YEDİTEPE ÜNİVERSİTESİ
AR-GE VE ANALİZ MERKEZİ
YÜ-AGAM

YÜ-AGAM KOZMETİK VE BİYOSİDAL ANALİZ LABORATUVARI ANALİZ RAPORU

Rapor No	: KBL21001257
Numuneyi Gönderen / Adresi	: ENKA HİJYEN ÜRÜNLERİ SAN. ve TİC. AŞ. / 5.Org.San.Böl. 83.535 Nolu Cad. No: 15 Şehitkamil Gaziantep/
Teklif No	: KBL210791-03-DLR
Analizin Başlama ve Bitiş tarihi	: 15/12/2021 / 28/01/2022
Numune Kabul Tarihi	: 15/12/2021
Numune Geliş Şekli / Sıcaklığı	: Kargo / 20 °C
Numune Türü	: HASTA BEZİ
Ambalaj	: Plastik Poşet
Ambalaj Miktarı	: 1
Üretim ve SKT	: 13/11/2021 / 12/11/2024
Seri - Lot	: 13112021
Miktar	: 20 Adet
Üretici Firma/Marka	: / PADDLERS
Raporun Yayımlandığı Tarih	: 31/01/2022

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Sıra No	Analiz	Analiz Metodu	Ölçüm Limiti	Geri Kazanım	Analiz Sonuçları	Limit Değer	Değerlendirme
1	Dermatolojik Test (15 Gönüllü-Hassas Cilt) (^)	Patch Test	-	-	İritasyon veya Alerjenite Tespit Edilemedi		

Yapılan muayene ve analiz sonucunda yukarıda belirtilen değerler tespit edilmiştir

Not 1. Bu Analiz raporu reklam amacıyla kullanılamaz.
Not 2. Bu analiz raporunun hiçbir bölümü tek başına veya ayrı ayrı kullanılamaz.
Not 3. Analiz sonuçları yukarıda belirtilen numune için geçerlidir.
Not 4. İzin alınmadan raporlarımız çoğaltılamaz ve yayınlanamaz. İmzasız raporlar geçersizdir.
Not 5.(*) İşaretli analizde laboratuvarımız TÜRKAK'tan akreditedir.
Not 6. (**) İşaretli analizde laboratuvarımız T.C. Tarım ve Orman Bakanlığı'ndan yetkilidir.
Not 7. (***) İşaretli analizde laboratuvarımız T.C. Tarım ve Orman Bakanlığı'ndan yetkili, TÜRKAK'tan akreditedir.
Not 8. Uygunluk beyanı, genişletilmiş belirsizlik için %95 kapsama olasılığına dayanmaktadır.
Not 9. Müşteri tarafından sağlanan, numune ile ilgili bilgi ve hizmetlerin, analiz sonuçlarına etkisinden laboratuvarımız sorumlu değildir.
Not 10. Numune alma işlemi laboratuvarımız tarafından yapılmamış olup, sonuçlar numunenin teslim alındığı hali için geçerlidir.
Not 11. Bu rapora ait analiz sonucu sadece belirtilen numune türü ve seri-lot numarası için geçerlidir.
Not 12. (^) İlgili analiz tedarikçi laboratuvarda rapor BST/2021/12/0814-1/9 no'lu analiz sonuçları esas alınarak eklenmiştir.

Mikrobiyoloji Laboratuvari Birim Sorumlusu
Neşe GÜLDÜR ÇALIK
Biyolog
31/01/2022

Numune Kabul ve Rapor Duzenleme Birim Sorumlusu	Gıda Kontrol Laboratuvar Müdürü	Laboratuvarlar Grup Müdürü Genel Müdür
Sedat Süleyman DEMİRTAŞ	Hikmet Tuğrul TEKELİ	Sibel ŞİMŞEK YAZICI
Kimyager	Yüksek Kimyager	Kimya Mühendisi
31/01/2022	31/01/2022	31/01/2022

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THE REPORT FROM DERMATOLOGICAL RESEARCH
OF COSMETIC PRODUCT
BST/2021/12/0814-1/9

Product **KBL21001257-HASTA BEZİ**

Responsible Person YÜ-AGAM

Acıbadem Mahallesi Bağ Sokak No: 8 İSTEK Vakfı Binası Kadıköy - İstanbul

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DERMATOLOGICAL RESEARCH
BST/2021/12/0814-1/9

1. RESEARCH BASIS

Order date	23.12.2021
Research time frame	27.12.2021-03.01.2022
Order number	2021/12/0814-1

Responsible person name	
Company name	YÜ-AGAM
Address	Acıbadem Mahallesi Bağ Sokak No: 8 İSTEK Vakfı Binası Kadıköy - İstanbul

2. SUBJECT OF THE STUDY

2.1. Ingredients

Product name	**KBL21001257-HASTA BEZİ**
Ingredients	Polyethylene, Polypropylene,Polyester,Holt Melt Glue, Pulp,Elastıc, Salt Of Polyacrylic Acid.

2.2. Product characteristic

Product appearance	Blue diaper
Product purpose	Skin hygiene

The responsible person is responsible for conformity with declared qualitative and quantitative 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 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 assessment of the allergenic and irritant features was made on a group of 15 healthy volunteers 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. THE AIM OF STUDY

The study conducted in order to determine local skin tolerance of the product in a group of healthy volunteers with increased sensitivity and positive allergenic screening of the skin to establish possible irritant and/or sensitizing properties of the product.

5. SUBJECT – VOLUNTEERS SELECTION

The selection of probants – 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.
15 skin-healthy volunteers aged 26-54 (women) were chosen to become subjects in the study. All the volunteers 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.

6. 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 efflorescences other than papules and vesicles	Irritant reaction, this kind of reactions may cause many problems upon interpretation

7. RESULTS

Volunteers characteristic				**Results after 48h**	**Results after 72h**
No.	**Sex**	**Age**	**Skin parameters**	**Skin reaction**	**Skin reaction**
1	W	26	S	-	-
2	W	35	S	-	-
3	M	38	S	-	-
4	W	35	S	-	-
5	W	33	S	-	-
6	W	32	S	-	-
7	W	34	S	-	-
8	W	31	S	-	-
9	W	42	S	-	-
10	M	41	S	-	-
11	W	30	S	-	-
12	M	36	S	-	-
13	W	54	S	-	-
14	W	34	S	-	-
15	W	43	S	-	-

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

RESULTS: In 15 subjects, the results of patch tests were **negative**, which means that the product does not cause irritation or allergy reaction in those subjects.

8. CONCLUSION

1. Having carried out the patch tests on the chosen population with increased sensitivity of the skin, it has been determined that the product **KBL21001257-HASTA BEZİ** 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 **KBL21001257-HASTA BEZİ** 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.