YEDİTEPE ÜNİVERSİTESİ
AR-GE VE ANALİZ MERKEZİ
YÜ-AGAM

YÜ-AGAM KOZMETİK VE BİYOSİDAL ANALİZ LABORATUVARI ANALİZ RAPORU

Rapor No : KBL20001650
Numuneyi Gönderen : ENKA HİJYEN ÜRÜNLERİ SAN. ve TİC. AŞ.

Teklif No : KBL201390-02-DLR
Analizin Başlama ve Bitiş tarihi : 02/12/2020 / 13/01/2021
Numunenin Laboratuvara Geldiği Tarih : 01/12/2020
Numune Geliş Şekli / Sıcaklığı : Kargo / 22 °C
Numune Türü : Hasta Bezi

Ambalaj : Orijinal Ambalaj
Ambalaj Miktarı : 1

Üretim ve SKT : 25/10/2020 / 25/10/2022
Seri - Lot : 25.10.2019

Miktar : 1 Paket
Üretici Firma /Marka : / Paddlers

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 sonuçları sadece belirtilen numune türü ve seri-lot numarası için geçerlidir.
Not 12. (^) İlgili analiz tedarikçi laboratuvarda BST/2020/12/0706-2/11 rapor no'lu analiz sonuçları esas alınarak eklenmiştir.

Doküman No:PR.510.001-EK-5
İlk Yayın Tarihi: 21.11.2013
Rev No: 02
Rev Tarihi:02.08.2018

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Neşe GÜLDÜR ÇALIK
Biyolog
Mikrobiyoloji Laboratuvari Birim Sorumlusu
13/01/2021

Candan EREN
Gıda Mühendisi
Numune Kabul ve Rapor Duzenleme Birim Sorumlusu
13/01/2021

Tasdik Olunur
13/01/2021

Sibel ŞİMŞEK YAZICI
Kimya Mühendisi
Laboratuvarlar Grup Müdürü
Genel Müdür

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THE REPORT FROM DERMATOLOGICAL RESEARCH OF COSMETIC PRODUCT WITH EXTENDED SEMI-OPEN PATCH TEST BST/2020/12/0706-2/11

Product	**KBL20001650 HASTA BEZİ**
Responsible Person	YÜ-AGAM Acıbadem Mahallesi Bağ Sokak No: 8 İSTEK Vakfı Binası Kadıköy - İSTANBUL

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1. RESEARCH BASIS

Order date	10.12.2020
Research time frame	15.12.2020-21.12.2020
Order number	2020/12/0706-2

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	**KBL20001650 HASTA BEZİ**
Ingredients	Polyethylene, Polypropylene, Polyester, Holt Melt Glue, Pulp, Elastic, Salt Of Polyacrylic Acid.

2.2. Product characteristic

Product appearance	White diaper
Product purpose	Baby use

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.
- 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 15 healthy volunteers with no allergological history. 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.

4. THE AIM OF STUDY

The study conducted in order to determine local skin tolerance of the product in a group of healthy volunteers 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 21-71 (both men and 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 to the skin.
The skin, where the patch tests were applied, was healthy, free of any changes.
The subjects were informed not to expose their skin nor 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	M	37	S	-	-
2	W	23	S	-	-
3	W	40	S	-	-
4	M	22	S	-	-
5	W	31	S	-	-
6	W	31	S	-	-
7	W	39	S	-	-
8	W	38	S	-	-
9	M	34	S	-	-
10	M	31	S	-	-
11	W	23	S	-	-
12	M	23	S	-	-
13	W	71	S	-	-
14	W	33	S	-	-
15	W	21	S	-	-

Skin type: S – sensitive 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, it has been determined that the product **KBL20001650 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 **KBL20001650 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.