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Sponsor

Study number ST-AT-2024-00184

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Muenster, 4 November 2024

Expert report by dermatological specialist about a clinical-dermatological application study (Test period September/October 2024)

on 20 subjects with application (home in-use) of test product several times daily in the intimate area

over a period of four weeks

examination for dermal tolerability

Milk Baby Diapers for Sensitive Skin

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1 General information

Title

Clinical application study under dermatological control

Testing body

Dermatest GmbH
Nevinghoff 30
D-48147 Münster

Specialist in dermatology

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

Study coordinator

PhD Jens Klokkers
Biotechnologist

1.1 Synopsis

Table 1: Synopsis of the study

Study title	Clinical application study under dermatological control
Test product	**Milk Baby Diapers for Sensitive Skin**
Product type	diaper
Study design	Single-centre
Testing body	Dermatest GmbH Nevinghoff 30 D-48147 Münster
Expert report version and date	Version 1, 4 November 2024
Test period	September/October 2024
Primary study objectives	Assessment of skin tolerability Assessment of the sensitisation potential
Quantity of subjects	20
Application period	Four weeks (home in-use)
Test area	Intimate area
Frequency of application	Several times a day, as needed
Inclusion criteria	- Aged from 1 year up to 5 years - Female and male healthy volunteers - Skin type: sensitive - Written informed consent of the legal guardian is available
Exclusion criteria	- Severe or acute skin inflammations - Severe internal or acute diseases - Short-term and acute intake of medications that may interfere with skin reactions (glucocorticoids, anti-allergics, immunomodulators, etc.) - Application of prescription preparations and skin care products 7-10 days before the start of the test - Severe allergies or any serious side effects of cosmetic preparations ever occurred - Intensive sun baths or solarium visits during the study - Acute neoplastic disease

1.2 Schedule

Table 2: Schedule of the study

Study day	Day 0	Day 28
Information of the subjects	✔	
Informed Consent Form Sheet	✔	
Medical history	✔	
Dermatological examination	✔	✔
Compliance with the inclusion and exclusion criteria	✔	✔

1.3 Risk assessment

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 no prohibited ingredients as defined in cosmetics Regulation (EC) No 1223/2009 are not contained in the product as well as substances with a known increased allergenic or sensitizing or irritating potential when applied to the skin: No allergenic fragrances as listed in Annex III of Regulation (EC) 1223/2009, no p-Phenylenediamine and its salts, no azo dyes, no lanolin, no lanolin alcohol, no propolis cera (propolis wax), no colophonium, no rosin, no chamomilla ingredients, no sodium lauryl sulphate, no cetyl alcohol, no cetearyl alcohol, no formaldehyde (and formaldehyde releasers), no parabens, no isothiazolinones, no methyldibromoglutaronitrile and no benzophenone-3 shall be added in the test product.

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 analysis of the skin tolerability of products, application studies, so-called home-in-use tests, can be carried out. The product to be tested is applied over a prolonged period on the intended application area. Inclusion and exclusion criteria of the subjects are adapted to the target group as far as possible. Before each testing the risk of all ingredients of the test product are assessed. All available information are systematically analysed in order to identify potential hazards and to avert risks.

3 Study objective

The objective of this study was to precisely investigate the skin tolerability of the product **Milk Baby Diapers for Sensitive Skin** according to clinical-dermatological test criteria.

Before inclusion the dermatological integument of all subjects was investigated regarding health and integrity. In case of necessary medical treatment the subjects were excluded. Furthermore, 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. All 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 or with agreement of their legal guardians 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. According to the schedule, all dermatological examinations were done.

3.1 Primary outcomes

Assessment of skin tolerability and possible sensitisation potential

- Application study

3.2 Study parameters

Monocentric clinical trial over a period of four weeks in total.

4 Selection of subjects

The study was carried out with 9 female and 11 male subjects aged from 1 year up to 5 years according to the inclusion and exclusion criteria. All subjects were selected from the subject database or recruited by flyers, social networks and newspapers.

4.1 Information of the subjects

Before the study the parents were informed about the course of the study by the attending study nurse or the attending dermatologist. Participation in the study was voluntary. All parents could discontinue the study for their child at any time and without giving any reason as well as without any negative consequences for the subjects.

4.2 Inclusion criteria

- Aged from 1 year up to 5 years
- Female and male healthy volunteers
- Skin type: sensitive
- Written informed consent is present

The parents 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 skin inflammations
- Severe internal or acute diseases
- Short-term and acute intake of medications that may interfere with skin reactions (glucocorticoids, anti-allergics, immunomodulators, etc.)
- Application of prescription preparations and skin care products 7-10 days before the start of the test
- Severe allergies or any serious side effects of cosmetic preparations ever occurred
- Intensive sun baths or solarium visits during the study
- Acute neoplastic disease

4.4 Exclusion of subjects from the clinical-dermatological application study

The investigator could exclude a subject from the clinical-dermatological application study if any 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 happened, it was documented completely. Supervision of these and all subjects continues for reasonable time in order to control clinical condition and occurrence of adverse events.

4.5 List of subjects

Table 3: List of subjects

Subject №	Sex [f/m]	Age [years]
1	m	7 months
2	m	0 months
3	m	1
4	f	4 months
5	m	5 months
6	f	6 months
7	f	6 months
8	m	2 months
9	f	1
10	f	8 months
11	f	1
12	f	1
13	m	3 months
14	m	3 months
15	m	9 months
16	m	9 months
17	m	10 months
18	f	9 months
19	m	4 months
20	f	4 months

5 Test product

5.1 Application of the investigational product

Instructions for use: Please change your child's diapers as usual, as with the previously used product. The subjects were instructed not to use any equivalent product in the test area during the test period.

5.2 Interruptions / Discontinuation of the application

Application of the test product could be discontinued at any time by the subject or according to the decision of the investigator, if the clinical condition required so. Each discontinuation was documented completely. It was the responsibility of the investigator to assess, whether conditions for discontinuation were given.

6 Benefit-risk consideration and precautions

There was no known risk for use of the product. If a residual risk was recognised or if a change in acceptance of the product was evident, the sponsor was notified immediately.

If during the study 10 % or more of the test subjects experienced a product-related reaction, that was not acceptable for the corresponding product category, the study was terminated immediately and the sponsor was informed accordingly.

7 Methods

7.1 Dermatological examination

7.1.1 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 4: 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

7.1.2 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.

8 Results

8.1 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 application study. 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.

Table 5: Dermatological examination results

Subject №	Findings before	Findings after	Type of reaction
1	–	–	
2	–	–	
3	–	–	
4	–	–	
5	–	–	
6	–	–	
7	–	–	
8	–	–	
9	–	–	
10	–	–	
11	–	–	
12	–	–	
13	–	–	
14	–	–	
15	–	–	
16	–	–	
17	–	–	
18	–	–	
19	–	–	
20	–	–	

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

9 Assessment of the study results

9.1 Skin tolerability

The test product **Milk Baby Diapers for Sensitive Skin** was applied several a day onto the diaper area over a period of four weeks by 20 subjects. From the clinical-dermatological perspective no relevant skin reactions arose, the product was tolerated very well. Neither intolerance reactions in terms of skin irritation nor allergic reactions (contact dermatitis) were detected.

Accordingly, from the dermatological point of view, the tested product **Milk Baby Diapers for Sensitive Skin** exhibits no high potential for skin irritation and sensitisation, when used as intended.

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

Signature

PhD Jens Klokkers
Biotechnologist

Signature

10 Addendum

10.1 Quality control, quality assurance and data protection

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

The provisions of the applicable data privacy legislature were respected. All data of the subjects were handled confidentially and are disclosed to the sponsor only in a pseudonymised version. All data are stored for ten years.

10.2 Certificate

- Skin tolerability

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Muenster, 4 November 2024

Certificate

about the product

Milk Baby Diapers for Sensitive Skin

Clinical application study under dermatological control
(Test period September/October 2024)

Study number ST-AT-2024-00184

The test product was applied over a period of four weeks by 20 subjects several times daily on the diaper area. From the clinical-dermatological point of view no relevant skin reactions occurred in the test area. The product was tolerated

„excellently".

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

Based on the study design chosen and the confirmed skin tolerability, **the 5-star seal can be used** for the test product.

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