ita-test laboratorium

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Warsaw, 15.05.2020

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REPORT FROM DERMATOLOGICAL RESEARCH

A SEMI-OPEN PATCH TEST

No. B 71554/17126/20

Immunetec Antimicrobial hand and skin care

submitted by

Immunetec Proof Kft.

5008 Szolnok, Krúdy Gyula utca 112.

Hungary

1.	**Basis for conducting the research**	• Order of 11.05.2020 registered as No. B – 71554/17126/20. • Material for tests: samples supplied by the Client in a substitute packaging. • Qualitative composition of the product according to INCI nomenclature : *INCI: AQUA, STEARIC ACID, GLYCERIN, SODIUM BENTONITE, PHEOXYETHANOL, ACRYLATE COPOLYMER, TRIETANOLAMINE, CAPRYTYL GLYCOL, (TITANIUM DIOXIDE + SILVER CHLORIDE 0,3%)* • Negative microbiological tests results sent by the Client. 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 laboratory test:** **Appearance:** homogeneous, shiny emulsion. **Fragrance:** faint. **Package:** commercial - plastic tube, with a label giving name of the product, name of the Client, INCI composition, the usefulness after opening - 12 months, designation: 20467 04 2022, method of use.
3.	**Declared product's usage**	The product is used for hand and 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 48, 72 hours and in the case of positive skin reactions - also after 96 hours.
6.	**Selection of volunteers for the research**	**The tests are carried out in accordance with the Test Procedure 07/ DA ITA – TEST, ed. I of on 20.03.2005, by a dermatologist in the group of 20 volunteers by a contact test – a semi-open test.**

The selection of volunteers is made in accordance with the Test Procedure 01/DA, ed. II 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 (18 women and 2 men) were selected for the research in this 11 people with known positive medical history of allergy.

In this group:

- None of the people was proved to be hypersensitive and none reported in the interview any adverse reactions to particular ingredients of the tested product.
- All people reported in the interview the occurrence of different types of adverse reactions of skin to some of the applied cosmetics and washing products (people with positive case history towards allergy and/or atopy).
- All people met the criteria concerning inclusion into the tests,
- All people signed the consent to conscious participation in the test, and were informed about the aim of the test, the way of conducting the test and the potential undesirable effects.

Skin in the test application area (inner arms and back) was normal, with no pathological changes.

The participants of the tests 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 test can be influenced by such factors as: nutrition diet, individual predilections, 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 0,1g** *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 48h. 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. 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 12.05.2020 until 15.05.2020.**

RESULTS OF DERMATOLOGICAL RESEARCH

In the group of tested 20 people in this 11 people with positive medical history of allergy had no allergic reaction, which proves, that the product does not reveal any irritating or sensitizing properties.

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

Table No. 1

No. of the volunteer	*Age*	*Sex*	*Type of skin*	*Test result after 48h*	*Test result after 72h*
1	*49*	*W*	*D*	(-)	(-)
2	*41*	*W*	*N*	(-)	(-)
3	*53*	*W*	*D*	(-)	(-)
4	*35*	*W*	*N*	(-)	(-)
5	*43*	*W*	*D*	(-)	(-)
6	*34*	*M*	*N*	(-)	(-)
7	*25*	*W*	*N*	(-)	(-)
8	*41*	*W*	*D*	(-)	(-)
9	*26*	*W*	*D*	(-)	(-)
10	*53*	*W*	*N*	(-)	(-)
11	*42*	*W*	*D*	(-)	(-)
12	*42*	*W*	*D*	(-)	(-)
13	*25*	*W*	*N*	(-)	(-)
14	*28*	*W*	*N*	(-)	(-)
15	*23*	*W*	*N*	(-)	(-)
16	*36*	*W*	*N*	(-)	(-)
17	*48*	*W*	*D*	(-)	(-)
18	*25*	*W*	*N*	(-)	(-)
19	*40*	*W*	*D*	(-)	(-)
20	*60*	*M*	*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

Sex:
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.

The test results refer only to the tested sample.

Surname and signature of the person preparing the test report	*Surname ads signature of the person responsible for dermatological assessment*
	Dr n. med. PAWEŁ REBANDEL SPECJALISTA ALERGOLOG DERMATOLOG I WENEROLOG tel. (22) 836-42-12 6170611

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