

Attachment No. F/12403/05 to the Test report

Product name: Biyba Nemlendiricili Duş Jeli
Sample number: 12403/05/23
Test type: Dermatological (patch test) – sensitive skin
Date of test start: 15.05.2023
Date of test end: 19.05.2023

Purpose of the study

Assessment of irritation / allergenic effect of the product.

Microbial purity testing

The microbiological purity tests carried out in GBA POLSKA Laboratory / delivered by the Customer.

Product characteristics

Appearance: Gelled solution
Color: Transparent
Fragrance: Perceptible smell of fragrance composition
Product purpose: Cleansing and skin care
How to use: No data
Packaging: Replacement

Qualitative product composition

INCI composition (*): AQUA, COCAMIDOPROPYL BETAINE, AMONIUM LAURYL SULPHATE , PEG-120 METHYL GLUCOSE DIOLEATE, PARFUM, GLYCERIN, PEG-40 HYDROGENATED CASTOR OIL, SODIUM HYALURONATE, CALENDULA OFFICINALIS FLOWER EXTRACT, CHAMOMILLA RECUTITA FLOWER EXTRACT, SACCHARIDE ISOMERATE, SODIUM PCA , POLYQUATERNIUM-7, PHENOXYETHANOL, SODIUM CITRATE, POTASSIUM SORBATE, SODIUM BENZOATE, CITRIC ACID, LINALOOL.

(*) - The Customer bears full responsibility for compliance of samples delivered for testing with the declared qualitative composition. The Laboratory does not analyse the composition in regard to the current regulatory requirements.

The scope of tests in accordance with:

- » Regulation of the European Parliament and of the Council (WE) No. 1223/2009 dated 30.11.2009 regarding cosmetic products
- » COLIPA Guidelines
- » „Product test Guidelines for the Assessment of Human Skin Compatibility 1997”
- » „Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008”
- » Memorandum on use of Human Data in risk assessment of skin sensitisation – SCCS/1567/15
- » The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 11th Revision – SCCS/1628/21 Final version

Testing methodology

The study was conducted in accordance with the Research Procedure PB-8/LK.

The tested substance is applied to the skin using special chambers fixed on a hypoallergenic adhesive (chambers IQ Ultimate®). The chambers are filled with the substances being tested, and then affixed to the skin of the back in the shoulder blade area. During the tests one cannot soak his/her back and should avoid sudden movements and sweating. Patches with test substances are left on the test skin for 48 hours.

After removal of the adhesives with the chambers, the excess of test substances is removed by pressing a paper towel onto the skin. The skin reaction is assessed after 15 minutes after removing the adhesives (after 48 hours) and after 72 hours according to a scale that is consistent with the scale generally accepted in dermatological tests. Additionally, in the case of positive skin reactions, the skin reaction is also assessed after 96 hours.

Evaluation parameters

The patch test readings were made according to the International Contact Dermatitis Research Group (ICDRG) Graphical scale of the ICDRG patch test reading:



- | | |
|-------------------------|---|
| (–) negative reaction | no reaction |
| (?) doubtful reaction | subtle erythema, palpably undetectable erythematous spot |
| (+) weak reaction | palpable erythema, suggestive of mild edema / infiltration, clumping may occur, no blisters |

(++) strong reaction	increased swelling, infiltration, clots, blisters
(+++) very strong reaction	blisters, erosions, ulceration
(IR) irritative reaction	shiny skin, dry skin, pimples, erythema

Selection of Study Participants

The selection of Study Participants was carried out in accordance with the Research Procedure, taking into account:

»Helsinki Declaration of 1964 (with later additions)

»Current Polish and European legal regulations

»Cosmetics Europe guidelines using the inclusion and exclusion criteria

20 skin-healthy volunteers with sensitive skin aged 30-68 (18 women and 2 men) were chosen to become subjects in the study.

Volunteers filled out a detailed survey regarding their lifestyle, current state of health, past illnesses, eating habits, medicines and the use of stimulants and the survey on coexisting skin problems (allergy issues included). The application of the patch tests was preceded by dermatology examination assessing, above the others, the type of skin and presence of any pathological changes on the skin.

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.

All volunteers selected for the study met the requirements for inclusion in the study and signed consent for conscious participation in the study, and were informed about the purpose of the study, how it was conducted and about possible side effects. The skin, where the patch tests were applied, was healthy, free of skin lesions.

Results

Volunteers characteristic				Results after 48h	Results after 72h
No.	Sex	Age	Skin type	Skin reaction	Skin reaction
1	F	56	S	(-)	(-)
2	M	36	S	(-)	(-)
3	M	68	S	(-)	(-)
4	F	52	S	(-)	(-)
5	F	42	S	(-)	(-)
6	F	62	S	(-)	(-)
7	F	63	S	(-)	(-)
8	F	33	S	(-)	(-)
9	F	48	S	(-)	(-)
10	F	30	S	(-)	(-)
11	F	62	S	(-)	(-)
12	F	46	S	(-)	(-)
13	F	51	S	(-)	(-)
14	F	52	S	(-)	(-)
15	F	37	S	(-)	(-)
16	F	47	S	(-)	(-)
17	F	36	S	(-)	(-)
18	F	49	S	(-)	(-)
19	F	33	S	(-)	(-)
20	F	32	S	(-)	(-)

Legend: F – female, M – male, A – positive allergic screening, S – sensitive

SUMMARY

In the group of 20 people who underwent the study, no positive contact allergy or irritant reaction was observed after using the product.

The lack of positive reactions indicates that the tested product does not show irritating and sensitizing effects in contact with the sensitive skin.

Based on the results of the tests performed, we conclude that the „Biyba Nemlendiricili Duş Jeli” product meets the requirements of the Skin Compatibility Test and may be estimated as non-irritant.

The issued opinion does not apply to people who are allergic to any of the components of the product under evaluation.

THE END of the Attachment

Prepared on: 23.05.2023	Prepared by: GBA POLSKA Employee no.: 2611	Authorized by: GBA POLSKA Employee no.: 2426
-----------------------------------	--	--

Signed with a qualified electronic signature
Dr Aleksandra Błazik - specialist in dermatology