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Warsaw, 26.04.2016

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REPORT FROM DERMATOLOGICAL RESEARCH

A SEMI-OPEN PATCH TEST

No. B – 48814/11345/16/S

DISPOSABLE TOOTHBRUSH WITH A PORTION OF TOOTHPASTE

submitted by

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1.	**Basis for conducting the research**	• Order of 07.04.2016 registered as No. B 48814/11345/16/S. • Material for tests: samples supplied by the Client in a commercial packaging. • Qualitative composition of the product according to INCI nomenclature /Appendix No. 1/. • Negative microbiological tests results done in "ITA – TEST" Laboratory. The Client is responsible for consistence of the samples sent for the research with the declared qualitative composition.
2.	**Characteristics of the product**	**Sample for the laboratory test:** **Appearance:** disposable plastic toothbrush with a portion of green toothpaste. **Fragrance:** pleasant. **Package:** commercial - a plastic bag with a overprint giving the name of the product, the name and the address of Client, date of suitability for use – 04/2017
3.	**Declared product's usage**	The product is used to teeth 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**	Evaluation of local skin tolerance of a cosmetic product with healthy, adult volunteers through single application of a patch test and reading of skin reaction after 72 hours.
6.	**Selection of volunteers for the research**	**The tests are conducted in accordance with the Research Procedure 07/ DA ITA-TEST by a dermatologist on the group of 20 volunteers (a semi-open patch test method).** ***The selection of volunteers was made in accordance with the Research Procedure 01/DA ITA-TEST by the dermatologist with regard to the Helsinki Declaration of 1964 (with later amendments), Polish laws, EU laws, and COLIPA regulations. The selection of panelists takes into consideration the criteria of inclusion and exclusion from the research.*** **20 healthy persons** of Caucasian type (20 women) were selected for the research in this 14 persons 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 cut parts of toothbrush (area with toothpaste) 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 directly after removing the sample, the next after 72h from application of the test. The evaluations of reactions were made according to the scale, which is consistent with the generally accepted scale in dermatological research. Characteristics of the volunteers and results of the research are presented in the table No.1.
8.	**Duration of the research**	The tests were performed **from 19.04.2016 until 22.04.2016.**

Corrected report from dermatological research No. B – 48814/11345/16/S

RESULTS OF DERMATOLOGICAL RESEARCH

In the group of tested 20 persons in this 14 persons 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*	*Result of research*
1	26	W	D	(-)
2	40	W	D	(-)
3	51	W	D	(-)
4	50	W	D	(-)
5	52	W	N	(-)
6	59	W	D	(-)
7	34	W	D	(-)
8	33	W	D	(-)
9	59	W	N	(-)
10	44	W	N	(-)
11	37	W	N	(-)
12	33	W	N	(-)
13	26	W	D	(-)
14	30	W	N	(-)
15	51	W	D	(-)
16	34	W	D	(-)
17	36	W	N	(-)
18	51	W	D	(-)
19	57	W	D	(-)
20	26	W	D	(-)

Evaluation of the skin condition made by a dermatologist

0 or (-) - no reaction, 1 or (+ / -) – weak, short-lived itch,

2 or (+) - weak itch and local weak erythema,

3 or (++) – itch and local erythema,

4 or (+++) – itch, extensive erythema and papules.

Sex:
W– woman
M - man

Type of body skin:
N – normal, **D** –dry, **S** –seborrhea, **M** - mixed

Corrected report from dermatological research No. B – 48814/11345/16/S

OPINIONS AND INTERPRETATIONS

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

DISPOSABLE TOOTHBRUSH WITH A PORTION OF TOOTHPASTE

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.

Name and address of the person responsible for dermatological evaluation

Dr n. med.
Hanna Rywik
specjalista dermatolog

Dermatologist, M.D.

Attachments:

1- Qualitative composition of the product enclosed by the Client /Appendix No. 1/

The report distribution:

Copy 1, 2: The Client

Copy 3 ITA-TEST a/a (B-48814/11345/16/S)

INCI: Aqua(Water), Sorbitol, Glycerin, Hydrated Silica, Propylene Glycol, Salvia Officinalis (Sage) Extract, Sodium lauryl Sulfate, Cellulose Gum, Aroma (Flavor), Limonene, Panthenol, Sodium Fluoride, Sodium Saccharin, Titanium Dioxide, Sodium Benzoate, CI42090, CI19140,

Specialized Testing Laboratory
ita-test
B- 48814/11345/116/S
Appendix No 4