DR KOZIEJ
IN VIVO TESTING

THE REPORT FROM DERMATOLOGICAL RESEARCH OF COSMETIC PRODUCT
No. Z-12006 / ZBP-20696

Based on BST Z-10598/ ZBP-13000

Product	**BİYBA NATURA TÜY İNCELTİCİ SERUM/ BİYBA NATURA HAIR THINNING SERUM**
Responsible person	Biyba Natura Kozmetik Ürünleri San.Ve Tic. Ltd.Şti.
Address	Atıfbey Mahallesi 67.Sokak No:33 İç Kapı No:34 Gaziemir/İZMİR
Research time frame	07.02.2023-17.02.2023

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1. SUBJECT OF THE STUDY

INCI and Product characteristic

Ingredients	Aqua,Glycerin, Propylene Glycol, Narcissus TazettaBulb Extract, PEG-40 Hydrogenated Castor Oil, Phenoxyethanol, Parfum, Chamomilla Recutita Flower Extract, Hamamelis Virginiana Leaf Extract, Sodium Benzoate, Potassium Sorbate, Humulus Lupulus Extract,Trifolium Pratense Extract, Xanthan Gum, Panthenol, Citric Acid, Tetrasodium Edta, Rosmarinus Officinalis Leaf Oil, Ethylhexylglycerin
Appearance	Colourlesssolution
Product purpose	Scalpcare

The Responsible Person is responsible for conformity with the declared qualitative and quantitative composition and microbiological purity of the delivered samples. The Responsible Person confirms that the product is compliant with the law as at the date of the order.

2. THE AIM OF STUDY

The study conducted in order to determine local skin tolerance of the product in a group of healthy subjects to establish possible irritant and/or sensitizing properties of the product.

3. METHODOLOGY

The study was conducted in accordance with Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetics.
The study was conducted in accordance with recommendation of Cosmetics Europe – The Personal Care Association Guidelines.

- Product Test Guidelines for the Assessment of Human Skin Compatibility 1997,
- Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008.

The tests were carried out in accordance with the internal procedure of Dr Koziej Sp. z o. o. Sp. k.-Patch tests according to Jadassohn-Bloch with Rudzki modifications were conducted under careful supervise of medical specialist – dermatologist. The assessment of the allergenic and irritant features was made on a group of healthy subjects with sensitive skin, without allergy to any of the formulation ingredients. The subjects obliged to following all the guildelines included in the procedures of particular carefulness during the study. The patch tests were assessed after 48 and 72 hours.
Examination was performed with the semi open patch test using Finn Chamber patches.

4. SUBJECTS

The selection of subjects was conducted by a dermatologist according to the Declaration of Helsinki of 1964 (with subsequent amendments), Polish laws, Cosmetics Europe directives with applying inclusion and exclusion criteria.
All the subjects were familiar with the procedure of the study and signed conscious consent to take part in the study. The application of the patch tests was preceded by a health survey including information on the present and former illnesses, the survey on coexisting skin problems (allergy issues included) and dermatology examination assessing, above the others, the type of skin and presence of any pathological changes on the skin. The skin, where the patch tests were applied, was healthy, free of skin lesions.
The subjects were informed not to expose their skin to UV radiation or to take any anti-histamine or other pharmaceutical drugs (both systemic and local) which could come into interference with the applied product and have any influence on the results of the study.

5. EVALUATION PARAMETERS

Evaluation scale		
Classification	**Description**	**Interpretation**
-	No skin changes	Negative
?+	Faint, non-palpaple erythema	Doubtful reaction
+	Palpable erythema	Weak reaction
++	Strong erythema, papules	Strong reaction
+++	Strong erythema, papules, vesicles or/and ulceration	Extreme reaction
IR	Inflammation sharply limited to the exposed area, lack of infiltrate, small petechiae, pustules and lesions other than papules and vesicles	Irritant reaction, this kind of reactions may cause many problems upon interpretation

6. RESULTS

Subjects characteristic				Results after 48h	Results after 72h
No.	**Sex**	**Age**	**Skin type**	**Skin reaction**	**Skin reaction**
1	W	20	N	-	-
2	W	24	C	-	-
3	W	28	N	-	-
4	W	31	N	-	-
5	M	31	N	-	-
6	M	34	C	-	-
7	M	34	N	-	-
8	W	35	C	-	-
9	W	35	C	-	-
10	W	36	D	-	-
11	W	37	C	-	-
12	M	38	N	-	-
13	W	38	C	-	-
14	W	39	N	-	-
15	W	42	C	-	-
16	W	45	C	-	-
17	W	48	C	-	-
18	W	49	C	-	-
19	W	52	C	-	-
20	M	54	N	-	-

S – sensitive, A – positive allergic screening.
N – normal, D – dry, C – combination, O – oily W – woman, M – man

In 20 subjects, the results of patch tests were **negative**, which means that the product does not cause irritation or allergy reaction in those subjects.

7. CONCLUSION

1. Having carried out the patch tests on the chosen population, it has been determined that the product should not cause any irritating effect.
2. The results of the study apply only to the individuals not allergic to any ingredient in the product.
3. The product meets the requirements of the skin tolerance test and may be estimated as **non-irritant**.
4. The product meets the requirements of the cosmetics products with declared human health safety properties.
5. Issued opinion does not include the ingredient analysis of the product.

8. STUDY INVESTIGATORS

MD, PhD Anna Erkiert-Polguj
Dermatologist

The persons preparing and authorising the report

Olga Berlińska

Signature Not Verified

Dokument podpisany przez
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