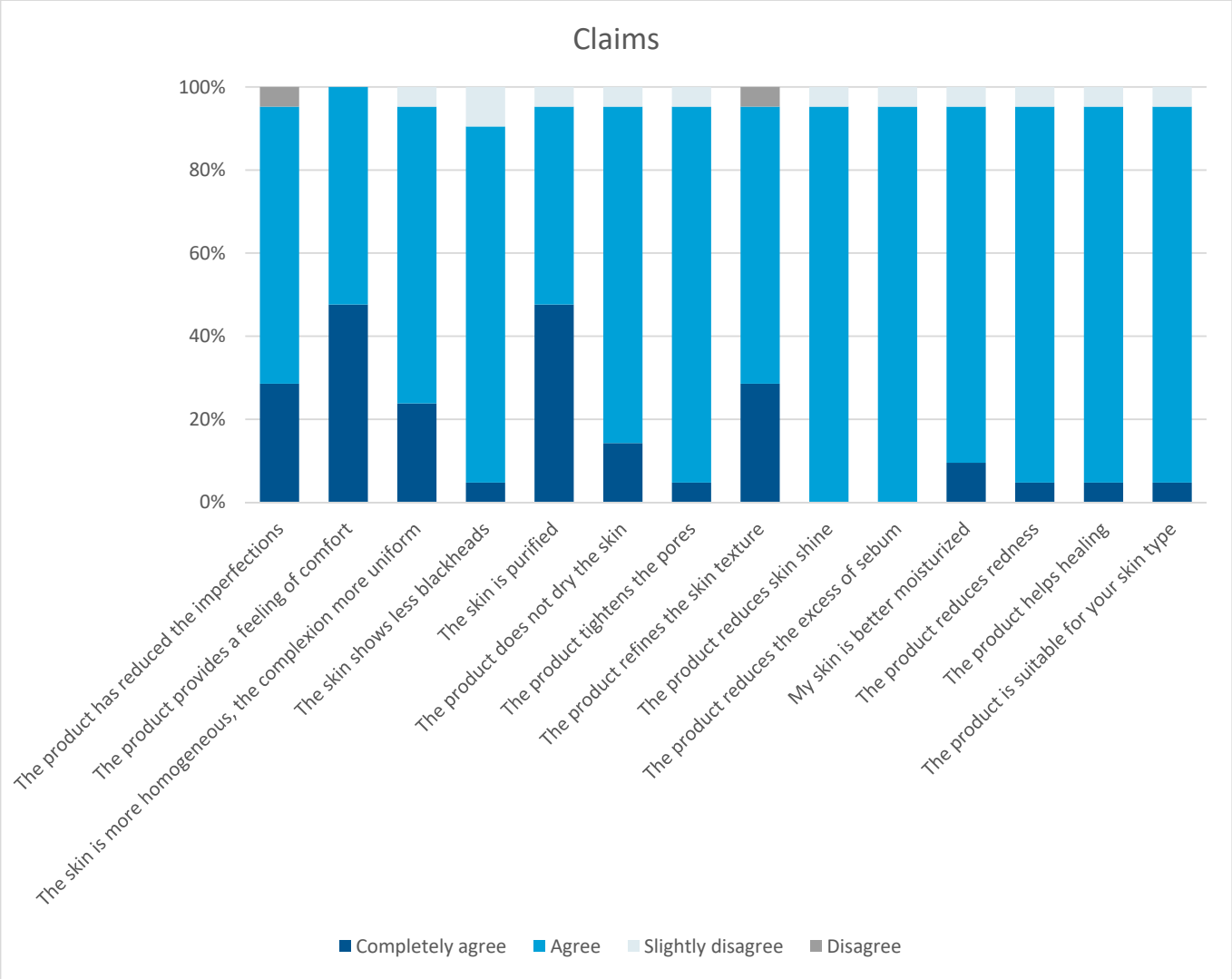
No clinical sign of intolerance was observed.
No sensation of discomfort was reported.

### 5.2.3. Cosmetic acceptability

The volunteers evaluated the properties of the product after a 28-day period of application:

- Overall satisfaction: 95%
- Purchasing intention: 20 volunteers out of 21
- Items related to efficacy of the product (positive responses ≥ 75% *):
  - The product has reduced the imperfections
  - The product provides a feeling of comfort
  - The skin is more homogeneous, the complexion more uniform
  - The skin shows less blackheads
  - The skin is purified
  - The product does not dry the skin
  - The product tightens the pores
  - The product refines the skin texture
  - The product reduces skin shine
  - The product reduces the excess of sebum
  - My skin is better moisturized
  - The product reduces redness
  - The product helps healing
  - The product is suitable for your skin type

** Statistical significant threshold for 21 analysed volunteers*




### 5.2.4. Standardised photographs

Standardized photographss taken during the study for each analysed volunteer have been sent in native resolution using an internet file transfer service.

We created contact sheet and sent them using an internet file transfer service.

## 6. CONCLUSION

**Under the conditions of the study, the product exhibited:**

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- **an anti-acne potential;**
- **an excellent dermatological tolerance, according to the adopted table, for mixed oily to oily facial skin;**
- **and a very good cosmetic acceptability, with 95% favourable opinions**