

ANALYSIS REPORT

Report Number : B26-000357
Purpose of Analysis : SPECIAL REQUEST
Place of the sample taken : YENİGÜN ORM. ÜR. VE KAĞ. SAN. TİC. LTD. ŞTİ
Address : H. SABANCI ORG. SAN. BÖLGESİ SANAYİ CADDE SARIÇAM ADANA
Kind of sample : DOLFY BABY DIAPER SIZE 3
Production Date/Expiration Date : 14.01.2026 - 14.01.2031
Sample of Description and Batch Num. : 14012026
Type of Sample : -
Sample Arrival Date / Time : 28.01.2026 / 14:01:36
Analysis Start and End Date : 03.03.2026 / 17.03.2026
Sample Quantity / Packaging Status : 40 Piece / ORIGINAL PACKAGING

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REPORT FROM DERMATOLOGICAL TEST

1. GENERAL INFORMATION

Date of report		23.03.2026
Report number / sample number		03/03/26/D/1
Information given by the Principal	Sample name	DOLFY BABY DIAPER SIZE 3
	Identification number given by Principal (series / production date / internal number)	PRODUCTION DATE: 14.01.2026 / EXPIRATION DATE: 14.01.2031 / SERIES NUMBER: 14012026
	Product type	Baby Diaper
	Product composition / INCI	Sodium polyacrylate , Bleached Pulp , Polypropylene , Polyethylene Films , Polyethylene terephthalate , Lycra , Glues.
	Principal / responsible person	Ayşegül Kurt İstanbul Deri OSB. Kumpas Cad. Süt Sk. 12. Yol L3-4C Parsel Tuzla/İstanbul
Beginning of research		03.03.2026
Completion of research		17.03.2026
Comments on sample state		None
Volunteers group		20 volunteers
Skin type		sensitive
Method additions / deviations / limitations		-
Comments		-

2. BASIS FOR RESEARCH IMPLEMENTATION

- Order form and test samples delivered by Principal
- Confirmation of microbiological purity / microbiological insensitivity

The Principal is responsible for compliance with the declared qualitative composition and microbiological purity of the samples submitted for testing.

3. PURPOSE OF RESEARCH

Product evaluation of skin tolerance in a group of volunteers in terms of potential irritating and allergenic properties.

4. SCOPE OF RESEARCH

4.1. LEGAL BASE OF RESEARCH

- 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 2227.
- Test procedure by SKINLAB P.S.A.: PB.01 Dermatological tests.

5. VOLUNTEERS SELECTION

5.1. INCLUSION CRITERIA IN ACCORDANCE WITH LEGAL STANDARDS

- Current European and Polish law.
- Cosmetics Europe- The Personal Care Association.
- Declaration of Helsinki (1964-2013).
- Test procedure by SKINLAB P.S.A.: PB.01 Dermatological tests.

5.2. EXCLUSION CRITERIA

- Use of antibiotics
- Pregnancy/breastfeeding
- Chemotherapy/radiotherapy
- Fever
- Infection (e.g. Cold)
- Use of anti-allergic drugs/ointments
- Skin with lesions
- Persons under 18 years of age

6. INFORMED CONSENT OF THE VOLUNTEERS

All volunteers selected for the study met the requirements for inclusion in the study and signed consent to voluntary participation in the study, and were informed about the purpose of the study, how it was conducted and about possible side effects. During the entire study, the volunteers were under the constant care of a dermatologist.

REPORT FROM DERMATOLOGICAL TEST

7. METHODS OF RESEARCH

The test was performed in accordance with the research procedure of SKINLAB P.S.A. (PB.01 Dermatological tests) under the supervision of a dermatologist. The test consisted in a single application of the product to a selected area of the skin, and then observing the condition of the skin at intervals. The recording of the results and the classification of the product are made on the basis of the assessment according to the ICDRG criteria and the point scale (0–4) of the skin reaction. Qualification, sample application and readings take place at SKINLAB P.S.A. in Cracow.

8. RESULTS

8.1. VOLUNTEERS IDENTIFICATION

8.1.1. READINGS FROM THE TEST - POINT CLASSIFICATION

VOLUNTEER IDENTIFICATION NUMBER	SEX F – female M – male	AGE	SKIN TYPE N – normal S – sensitive	RESULT	
				AFTER 48 h	
				Erythema	Swelling
1	F	51	S	0	0
2	F	22	S	0	0
3	F	37	S	0	0
4	F	51	S	0	0
5	F	43	S	0	0
6	F	53	S	0	0
7	F	22	S	0	0
8	F	47	S	0	0
9	F	30	S	0	0
10	F	23	S	0	0
11	F	24	S	0	0
12	F	23	S	0	0
13	F	46	S	0	0
14	F	22	S	0	0
15	F	63	S	0	0
16	F	42	S	0	0
17	F	48	S	0	0
18	F	19	S	0	0
19	F	25	S	0	0
20	F	65	S	0	0

REPORT FROM DERMATOLOGICAL TEST

8.2. IRRITATION INDEX

The mean irritation index is calculated from the sum of the scores for erythema and swelling. Based on the irritation index, the product is classified according to the scale.

MEAN IRRITATION INDEX (x_{MSII})	PRODUCT CLASSIFICATION
$x_{MSII} < 0,5$	non-irritating
$0,5 < x_{MSII} < 2,0$	slightly irritating
$2,0 < x_{MSII} < 5,0$	moderately irritating
$5,0 \leq x_{MSII}$	strongly irritating

On the basis of the results presented in Table 8.1.1., the irritation index for the product under test was calculated, with a mean value of $x_{MSII} = 0$,

where $x_{MSII} = \frac{\text{sum of the scores}}{\text{volunteers number}}$

9. CONCLUSIONS / OPINIONS AND INTERPRETATIONS

The conclusions include opinions and interpretations, as well as statements of conformity

A dermatological study conducted on volunteers who were not allergic to any of the ingredients of the tested product "DOLFY BABY DIAPER SIZE 3" confirms that the tested product is **WELL TOLERATED BY THE SKIN**, as it did not show any irritating or allergenic properties. The product can be classified as **NON-IRRITATING**.

The study authorizes the responsible person to place the logo of the SKINLAB P.S.A. specialist research laboratory on the label of the product "DOLFY BABY DIAPER SIZE 3" and to use the following statement: "Dermatologically tested by the independent research and consulting laboratory SKINLAB P.S.A."

10. RESULTS AUTHORIZATION

Doctor of medicine Specialist in dermatology and venereology (medical supervisor)	Dr. BARBARA WNUK Medical License Number (Poland – PWZ): 5562935
Report prepared by	Aleksandra Dutka R&D Coordinator
Report authorized by (electronic signature)	Olga Gruca Junior Cosmetics Implementation Specialist

The results relate exclusively to the tested samples

----- END OF THE REPORT -----