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REPORT FROM DERMATOLOGICAL RESEARCH

A SEMI-OPEN PATCH TEST

No. B – 01011/18077/21

Aseptica kéz- és felületfertőtlenítő szer

submitted by

Bio-Cleaner Kft. 2310 Szigetszentmiklós, Üdülő köz 37. Hungary

1.	**Basis for conducting the research**	• Order of registered as 18.12.2021 No. B – 01011/18077/21. • Material for tests: samples supplied by the Client. • Qualitative composition of the product according to INCI nomenclature sent by the Client. *Ingredients: Isopropyl alcohol, aqua, sodium lauryl ether sulfate, potassium hydroxide, Glycerin, Benzalkonium chloride, parfum* The Client is responsible for consistence of the samples sent for the research with the declared qualitative composition and microbiological purity.
2.	**Characteristics of the product**	**Sample for the test:** **Appearance:** homogenous, dense, transparent liquid. **Fragrance:** from ingredient, intensive. **Packaging:** commercial – plastic bottle, with the label giving the name of the product, the name and the address of Manufactured, capacity – 250ml, designation: 2020 okt. 12.
3.	**Declared product's usage**	The product is used for hand skin care.
4.	**Scope of the research consistent with**	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**	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.
6.	**Selection of volunteers for the research**	**The tests are conducted in accordance with the Research Procedure 06/ DA ITA – TEST, ed. 1 of on 20.03.2005, by a dermatologist on the group of 20 volunteers (a semi-open patch test method).**

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 of 1964 (with later amendments), Polish 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.

20 healthy people of Caucasian type (19 women, 1 man) were selected for the research in this 12 people with known positive medical history of allergy.
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.	**The procedure of conducting the research**	**The tested product** was applied **in commercial form in amount of 0,1ml** *on tissue paper pads (Whatmann 3)*, which were secured with porous hypoallergenic (surgical) adhesive tape to the inner arms or back. The samples were removed after 24h. The first reading was made 15 min after removing the samples, the second after 48 h from applying the test and in the case of positive skin reactions - also after 72 hours from the application of the test. The assessments of reactions were made according to the scale, which is consistent with the generally accepted scale in dermatological tests. Characteristics of the volunteers and results of the tests were shown in the table No.1.
8.	**Duration of the research**	The tests were performed **from 26.01.2021 until 28.01.2021.**

RESULTS OF DERMATOLOGICAL RESEARCH

In the tested group of 20 people, including 12 with positive allergic case history ***no positive reactions were found, what proves, that the tested product does not reveal irritating or sensitizing properties.***

Results of the research are presented in the Table No. 1.

Table No. 1

No. of the volunteer	*Age*	*Gender*	*Type of skin*	*Test result after 24h*	*Test result after 48h*
1	*46*	*W*	*D*	*(-)*	*(-)*
2	*35*	*W*	*D*	*(-)*	*(-)*
3	*60*	*W*	*D*	*(-)*	*(-)*
4	*48*	*W*	*D*	*(-)*	*(-)*
5	*59*	*W*	*D*	*(-)*	*(-)*
6	*51*	*W*	*D*	*(-)*	*(-)*
7	*43*	*W*	*D*	*(-)*	*(-)*
8	*35*	*W*	*N*	*(-)*	*(-)*
9	*58*	*W*	*D*	*(-)*	*(-)*
10	*50*	*W*	*D*	*(-)*	*(-)*
11	*27*	*W*	*N*	*(-)*	*(-)*
12	*42*	*W*	*N*	*(-)*	*(-)*
13	*42*	*W*	*D*	*(-)*	*(-)*
14	*40*	*W*	*D*	*(-)*	*(-)*
15	*55*	*W*	*D*	*(-)*	*(-)*
16	*50*	*W*	*D*	*(-)*	*(-)*
17	*58*	*W*	*D*	*(-)*	*(-)*
18	*53*	*M*	*D*	*(-)*	*(-)*
19	*54*	*W*	*D*	*(-)*	*(-)*
20	*53*	*W*	*D*	*(-)*	*(-)*

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, **S** –seborrhea, **M** - mixed

OPINIONS AND INTERPRETATIONS

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

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meets the requirements of compatibility with skin (Skin Compatibility Test).

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

Surname and signature of the person preparing the report

Specjalistyczne Laboratorium Badawcze
ita-test
Marta OLKOWSKA
Kosmetolog

Surname and signature of the person responsible for dermatological assessment

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