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REPORT FROM DERMATOLOGICAL RESEARCH

A SEMI-OPEN EXTENDED TEST

No. B – 88246/21429/24

Sensitive Cleanser – Hypoallergenic

submitted by

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HUNGARY

1.	Basis for conducting the research	<ul style="list-style-type: none"> • Order of 02.04.2024 registered as No. B – 88246/21429/24. • Test material: samples provided by the Customer in commercial packaging • Qualitative composition of the product supplied by the Client: Ethanol, Isopropyl Alcohol <div style="border: 1px solid black; background-color: #e0e0e0; padding: 5px; text-align: center;"> <p>The Client is responsible for consistence of the samples sent for the research with the declared qualitative composition.</p> </div>
2.	Characteristics of the product	<p>Sample for the laboratory test: Appearance: homogeneous, clear liquid. Color: colorless. Fragrance: characteristic of the raw materials used. Package: commercial - a bottle with a label that provides: product name, description, composition, customer's name and address, capacity 500 ml, shelf life after opening 12M, marking: 0052022.</p>
3.	Declared product's usage	<p>The product is used for paint nails.</p>
4.	Scope of the research consistent with	<ol style="list-style-type: none"> 1. Regulation of the European Parliament and Council Regulation (EC) No. 1223/2009 of 30 November 2009. relating to cosmetic products 2. Cosmetics Europe – The Personal Care Association (formerly COLIPA) Guidelines „Product test Guidelines for the Assessment of Human Skin Compatibility 1997”
5.	Aim of the research	<p>The assessment of local skin tolerance to the product with a healthy, adult volunteer through a single application of a patch test and reading of skin reaction after 24, 48 hours and in the case of positive skin reactions - also after 72 hours.</p>
6.	Selection of volunteers for the research	<p>The tests are conducted in accordance with the Research Procedure 07/ DA [REDACTED], ed. 1 of on 20.03.2005, by a dermatologist on the group of 40 volunteers by a contact test – a semi-open extended test.</p> <p><i>The selection of volunteers is made in accordance with the Test Procedure 01/DA, ed. 2 of on 12.02.2013, by the dermatologist with regard to the Helsinki Declaration</i></p>

of 1964 (with later amendments), [REDACTED] and EU laws, guidelines of the Cosmetics Europe – The Personal Care Association (former COLIPA).

The selection of the panelists takes into account the inclusion and exclusion criteria.

40 people were selected for the tests (36 women and 4 men) Caucasian, healthy, among them:

- ◆ with atopic case history – 24 people
- ◆ with documented contact allergy – 21 people
- ◆ with non-documented allergy (from case history) – 40 people
- ◆ with skin hypersensitivity to cosmetics, household chemicals and detergents – 40 people

In this group:

- none of the persons was proven to be hypersensitive and none reported during an interview any adverse reactions to particular ingredients of the tested product,
- all persons reported during an interview the occurrence of different types of adverse reactions of skin to some of the applied cosmetics and washing products (persons with known positive history of allergy and atopy),
- all persons met the requirements concerning inclusion into the research,
- all persons signed the consent to conscious participation in the research and were informed about the aim of the research, the way of conducting the research and the potential undesirable effects.

Skin in the test application area (inner arms or back) was normal, with no morbid symptoms.

The participants were not given any special requirements, with the assumption that this kind of product should be tested in normal conditions, in which it will be used in practice. However, it should be noted, that in special cases the results of the research can be influenced by such factors as: nutrition diet, individual preferences, lifestyle, kind of work one performs, stress and environmental conditions etc.

7.	<p>The procedure of conducting the research</p>	<p>The tested product was applied in commercial form in amount of 0,1ml on tissue paper pads (Whatmann 3) which were fastened to the skin with porous hypoallergenic (surgical) adhesive tape on the inner arms or back. The samples were removed after 48 h. The first reading was made 15 min after removing the samples, the second after 72 h from applying the test and in the case of positive skin reactions - also after 96 hours from the application of the test.</p> <p>The assessments of reactions were made according to the scale, which is consistent with the generally accepted scale in dermatological tests.</p> <p>Characteristics of the volunteers and results of the tests were shown in the table No.1.</p>
8.	<p>Duration of the research</p>	<p>The tests were performed from 02.04.2024 until 05.04.2024.</p>

RESULTS OF DERMATOLOGICAL RESEARCH

In the tested group of 40 people, including 40 with positive allergic case history ***no positive reactions were found, what proves, that the tested product does not reveal irritating or sensitizing properties.***

Test results were presented in the table No. 1.

Table No. 1

No. of the volunteer	Age	Gender	Type of skin	A history of atopy / allergies	Test result after 48h	Test result after 72h
1	45	W	N	IN	(-)	(-)
2	39	W	N	IN	(-)	(-)
3	25	W	N	IN	(-)	(-)
4	39	W	N	AC, IN	(-)	(-)
5	59	W	D	AT, IN	(-)	(-)
6	65	W	D	AT, IN	(-)	(-)
7	65	M	D	AT, AC, IN	(-)	(-)
8	59	W	D	AC, IN	(-)	(-)
9	56	M	D	AC, IN	(-)	(-)
10	23	W	D	AT, AC, IN	(-)	(-)
11	28	W	N	AC, IN	(-)	(-)
12	65	W	D	AT, AC, IN	(-)	(-)
13	57	W	D	AT, IN	(-)	(-)
14	65	W	D	AT, IN	(-)	(-)
15	51	W	N	AT, AC, IN	(-)	(-)
16	65	W	D	AC, IN	(-)	(-)
17	45	M	N	IN	(-)	(-)
18	65	W	D	AT, AC, IN	(-)	(-)
19	65	W	D	AT, AC, IN	(-)	(-)
20	65	W	D	AC, IN	(-)	(-)
21	40	W	N	AT, AC, IN	(-)	(-)
22	40	W	N	AT, AC, IN	(-)	(-)
23	52	W	N	AT, AC, IN	(-)	(-)
24	54	W	N	AT, AC, IN	(-)	(-)
25	65	W	D	AT, AC, IN	(-)	(-)
26	26	W	D	AT, AC, IN	(-)	(-)
27	29	W	N	AT, IN	(-)	(-)
28	47	W	D	AT, AC, IN	(-)	(-)
29	64	W	D	AT, IN	(-)	(-)
30	41	W	D	AT, AC, IN	(-)	(-)
31	59	W	D	AT, IN	(-)	(-)
32	65	W	D	AT, IN	(-)	(-)
33	52	W	N	AT, AC, IN	(-)	(-)
34	36	W	N	IN	(-)	(-)
35	65	W	D	AT, IN	(-)	(-)
36	28	W	N	IN	(-)	(-)
37	64	M	N	IN	(-)	(-)
38	57	W	N	IN	(-)	(-)
39	65	W	D	IN	(-)	(-)
40	44	W	N	AC, IN	(-)	(-)

Evaluation of the skin condition made by a dermatologist

- 0 or (-) - no reaction.
- 1 or (+ / -) - faint erythema
- 2, or (+) - erythema
- 3, or (++) - erythema, papules
- 4 or (+++) - erythema, edema weak
- 5 or (++++) - erythema. infiltration and blisters

Gender:

W – woman
M – man

Type of body skin:

N – normal, D – dry, M – mixed, S – normal with tendency to oiling in the seborrhoeic region of the trunk

A history of atopy / allergies:

AT – atopy, AC – documented contact allergy or allergic reactions,
IN – non-documented allergic reactions and intolerance to cosmetics and household chemicals

OPINIONS AND INTERPRETATIONS


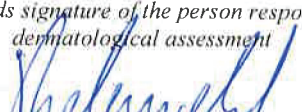

On the basis of results of the performed semi-open patch tests we state, that the dermatologically tested

Sensitive Cleanser – Hypoallergenic

meets the requirements of the compliance test and atopic skin especially sensitive, readily irritation (Skin Compatibility Test) and meets the requirements of the cosmetic qualities to the declared properties so-called hypoallergenic.

CAUTION: The issued evaluation does not refer to people who are allergic to any of the ingredients of the evaluated product.

The test results refer only to the tested sample.


<p>Surname and signature of the person preparing</p> 	<p>Surname and signature of the person responsible for dermatological assessment</p>  
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