DR KOZIEJ
INSTYTUT BADAŃ KOSMETYKÓW

B – (97/02/2016)

THE REPORT FROM DERMATOLOGICAL RESEARCH OF COSMETICAL PRODUCT WITH HALF OPEN PATCH TEST

Product	**Biobellinda Permanent Hair Dye Cream 7.3 Honey Foam** **Biobellinda Kalıcı Krem Saç Boyası 7.3 Bal Köpüğü**
Responsible Person	**Biobellinda Kozmetik Ve Temizlik Ürünleri Pazarlama A.Ş.**
Report number	**B-0179/16**
Issue date	**14.03.2016**

Dr Koziej spółka z ograniczoną odpowiedzialnością spółka komandytowa
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1. RESEARCH BASIS

Order date	25.02.2016
Order number	97/02/2016
Research time frame	29.02.2016 – 11.03.2016
Report issue date	14.03.2016

CUSTOMER NAME
Pim Eğitim ve Danişmanlik Hizmetleri, Göktürk Cad. Suvenue Sitesi B Blok Kat:3 D:7 Eyüp-İstanbul

RESPONSIBLE PERSON NAME	
Company name	Biobellinda Kozmetik Ve Temizlik Ürünleri Pazarlama A.Ş.
Address	

Product name	Biobellinda Permanent Hair Dye Cream 7.3 Honey Foam Biobellinda Kalıcı Krem Saç Boyası 7.3 Bal Köpüğü
Ingredients	Aqua/Water, Cetearyl Alcohol, Ethanolamine, Ceteareth-20, Propylene Glycol, p-Phenylenediamine, 2-metylresorcınol, 4-Amino-2-Hydroxytoluene, m-Aminophenol, Resorcinol, Prunus Amygdalus Dulcis Oil, Sodium Sulfite, Ascorbic Acid, Disodium EDTA

2. PRODUCT CHARACTERISTIC

Product Package	Supplementary – white, plastic bottle and white metal tube labeled with product's name
Product Appearance	White cream and yellow gel with specific scent
Product purpose	Hair dye

The responsible person is responsible for conformity with declared qualitative and quantitative composition and microbiological purity of the delivered research samples.

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 cosmetic.
- 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.
- Patch tests according to Jadassohn-Bloch with Rudzki modifications were conducted under careful supervise of medical specialists – dermatologists. The assessment of the allergenic and irritant features was made on a group of 30 healthy volunteers no allergological history, familiarized with contraindications and recommendations for the study /not currently taking any medication that may have any effect on the result of the test/, familiarized with contraindications and recommendations for the study. The probands' selection, samples application and reading took place in Diagnostic Test in Bialystok. The tested preparation in a commercial formulation is applied to chamber cell-petal patches of Finn Chamber® which are put around a vane. Patches are removed after 48 hours and the first reading is conducted. Another reading takes place 72 hours

after insertion of the sample. A dermatologist based on the observations of skin reactions evaluates allergenic action of the conducted substance. Positive reaction (erythema) confirms allergenic properties of the formulation, negative reaction (no erythema) confirms the absence of allergenic properties of the formulation.

4. THE AIM OF STUDY

- The aim is to assess irritating and allergenic properties of the product in a healthy adult volunteer by single insert of patch test and the reading of skin reaction after 48 and 72 hours.

5. SUBJECT – VOLUNTEERS SELECTION

- The selection of probands – volunteers 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. 30 people took part in the study at the age of 22 - 59 years old: 17 women and 13 men who met the requirements for entering the study and agreed to informed consent to participate in the study. The skin at the selected area was normal, without any lesions. Subjects were informed not to use any kinds of antihistamines or pharmacological agents at the time of test, which may affect the tests' results.

6. RESULTS

Subject	Age	Sex	Erythema	Oedema	Scaling	Subject	Age	Sex	Erythema	Oedema	Scaling
1	57	F	(0)	(0)	(0)	**16**	23	F	(0)	(0)	(0)
2	22	F	(0)	(0)	(0)	**17**	28	M	(0)	(0)	(0)
3	52	M	(0)	(0)	(0)	**18**	35	F	(0)	(0)	(0)
4	36	F	(0)	(0)	(0)	**19**	38	F	(0)	(0)	(0)
5	40	M	(0)	(0)	(0)	**20**	44	M	(0)	(0)	(0)
6	32	F	(0)	(0)	(0)	**21**	47	M	(0)	(0)	(0)
7	38	M	(0)	(0)	(0)	**22**	39	F	(0)	(0)	(0)
8	57	F	(0)	(0)	(0)	**23**	25	F	(0)	(0)	(0)
9	26	F	(0)	(0)	(0)	**24**	55	M	(0)	(0)	(0)
10	33	M	(0)	(0)	(0)	**25**	59	F	(0)	(0)	(0)
11	41	F	(0)	(0)	(0)	**26**	46	M	(0)	(0)	(0)
12	38	M	(0)	(0)	(0)	**27**	32	F	(0)	(0)	(0)
13	28	M	(0)	(0)	(0)	**28**	23	F	(0)	(0)	(0)
14	33	M	(0)	(0)	(0)	**29**	25	F	(0)	(0)	(0)
15	45	F	(0)	(0)	(0)	**30**	40	M	(0)	(0)	(0)

Legend:

E (erythema) - (0) – zero; (1) – weak; (2) – moderate; (3) – strong; (4) – very strong

O (oedema) - (0) – zero; (1) – weak; (2) – moderate; (3) – strong; (4) – very strong

S (scaling) - (0) – zero; (1) – weak; (2) – moderate; (3) – strong; (4) – very strong

(-) – negative result, (?) – questionable result

M – man, F – woman

RESULTS: In 30 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 conducted patch tests, one may state that the cosmetic product “Biobellinda Permanent Hair Dye Cream 7.3 Honey Foam/ Biobellinda Kalıcı Krem Saç Boyası 7.3 Bal Köpüğü” does not have irritant or allergenic action.
2. The issued opinion does not apply to anybody with an allergy to any of the ingredients of the tested preparation.
3. The issued opinion does not include analysis of the composition of the product.
4. The tested preparation fulfills requirements for cosmetic products of declared specification, in regards to human health safety.

Stamp and Signature of investigator

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3. The results refer only to the product of the composition given by the Principal.