Sponsor **Study number ST-ET-2025-00038 (Epi), ST-SENS-2025-00014 (AT), Version V 01**

Flying Baby Sdn Bhd
A-05-08, Oasis Square, No 2, Jalan PJU, 1A/7A, Ara Damansara
47301 Petaling Jaya, Selangor
Malaysia

Testing centre

Dermatest GmbH
Nevinghoff 30
D-48147 Muenster

Muenster, 09.04.2025

Expert report by dermatological specialist about a clinical-dermatological study for the examination of skin tolerability on sensitive skin

(Test period: March 2025)

Milk Safe & Clean Plastic-free Pure Wipes for Sensitive Skin

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1. General information

Titel

Expert report by dermatological specialist about a clinical-dermatological study for the examination of skin tolerability on sensitive skin

Testing body

Dermatest GmbH
Nevinghoff 30
D-48147 Münster

Specialists in dermatology

Dr. med. Werner Voss

Medical Specialist in Dermatology,
Venereology, Allergology,
Phlebology and Environmental Medicine

Study coordinator

Dr. rer. nat. Imke Göllner
Biologist

Dr. rer. nat. Tanja Emmler
Biologist

1.1. Synopsis

Study title	**Expert report by dermatological specialist about a clinical-dermatological study for the examination of skin tolerability on sensitive skin**
Test product	Milk Safe & Clean Plastic-free Pure Wipes for Sensitive Skin
Product type	Cosmetic product
Study design	Single-centre
Testing body	Dermatest GmbH Nevinghoff 30 D-48147 Münster
Expert report version and date	V 01, 09.04.2025
Test period	March 2025
Study objectives	Assessment of skin tolerability on sensitive skin
Quantitiy of subjects	Epicutaneous test: 30 Safety in-use test: 10
Control	Epicutaneous test - Negative control: Aqua de st.
Test area	Epicutaneous test: back Safety in-use test: body, face, and diaper area
Application	Epicutaneous test - 24-hour, single occlusive application - Assessments: 24, 48 and 72 hours after application - Undiluted Safety in-use test - 1 week, several times daily
Inclusion criteria	Epicutaneous test - female/male, 18 years and older - healthy skin - sensitive skin - Written declaration of consent from the test subjects is available

	Safety in-use test - female/male, 0 to 3 years old - healthy skin - sensitive skin - Written declaration of consent from the test subjects is available
General exclusion criteria	• Severe or acute skin inflammation Severe internal or acute illnesses (incl. acute cancer) • Short-term and acute intake of medication that can impair the skin reaction (glucocorticoids, anti-allergic drugs, immunomodulators, etc.) • Application of prescription preparations and care products in the test area 7-10 days before the start of the test (incl. anti-acne preparations) • Intensive sunbathing or visits to the solarium during the study

1.2. Schedule

1.3. Schedule of epicutaneous testing

Time	0 h	24 h	48 h	72 h
Information of the subjects	✓			
Informed Consent	✓			
Anamnesis	✓			
Dermatological examination	✓	✓	✓	✓
Compliance with inclusion and exclusion criteria	✓	✓	✓	✓
Patch application	✓			
Patch removal		✓		

1.4. Schedule of safety in-use test

Study day	Day 0	Day 7
Information of the subjects	✓	
Informed Consent	✓	
Anamnesis	✓	
Dermatological examination	✓	✓
Compliance with the 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 superimposed 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 the analysis of skin tolerability of products, studies on humans can be carried out.

To ensure that products are suitable for sensitive skin, studies on test subjects with sensitive skin are important. Therefore we created a holistic approach consisting of the combination of an epicutaneous test and a safety in-use test.

3. Study objective and study parameters

The aim of this study was to investigate the tolerability of the product Milk Safe & Clean Plastic-free Pure Wipes for Sensitive Skin according to clinical-dermatological test criteria.

3.1. Primary outcomes

Assessment of skin tolerability on sensitive skin

- Epicutaneous test
- Safety in-use test

4. Selection of subjects

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.

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.

4.2. Inclusion criteria

- Epicutaneous test

- female/male, 18 years and older
- healthy skin
- sensitive skin
- written declaration of consent from the test subjects is available

- Safety in-use test

- female/male, 0 to 3 years old
- healthy skin
- sensitive skin

- Written declaration of consent from the test subjects is available

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 to product ingredients
- intensive sunbathing or visits to solarium during the testing

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. List of test subjects for epicutaneous testing

Subject No.	Gender [f / m]	Age
1	f	64
2	f	69
3	f	72
4	f	56
5	f	55
6	f	29
7	f	27
8	m	31
9	f	28
10	f	67
11	f	40
12	f	31
13	f	58
14	m	44
15	f	41
16	f	56
17	f	55
18	f	67
19	f	66
20	m	72
21	f	69
22	f	30
23	f	43
24	f	43
25	f	33
26	f	58
27	m	31
28	f	32
29	m	75
30	f	21

4.6. List of test subjects for safety in-use test

Subject No.	Gender [f / m]	Age
1	f	2
2	m	1
3	f	8 months
4	f	1
5	f	3
6	m	2
7	m	2
8	f	2
9	m	3
10	f	8 months

5. Implementation

To confirm the skin compatibility of the product, an epicutaneous test on 30 test persons and a safety in-use test on 10 test persons were carried out.

5.1. Risk analysis

Before the final testing on humans, the product undergoes a thorough examination of the ingredients as part of the internal risk analysis. It is a mandatory for testing that prohibited ingredients as defined in cosmetics Regulation (EC) No 1223/2009 are not contained in the product.

5.2. Method and execution of the epicutaneous test

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. 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.

5.2.1. Test interpretation of the epicutaneous test

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

Description of response	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.

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)	sensitisation
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”.

5.3. Method and execution of the safety in-use test

5.3.1. Evaluation of skin condition

The examinations are carried out by a dermatologist or trained specialist according to clinical-dermatological assessment criteria. For this purpose, all subjects are examined at the beginning and

end of the application period. The examination includes all symptoms of pathological skin changes or signs of intolerance caused by the test product used. Typical signs of intolerance are redness, itching, scaling, swelling and any other undesirable skin reaction, e.g. a feeling of tightness, change in colour or inflammation. The skin condition is assessed and analyzed for its significance for the area of application.

Table 1: Assessment of possible skin reactions

If skin reactions occurred, the type of the reaction was assessed clinically dermatologically and documented according to following scale:

–	no pathological findings
1	mild reaction
2	moderate reaction
3	severe reaction

5.3.2. Adverse reactions / FM-050

Adverse skin reactions that occur during the dermatological examination or during the application period are documented in the FM-050 Detection of Adverse Reactions: intensity, occurrence, duration and evaluation of the reaction by a dermatologist.

6. Results

6.1. Results of the epicutaneous test – evalution of the test and control area

Subject Nr.	Test area				Control area			
	24 h	48 h	72 h	Reaction type [all./irr.]	24 h	48 h	72 h	Reaction type [all./irr.]
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	

6.2. Results of the safety in-use test

6.2.1. Dermatological examination results

The examinations were carried out according to clinical-dermatological evaluation criteria. All test persons showed healthy skin in the test area before, during and after the safety in-use test. No pathological skin lesions were found in any form. No test interruption, even less treatment by a specialist in dermatology was performed in any case. The product named was very well tolerated, and it did not lead to dermatologically relevant skin changes in any subject.

Subject No.	Findings before	FIndings after	Type of reaction
1	–	–	
2	–	–	
3	–	–	
4	–	–	
5	–	–	
6	–	–	
7	–	–	
8	–	–	
9	–	–	
10	–	–	

If skin reactions occurred, the type of the reaction was assessed clinically dermatologically and documented according to following scale:

–	no pathological findings
1	mild reaction
2	moderate reaction
3	severe reaction

7. Assessment of the study results

7.1. Skin compatibility

None of the 30 subjects with sensitive skin 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).

From a clinical dermatological point of view, no relevant product-specific skin reactions occurred in the test areas during the application period. The test product Milk Safe & Clean Plastic-free Pure Wipes for Sensitive Skin was applied in a safety in-use test over a period of 1 week by 10 test subjects several times daily on the body, face, and diaper area.

Accordingly, from a dermatological point of view, there is no high irritation potential for the tested product Milk Safe & Clean Plastic-free Pure Wipes for Sensitive Skin when used as intended.

Dr. med. Werner Voss
Medical Specialist in Dermatology, Venereology, Allergology, Phlebology and Environmental Medicine

Signature

Dr. rer. nat. Imke Göllner
Biologist

Signature

Dr. rer. nat. Tanja Emmler
Biologist

Signature

8. Addendum

8.1. 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.

8.2. Certificates

- Skin tolerability

Sponsor

Flying Baby Sdn Bhd
A-05-08, Oasis Square, No 2, Jalan PJU, 1A/7A, Ara Damansara
47301 Petaling Jaya, Selangor
Malaysia

Muenster, 09.04.2025

Certificate

about the Cosmetic product

Milk Safe & Clean Plastic-free Pure Wipes for Sensitive Skin

Epicutaneous testing and clinical safety in-use test

under dermatological control

(Test period: March 2025)

Study number ST-ET-2025-00038 (Epi), ST-SENS-2025-00014 (AT)

The test product was evaluated for skin tolerability by means of an epicutaneous test on 30 test persons and a safety in-use test of 1 week on 10 test persons with sensitive skin under the control of dermatological specialists and according to international guidelines.

In both studies, there were no relevant skin reactions from a clinical-dermatological point of view when the product was applied.

The product was tolerated

„excellently"

Neither intolerance reactions in the form of irritation nor allergic reactions (contact dermatitis) were detected. Accordingly, from the dermatological point of view there is no high potential for irritation by the tested product when used as intended.

Based on the study design chosen and the confirmed skin tolerability, the **Sensitive Skin Seal can be used for the test product.**

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dermatest®
Dermatest® GmbH • dermatest.com
Nevinghoff 30 • 48147 Münster

Dr. med. Werner Voss

Medical Specialist in Dermatology, Venereology, Allergology, Phlebology and Environmental Medicine

Dermatest GmbH
Nevinghoff 30 | 48147 Münster
Germany
www.dermatest.com

Marcel Voss
CEO
Tel. +49 (0) 251 481637-0
info@dermatest.com

VR-Bank Westmünsterland eG
IBAN: DE34 4286 1387 7001 689200
Amtsgericht Münster HRB 1348
USt-ID: DE126040147