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Study number ST-ET-2026-00106

Münster, 26.06.2026

Specialist, dermatological expert report on an epicutaneous test
for the examination of primary irritation via a single occlusive application

# sana. swiss Wash Lotion

| | |
|---|---|
| Test subjects: | 30 |
| Skin type: | Various skin types |
| Test concentration: | 0.5% diluted in Aqua dest. |
| Test period: | 22.06. – 25.06.2026 |
| Version number: | V 01 |



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# 1 General information

## Title

Specialist, dermatological expert report on an epicutaneous test for the examination of primary irritation via a single occlusive application

## Testing centre

Dermatest GmbH
Nevinghoff 30
D-48147 Münster

## Specialists in Dermatology

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*Venereology, Allergology,*
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## Study Management Epicutaneous Testing

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## 1.1 Synopsis

| | |
|---|---|
| Study title | Specialist, dermatological expert report on an epicutaneous test for the examination of primary irritation via a single occlusive application |
| Test product | sana. swiss Wash Lotion |
| Study design | Monocentric, occlusive |
| Duration of application | 24 hours |
| Dilution | 0.5% diluted in Aqua dest. |
| Further study information | Musternummer: 15062601DF |
| Testing centre | Dermatest GmbH Nevinghoff 30 D-48147 Münster |
| Expert report version and date | V 01, 22.06. – 25.06.2026 |
| Study objective | Testing of skin tolerability<br>Skin condition is assessed before, as well as 24 h, 48 h and 72 h after application |
| Number of subjects | 30 |
| Inclusion criteria | • 18 years and older<br>• healthy skin<br>• various skin types<br>• written informed consent of the subjects is available |
| Exclusion Criteria | • severe or acute inflammatory skin reactions as well as severe internal or acute diseases (incl. neoplastic disease)<br>• short term and acute intake of drugs that may affect the skin reaction (glucocorticoids, antiallergenics, immunomodulators, etc.)<br>• application of prescription preparations and prescription care products in the test area 7-10 days before the beginning of the study (incl. anti-acne preparations)<br>• severe allergies or previously occurring strong side effects via cosmetic preparation<br>• intensive sunbathing or visits to solarium during the testing<br>• pregnancy and nursing |



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## 1.2 Time schedule

| Time | 0 h | 24 h | 48 h | 72 h |
|---|---|---|---|---|
| Risk assessment | ✓ | | | |
| Declaration of consent | ✓ | | | |
| Demographic data | ✓ | | | |
| Anamnesis | ✓ | | | |
| Dermatological examination | ✓ | ✓ | ✓ | ✓ |
| Patch application | ✓ | | | |
| Patch removal | | ✓ | | |
| Compliance with inclusion and exclusion criteria | ✓ | ✓ | ✓ | ✓ |

# 2 Introduction

The human skin is the largest and functionally most versatile human organ. It delimits the organism against the outside world, protecting against dehydration and environmental influences. The skin consists of three layers: Epidermis (upper skin layer), dermis (true skin) and subcutis (hypoderm). The epidermis, in turn, is composed of five layers and consists of 90 % keratinocytes (horny cells). From outside to inside, the super-imposed layers are: Stratum corneum, Stratum lucidum, Stratum granulosum, Stratum spinosum and Stratum basale.

These days a lot of products, in particular cosmetics, consumer goods and medical devices, are in contact with the skin daily and often over long periods. Good tolerability is a prerequisite for application of these products. Since alternative test methods such as animal testing are prohibited and results of cell culture experiments can be applied to humans only in limited extent, tests under medical supervision are currently required from an ethical and scientific point of view. For analysis of the skin tolerability of products an epicutaneous test can be carried out.

The founder of the epicutaneous test is the German physician, Joseph Jadassohn. He developed this method as a non-invasive diagnostic tool for allergic contact dermatitis with low risk to the patients. The presentation of this technique, under the name "Functional Skin Examination", at the Congress of the German Society of Dermatology in 1895 is considered as the birth of the epicutaneous test. Already the first mentioned protocols recommended a 24-hour occlusive application on intact skin with measurements at least 48 hours after application.

Today, the epicutaneous test is an established procedure with internationally defined rules and guidelines that are constantly reviewed and updated.

In addition, expert groups, such as the International Contact Dermatitis Research Group (ICDRG), the German Dermatological Society (DDG), the German Society of Allergology and Clinical Immunology (DGAKI) and the European Cosmetic and Perfumery Association (Colipa) developed guidelines and recommendations for implementation. Furthermore, the DIN EN ISO 10993-23:2021 describes in section 8 and Annex E an irritation test for medical devices on the human skin.


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The epicutaneous test can be used not only to detect existing allergies, but also to analyze the potential for irritation. Thus, it is now routinely used in the industry to evaluate the skin tolerability of topical formulations and to supplement the product safety dossier of cosmetics and articles of daily use.

In the standard version, the tested substance is applied to the subject's skin for 24 hours using a film-patch test. The special patch specifically ensures an occlusive test environment that facilitates the penetration of the potential topical irritant (of the test substance) through the stratum corneum to the viable effector cells. These may trigger an immunological response mechanism, which typically leads to local erythema of the skin. Such an erythema in response to a substance applied in the epicutaneous test is then dermatologically evaluated.

Reactions to one-time applications can occur as a result of pre-existing allergies to any of the ingredients or due to irritant properties of the product. The primary goal of this testing is to examine products for skin tolerability and thereby rule out an irritative potential. The reaction type (irritative or allergic) can be differentiated according to both morphology and the course of the reaction. Therefore, dermatological examinations are conducted at three different time points. The dermatological diagnosis is then used to determine or rule out a primary irritation potential of a test substance.

# 3 Study objective and study parameters

The aim of this epicutaneous testing was to test the product for skin tolerability. An occlusive, uncontrolled, monocentric test took place over a period of 24 hours with subsequent observation (up to 72 hours).

# 4 Selection of subjects

The test was carried out with 30 male and female subjects, aged 18 and above. All subjects recruited had (very) dry, normal, combination or oily skin, as well as some with sensitive skin. The recruitment of the subjects occurred in the preparation phase of the studies, on the one hand from an existing subject panel and on the other hand via flyers, social media and newspaper advertisements.

Before inclusion the dermatological integument of all subjects was investigated regarding health and integrity. In case of necessary medical treatment, the subjects were excluded. the conditions of the study were explained to all subjects as well as the rights and duties of the subjects in the context of the study by the attending study nurse or the attending dermatologist. Subjects were included into the study only if they did not exhibit any pathological changes of the skin in the application area, signed the consent statement of their own free will and complied with all other inclusion and exclusion criteria. During the study all subjects could consult the attending study nurse or the attending dermatologist in case of any objective and subjective skin changes.

## 4.1 Information of the subjects

Prior to the study a pre-treatment consultation took place, in which the design and the conditions of the study as well as the rights and duties of the subjects in the context of the study were explained to the subjects by the attending study nurse or the attending dermatologist. Participation in the study was voluntary. All subjects could discontinue the study at any time and without giving any reason as well as without any negative consequences for the subjects.



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## 4.2 Inclusion criteria

- 18 years and older
- healthy skin
- Various skin types
- written informed consent of the subjects is available

The subjects had to be able to communicate with the attending study nurse or the attending dermatologist and to understand and follow the requirements of this clinic-dermatological application study.

## 4.3 Exclusion Criteria

- severe or acute inflammatory skin reactions
- severe internal or acute diseases (incl. neoplastic disease)
- short term and acute intake of drugs that may affect the skin reaction (glucocorticoids, antiallergenics, immunomodulators, etc.)
- application of prescription preparations and prescription care products in the test area 7-10 days before the beginning of the study (incl. anti-acne preparations)
- severe allergies or previously occurring strong side effects via cosmetic preparation
- intensive sunbathing or visits to solarium during the testing
- pregnancy and nursing

## 4.4 Exclusion of subjects from the study

The investigator could exclude a subject from the clinical examination, if one of the following conditions occurred:

- Revocation of the consent
- Occurrence of an undesirable event
- Deterioration of the clinical condition

If premature withdrawal of a subject occurred, it was documented completely. Supervision of all subjects continued for a reasonable time in order to control their clinical condition and the occurrence of adverse events as well as to document them.

## 4.5 Disruption / termination of the study

A subject could remove the patch and stop the testing at any time. Similarly, the attendant dermatologist or study manager could stop the testing, if they believed that the subject’s clinical status required such measures. Any exclusions had to be fully documented. It was the responsibility of the persons entrusted with the study management to assess the point, at which the clinical conditions for termination were met.
Unilateral withdrawal of consent or refusal to continue the study by the subject would have led to an immediate termination of the study for the subject in question.


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## 4.6 List of subjects

| Subject No. | Gender [f / m] | Age |
|---|---|---|
| 1 | f | 65 |
| 2 | f | 58 |
| 3 | m | 47 |
| 4 | f | 43 |
| 5 | m | 55 |
| 6 | f | 51 |
| 7 | m | 31 |
| 8 | f | 69 |
| 9 | f | 64 |
| 10 | f | 22 |
| 11 | f | 50 |
| 12 | f | 53 |
| 13 | f | 29 |
| 14 | f | 60 |
| 15 | m | 66 |
| 16 | f | 32 |
| 17 | f | 26 |
| 18 | f | 63 |
| 19 | m | 65 |
| 20 | m | 29 |
| 21 | f | 69 |
| 22 | f | 64 |
| 23 | f | 66 |
| 24 | f | 40 |
| 25 | f | 46 |
| 26 | f | 59 |
| 27 | f | 39 |
| 28 | f | 43 |
| 29 | f | 32 |
| 30 | m | 31 |



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# 5 Benefit-risk assessment and precautions

In studies involving human subjects, it is important to consider the specific potential risks to the subjects before starting a study. Therefore, for each product a risk assessment is conducted prior to the testing. This risk assessment comprises an evaluation of all ingredients of the product to be tested with regard to microbial quality and to allergenic or irritative potential depending on the study method. Products containing ingredients with known cancerogenic, mutagenic and/or reprotoxic potential, or in cases, where such potential has been discussed in serious scientific forums, are not authorized for testing by Dermatest GmbH.

According to product category, the requirements of the following legislative texts must be adhered to.

- Cosmetic products must comply with the requirements of the European Cosmetics Regulation (EC) No 1223/2009.
- Detergents and cleaning agents must comply with the requirements of the German Detergents and Cleaning Agents Act (WMRG), which refers to the European Detergents Regulation (EC) No 648/2004.
- Consumer goods as defined by the German Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch, LFGB) must not be capable of harming the health of consumers if used as intended.
- Medical devices, as distinct from cosmetic products, must comply in their material composition with the requirements of Regulation (EU) 2017/745 on Medical Devices.
- Food supplements must comply with the requirements of the Food Supplements Regulation (NemV), which implements the requirements of the European Directive 2002/46/EC.
- Biocides, if testing on humans is justifiable, must comply with the specifications of the European Biocide Regulation (EU) No 528/2012.

Most tested products are cosmetic products that comply with the requirements of the European Cosmetic Regulation, as well as Consumer Goods or Medical Devices, where only a minimal risk of causing reasonable skin alterations exists.

# 6 Implementation

## 6.1 Method and execution

The studies were executed in accordance with the guidelines of the DDG and DGAKI, the recommendations of the expert group Colipa as well as the ISO 10993-23:2021 (section 8 and Annex E) and based on the extensive specialist knowledge of Dermatest GmbH. Systematic studies on the methodology, particularly in relation to the analysis of the irritative potential of products (e.g., suitable test concentrations), are scarce. Published studies and all guidelines relate almost exclusively to the analysis of allergies. Analysis of the irritative potential of products often required testing at various concentrations, while buffer systems (among others) could not be used. Potential dilution media or so-called vehicles included Ethanol (70%, p.a.), petroleum jelly (Phr.Eur.), distilled water or olive oil (virgin). Optimal test conditions and in particular the concentrations at which the test substance was applied to the skin were calculated individually according to information regarding the intended use and the product composition. Exposure conditions (e.g., contact duration, concentration or possible occlusion) were typically intensified. Dermatological examinations were conducted according to the time schedule mentioned above.

Testing was carried out in air-conditioned, well-lit rooms. A suitable skin area, usually the back, served as a test area. This had to be untreated and free of acute or chronic skin alterations. Pre-existing, benign nevi in sporadic density, were acceptable within the test area. Test areas with significant hair growth had to be shaved two days prior to testing. The test patches (allergEAZE®clear Skin Patch Test Chambers (film)) were prepared shortly before application. 20 mg or 8-mm-diameter round punches of solid samples and 20 µl of liquid samples at the appropriate concentrations were applied. From solids of varying colours such as tattoos, bath or painting mats etc. representative test materials of as many colour variants as possible are punched. For multi-component



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products with secondary materials in various colors, the different color variants are tested on at least one-third of the test subjects. In products that have been colored using the so-called masterbatch process, the color pigments are evenly integrated into the base material. This significantly minimizes the risk of different skin tolerability between different colour variants of the same product and a representative test of one colour variant or a mixed test of all variants is sufficient. If necessary, test products in powder form were mixed with Vaseline. In general, the test products were prepared based on the instructions of use, however, in an intensified form.

The products were left occlusively on the test area for 24 hours. The first reading of potential reactions occurred 30-60 minutes after removal of the patch. Further assessments were made 48 and 72 hours after patch application.

For each test, a negative control (distilled water for undiluted tests or the respective dilution medium) was applied. This ensured that possible reactions were specific responses to the tested product and could be distinguished from non-product-specific irritations.

## 6.2 Test interpretation

The diagnostics of skin reactions is hindered by the complex, partly inter-individual different metabolization, diverse cofactors and individual immunological processes (Biovariability). A reliable evaluation is enabled via skilled, experienced specialists.

**Table 1: Evaluation of epicutaneous test reactions according to EN ISO 10993-23:2021 Human skin irritation test, grading scale**

| Grading | Grading |
|---|---|
| No reaction | 0 |
| Weakly positive reaction (usually characterized by mild erythema and / or dryness across most of the treatment site) | 1 |
| Moderately positive reaction (usually distinct erythema or dryness, possibly spreading beyond the treatment site) | 2 |
| Strongly positive reaction (strong and often spreading erythema with oedema and / or eschar formation) | 3 |

In principle, two types of reactions can be distinguished: irritative / toxic and allergic. The course and the severity of the reaction give insight about the type of the reaction.



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**Table 2: Differentiation of the reaction type according to Löffler et al., 2005**

| **Reaction type** | | **Course of the reaction** | **Interpretation** |
|---|---|---|---|
| positive reaction | Crescendo reaction | augmenting | allergic |
| | Plateau reaction | unchanging | allergic |
| | Decrescendo reaction | weakening | irritative |
| | Latrogenic late reaction | delayed (after 10-14 days) | sensitization |
| false-positive reactions | Cross-reactions | augmenting or unchanging | reactions to chemically similar substances |
| | Angry back / Excited Skin Syndrome | weakening | Hyper-irritability of the skin / Status eczematicus |
| false-negative reactions | - | no reaction | none |

Both allergic and irritative reactions can manifest themselves in erythema with a mild infiltrate up to oedema and / or eschar formation. In order to be able to assess the course of the reaction, three readings are mandatory. One can differentiate between crescendo, plateau and decrescendo reactions.

Crescendo and plateau reactions often imply allergic reactions, decrescendo indicate irritative reactions and delayed reactions (after 10 – 14 days) suggest sensitization.

Generally, reactions appearing for the first time at 72 hours or later, and are rated “1” to “3”, can be interpreted as “allergic”. Usually, several products are tested simultaneously in each study. If several reactions occur simultaneously in one subject (> 5 test products), false-positive reactions can normally be assumed. Possible false-positive reactions include so-called cross-reactions (to chemically similar test substances) and
the so-called “Angry back” / ”Excited Skin Syndrome” (to chemically unrelated substances). Normally, in a case that false-positive and / or allergic reactions appear, the affected subjects are excluded from the study.
False-negative reactions may occur, for example, due to insufficient occlusion, too low-test concentration, non-suitable vehicle, or reduced immunoreactivity as a result of intake / administration of immunosuppressive / topical medication.

Isolated, mild and transient reactions in the epicutaneous test are possible. Occurrence of such reactions in less than 10% of the subjects does not imply an enhanced irritative potential of the product. These reactions may rise due to the intensified conditions of the test compared with the intended use. Products in which 10% or more of the subjects show a product-related irritative skin reaction do not pass the test. In such a case, the products do not receive a certificate and cannot be advertised as “dermatologically tested”.



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# 7 Results

**Evaluations of the test and control area**

| Subj. No. | Test area | | | Control area | | |
|---|---|---|---|---|---|---|
| | 24 h | 48 h | 72 h | 24 h | 48 h | 72 h |
| 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | 0 | 0 | 0 | 0 | 0 | 0 |
| 10 | 0 | 0 | 0 | 0 | 0 | 0 |
| 11 | 0 | 0 | 0 | 0 | 0 | 0 |
| 12 | 0 | 0 | 0 | 0 | 0 | 0 |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 |
| 16 | 0 | 0 | 0 | 0 | 0 | 0 |
| 17 | 0 | 0 | 0 | 0 | 0 | 0 |
| 18 | 0 | 0 | 0 | 0 | 0 | 0 |
| 19 | 0 | 0 | 0 | 0 | 0 | 0 |
| 20 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 | 0 | 0 | 0 | 0 | 0 | 0 |
| 22 | 0 | 0 | 0 | 0 | 0 | 0 |
| 23 | 0 | 0 | 0 | 0 | 0 | 0 |
| 24 | 0 | 0 | 0 | 0 | 0 | 0 |
| 25 | 0 | 0 | 0 | 0 | 0 | 0 |
| 26 | 0 | 0 | 0 | 0 | 0 | 0 |
| 27 | 0 | 0 | 0 | 0 | 0 | 0 |
| 28 | 0 | 0 | 0 | 0 | 0 | 0 |
| 29 | 0 | 0 | 0 | 0 | 0 | 0 |
| 30 | 0 | 0 | 0 | 0 | 0 | 0 |



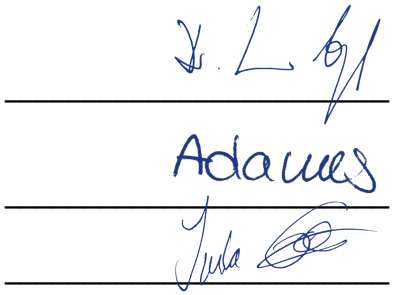
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## 8 Assessment of the study results

None of the 30 subjects showed skin alterations in the test area after
24 h, 48 h and 72 h following application of the epicutaneous test according to the recommendations of Colipa, the DDG, the DGAKI and ISO 10993-23:2021 (section 8 and Annex E). The product was tolerated very well.

Hence, it can be concluded that, from a dermatological point of view, the tested product does not exhibit a high irritative potential and that the product, if used as intended, will not lead to undesirable skin reactions.

**Dr. med. Werner Voss**
Medical Specialist in Dermatology,
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**Dr. rer. nat. Katja Adames**

**Dr. rer. nat. Imke Göllner**



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# 9 Addendum

## 9.1 Quality control, quality assurance and data protection

The quality of the study execution and of the data recording was ensured by ISO 9001 and controlled in regular intervals internally as well as externally by monitoring of TÜV Rheinland.

The provisions of the applicable data privacy legislature were respected. All data of the subjects were handled confidentially and were disclosed to the sponsors only in a pseudonymised or anonymized version. All data had been processed in compliance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27th of April, 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (DSGVO), as well as national data protection legislation, and stored in accordance with the statutory retention periods.

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