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### REPORT FROM DERMATOLOGICAL RESEARCH

# A SEMI-OPEN EXTENDED TEST No. B 87494/21257/24

Sensitive Top Gel - Hypoallergenic

submitted by

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1.	Basis for conducting the research	<ul> <li>Order of 19.01.2024 registered as No. B – 87494/21257/24.</li> <li>Material for tests: samples supplied by the Client in a commercial packaging.</li> <li>Qualitative composition of the product according to INCI enclosed by the Client.</li> <li>Ingredients: UV Oligomer, Hema, Hydroxypropyl methacrylate, Hydroxycyclohexyl Phenyl Ketone, Trimethylbenzoyl Diphenylphosphine oxide</li> <li>The Client is responsible for consistence of the samples sent for the research with the declared qualitative composition.</li> </ul>				
2.	Characteristics of the product	Sample for the laboratory test:  Appearance: homogeneous, dense, clear liquid.  Color: colorless.  Fragrance: intensive.  Package: commercial - glass bottle with a brush-shaped applicator, with a label giving the name of the product, description, name and address of the Customer, shelf life after opening 6M, capacity 10 ml, marking 39JOK - 230 513				
3.	Declared product's usage	The product is used for painting nails.				
4.	Scope of the research consistent with	<ol> <li>Regulation of the European Parliament and Council Regulation (EC) No. 1223/2009 of 30 November 2009. relating to cosmetic products.</li> <li>Cosmetics Europe – The Personal Care Association (formerly COLIPA) Guidelines ,, Product test Guidelines for the Assessment of Human Skin Compatibility 1997".</li> </ol>				
5.	Aim of the research	The assessment of local skin tolerance to the product with a healthy, adult voluntees through a single application of a patch test and reading of skin reaction after 48, 7 hours and in the case of positive skin reactions - also after 96 hours.				
6.		The tests are conducted in accordance with the Research Procedure 07/ DA 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.				

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), 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.

# Selection of volunteers for the research

**40 people** were selected for the tests (35 women and 5 men) Caucasian, healthy, among them:

- ♦ with atopic case history 19 people
- ♦ with documented contact allergy 26 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.

		The tested product was applied in commercial form in amount of 0,1ml on		
7.	The procedure of conducting the research	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.		
		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 23.01.2024 until 26.01.2024.		

# 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.

Results of the research are 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	62	W	D	AT, AC, IN	(-)	(-)
2	36	W	N	AC, IN	(-)	(-)
3	29	W	N	AC, IN	(-)	(-)
4	65	W	D	AT, AC, IN	(-)	(-)
5	46	W	D	AT, AC, IN	(-)	(-)
6	63	W	D	AC, IN	(-)	(-)
7	65	W	D	IN	(-)	(-)
8	26	W	D	AT, AC, IN	(-)	(-)
9	65	M	N	IN	(-)	(-)
10	65	M	N	AT, IN	(-)	(-)
11	65	W	D	AT, AC, IN	(-)	(-)
12	59	W	D	AC, IN	(-)	(-)
13	55	M	D	AC, IN	(-)	(-)
14	52	W	N	AT, AC, IN	(-)	(-)
15	64	W	N	IN	(-)	(-)
16	41	W	D	AT, AC, IN	(-)	(-)
17	53	W	D	AT, AC, IN	(-)	(-)
18	43	W	N	AT, AC, IN	(-)	(-)
19	56	W	N	AC, IN	(-)	(-)
20	63	W	D	AT, AC, IN	(-)	(-)
21	65	W	N	IN	(-)	(-)
22	23	W	N	AT, AC, IN	(-)	(-)
23	43	W	N	IN	(-)	(-)
24	27	W	N	IN	(-)	(-)
25	50	W	D	AC, IN	(-)	(-)
26	65	W	D	AT, AC, IN	(-)	(-)
27	65	W	D	AT, AC, IN	(-)	(-)
28	59	W	N	AT, AC, IN	(-)	(-)
29	65	W	D	AT, AC, IN	(-)	(-)
30	39	W	N	IN	(-)	(-)
31	56	W	N	IN	(-)	(-)
32	56	W	N	AC, IN	(-)	(-)
33	60	W	N	AC, IN	(-)	(-)
34	65	W	N	AT, IN	(-)	(-)
		M	N	AT, IN	(-)	(-)
35	65					
36	44	M	N	AC, IN	(-)	(-)
37	24	W	N	IN	(-)	(-)
38	34	W	N	IN	(-)	(-)
39	28	W	N	IN	(-)	(-)
40	43	W	D	AT, 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 (++++) - ervthema, infiltration and blisters

Gender: W – woman M – man Type of body skir:

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 - atophy, AC - documented contact allergy or

allergic reactions,

IN – non-documented allergic reactions and intolerance to cosmetics and household chemicals

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#### OPINIONS AND INTERPRETATIONS

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

## Sensitive Top Gel - 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.

Surname and signature of the person preparing the test report Surname ads signature of the person responsible for dermatplogical assessment

Normal

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