



T.C. YEDİTEPE ÜNİVERSİTESİ
AR-GE VE ANALİZ MERKEZ LABORATUVARLARI
YÜ-AGAM
ANALİZ RAPORU

Rapor No : ML 17002864 20/10/2017
Numuneyi Gönderen : AGORA KİMYA SAN. VE TİC. A.Ş.
Teklif No : KBL170735-01-STB
Analizin Başlama ve Bitiş tarihi : 09/09/2017 , 19/09/2017
Numune Kabul Tarihi : 08/09/2017
Numune Geliş Şekli / Sıcaklığı : Kargo , 24 °C
Numune Türü : SOOP Baby Beslenme Gereçleri Temizleyicisi / Beslenme Gereçleri Temizleyicisi SPBB001N
Ambalaj : Plastik Şişe
Üretim ve SKT : 22/08/2017 , 21/08/2019
Seri - Lot : SPBB001
Miktar : 500 ml
Üretici Firma / Marka : / SOOP

Sıra No	Analiz	Analiz Metodu	Ölçüm Limiti	Geri Kazanım	Analiz Sonuçları	Limit Değer	Değerlendirme
1	Hypo-Alerjen Analizi (^)	-	-	-	İrritasyon ve Allerjenite Tespit edilemedi		

Sonuçlar,... esas alınarak değerlendirilmiştir.

Yapılan muayene ve analiz sonucunda yukarıda belirtilen değerler tespit edilmiştir

- Not 1. Bu Analiz raporu Adli-idari işlemlerde ve 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 yayımlanamaz. İmzasız raporlar geçersizdir.
Not 5. (*) İşaretili analizde laboratuvarımız TÜRKAK'tan akredite edilmiştir.
Not 6. (**) İşaretili analizde laboratuvarımız Gıda, Tarım ve Hayvancılık Bakanlığı'ndan yetkilidir.
Not 7. (***) İşaretili analizde laboratuvarımız Gıda, Tarım ve Hayvancılık Bakanlığı'ndan yetkili, TÜRKAK'tan akredite edilmiştir.
Not 8. Bu rapordaki kapsam dışı analizler müşteri talebi ile Ar-Ge amaçlı olarak çalışılmıştır. 5996 sayılı kanun ve ilgili mevzuat kapsamında resmi işlemlerde kullanılamaz, resmi makamlara iletilemez.
Not 9. (^) İlgili analiz B-1156/17 no'lu ve 12.10.2017 tarihli raporla tedarikçi laboratuvarında gerçekleştirilmektedir.
Not 10. Test sonuçları ekte.

Leyla TARHAN ÇELEBİ

Biyolog

Mikrobiyoloji Laboratuvarı Birim Sorumlusu

Billur YESÜGEY

Gıda Mühendisi

Numune Kabul ve Rapor Düzenleme Birim Sorumlusu

Tasdik Olunur

20/10/2017

Sibel ŞİMŞEK YAZICI

Kimya Mühendisi

Laboratuvarlar Grup Müdürü
Genel Müdür Yardımcısı

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

Product **ML17002864- SOOP Baby Beslenme Gereçleri Temizleyicisi / Beslenme Gereçleri Temizleyicisi SPBB001N**

Responsible Person **YÜ-AGAM**

1. RESEARCH BASIS

Product name	ML17002864- SOOP Baby Beslenme Gereçleri Temizleyicisi / Beslenme Gereçleri Temizleyicisi SPBB001N
Ingredients	Aqua, Potassium Linoleate, Potassium Oleate, Potassium Palmitate, Potassium Laurate, NaCl, Potassium Myristate, Potassium Stearate, Glycerin, Citric Acid, Potassium Caprylate, Potassium Caprate, Benzyl Alcohol

2. PRODUCT CHARACTERISTIC

Product Package	Supplementary – clear plastic bottle, labeled with name of the product
Product Appearance	Clear gel with no scent
Product purpose	Equipment cleaner

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 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 specialists – dermatologists. The assessment of the allergenic and irritant features was made on a group of 30 healthy volunteers with a diagnosis-proven in studies or clinical history of sensitive skin, 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 with diagnosis-proven sensitive skin 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, who agreed to informed consent to participate in the study. The dermatologist made a previous evaluation of the clinical history of the volunteers to determine if they have sensitive skin. 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	Sensitive skin	Age	Sex	Result	Subject	Sensitive skin	Age	Sex	Result
AT_4	Yes	24	F	Negative(-)	MP_12	Yes	45	M	Negative(-)
CR_6	Yes	41	F	Negative(-)	CS_8	Yes	36	F	Negative(-)
PD_3	Yes	33	F	Negative(-)	MK_11	Yes	29	M	Negative(-)
ST_13	Yes	52	M	Negative(-)	NR_2	Yes	51	F	Negative(-)
SW_12	Yes	50	F	Negative(-)	SL_1	Yes	42	M	Negative(-)
AD_2	Yes	37	F	Negative(-)	JN_9	Yes	24	F	Negative(-)
BR_7	Yes	29	F	Negative(-)	ML_4	Yes	35	M	Negative(-)
AW_10	Yes	44	F	Negative(-)	MT_12	Yes	58	F	Negative(-)
LK_5	Yes	48	M	Negative(-)	ZL_3	Yes	47	M	Negative(-)
MD_4	Yes	30	F	Negative(-)	DD_5	Yes	37	M	Negative(-)
CT_8	Yes	35	F	Negative(-)	ER_8	Yes	38	F	Negative(-)
ZW_6	Yes	56	M	Negative(-)	MP_3	Yes	55	F	Negative(-)
EK_3	Yes	27	M	Negative(-)	NZ_13	Yes	39	M	Negative(-)
MR_12	Yes	33	F	Negative(-)	MM_8	Yes	49	M	Negative(-)
AR_3	Yes	40	M	Negative(-)	KJ_4	Yes	56	F	Negative(-)

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 **ML17002864- SOOP Baby Beslenme Gereçleri Temizleyicisi / Beslenme Gereçleri Temizleyicisi SPBB001N Temizleyicisi** does not have irritant or allergenic action to sensitive skin.
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, in regards to human health safety.

Stamp and Signature of investigator

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