



HACETTEPE UNIVERSITY



Hacettepe Teknokent  
**HT-TTM**  
TEKNOLOJİ TRANSFER MERKEZİ

Hacettepe Technopolis Technology Transfer Center

## SKIN IRRITATION TEST REPORT



*Bu belge resmi makamlara sunulmak üzere hazırlanmıştır, belgenin yayınlanması ve kopyalanması yasaktır. Test sonuçları, sadece tarafımıza lot numarası beyan edilerek ulaştırılan numune için geçerlidir. Kaşeli ve ıslak imzalı olmayan raporlar geçersizdir.*

Doküman Kodu: P10-F08

Yayın Tarihi:

Revizyon No/Tarih: 00/-

Sayfa No: 1/5

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www.biocompatibility.center  
www.biyoyumluluk.com



SKIN IRRITATION TEST REPORT  
FORM



Contract Number: ARGEDS-2016/19A

Customer Name/Address: ENKA HİJYEN ÜRÜNLERİ SAN. Ve TIC. A.Ş.  
2. ORGANİZE SANAYİ BÖLGESİ OTOBAN YOLU NO:4  
27120 GAZİANTEP

Test Sample Name: PADDLERS BABY DIAPER

Test Sample Lot Number: 14360001

Testing Facility: Hacettepe University Faculty of Pharmacy  
Pharmacology Department  
06100, Sıhhiye Ankara, Turkey

Arrival of the Test Sample: 17.02.2016

Date of Report: 05.04.2016

Attachment: Technical Information

RESULT

The test material "PADDLERS BABY DIAPER (Lot 14360001) does not cause skin irritation.

ADMINISTRATIVE DIRECTOR

Professor Serdar Uma

COORDINATOR

Professor İnci Erdemli



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Sayfa No: 2/5



# SKIN IRRITATION TEST REPORT FORM



## TECHNICAL INFORMATION

Contract Number: ARGEDS-2016/19A

### GUIDELINES

|                         |   |
|-------------------------|---|
| TS EN ISO 10993:        | Biological evaluation of medical devices                |
| TS EN ISO 10993-1:2014  | Evaluation and testing within a risk management process |
| TS EN ISO 10993-2:2006  | Animal welfare requirements                             |
| TS EN ISO 10993-10:2014 | Tests for irritation and skin sensitization             |
| TS EN ISO 10993-12:2013 | Sample preparation and reference materials              |

### DESIGN OF STUDYING

Test Sample Quantity: 6 pieces

Start of Test: 22.03.2016

End of Test: 25.03.2016

Practice\*:

| DIRECT CONTACT METHOD  | X | EXTRACTION METHOD  | - | OTHER/INSTRUCTIONS | - |
|--|---|--|---|--------------------|---|
| <b>Solid Samples:</b><br>Test sample is used directly in accordance with TS EN ISO 10993-10 "Tests for irritation and skin sensitization" standart.<br><b>Blank Sample:</b> <ul style="list-style-type: none"><li>• 25 x 25 mm four-ply gauze patch</li></ul> <b>Liquid Samples:</b><br>Test sample is absorbed with 25 x 25 mm four-ply gauze patch and applied directly in accordance with TS EN ISO 10993-10 "Tests for irritation and skin sensitization" standart.<br><b>Blank Sample:</b> <ul style="list-style-type: none"><li>• 25 x 25 mm four-ply gauze patch with physiological saline (0.9 % (m/v) NaCl) (water-based sample)</li><li>• 25 x 25 mm four-ply gauze patch with sesame oil (oil-based sample)</li></ul> |   | Test sample extract is prepared according to table of "Standart surface areas and extract liquid volumes" in TS EN ISO 10993-12 "Sample preparation and reference materials" standart. Extract is obtained by incubation of sample with physiological saline (% 0.9 (m/v) NaCl) at 37 °C for 72 hours.<br><b>Blank Sample:</b> <ul style="list-style-type: none"><li>• Physiological saline (0.9 % (m/v) NaCl)</li></ul> |   |                    |   |

\*SIGN THE SUITABLE CHOICE WITH "X", UNSUITABLE CHOICE WITH "-".

Bu belge resmi makamlara sunulmak üzere hazırlanmıştır, belgenin yayınlanması ve kopyalanması yasaktır. Test sonuçları, raporlar, beyanlar, imzalı olmayan raporlar sadece tarafımıza lot numarası beyan edilerek ulaştırılan numune için geçerlidir. Kaşeli ve ıslak imzalı olmayan raporlar geçersizdir.

Doküman Kodu: P10-F08

Yayın Tarihi:

Revizyon No/Tarih: 00/-

Sayfa No: 3/5





# SKIN IRRITATION TEST REPORT FORM



Contract Number: ARGEDS-2016/19A

## Test Procedure:

Three healthy adult albino rabbits (either sex, 2-3 kg) was used. On the day before the test, the fur on the back of the animals was shaved. A sufficient distance was kept on both sides of the spine for the application and observation of all test sites. Test material and blank sample that prepared in accordance with practice method were applied to the skin on both sides in two different areas of the rabbit. The application sites were wrapped with a semi-occlusive bandage for 4 h. At the end of the contact time the patches and dressings were removed and the position of the sites were marked by permanent ink.

## OBSERVATION AND CALCULATION

Application sites are observed for erythema and oedema at 1<sup>st</sup>, 24<sup>th</sup>, 48<sup>th</sup>, and 72<sup>nd</sup> hours following the removal of the patches. Only 24<sup>th</sup>, 48<sup>th</sup>, and 72<sup>nd</sup> hours observations are used for calculations. Irritation was scored by using ISO 10993-10, "Scoring system for skin reaction". Irritation grades are presented as mean of two application sites of either test or blank sample. The primary irritation score for each animal is calculated by dividing the sum of all the irritation scores by six (two test/observation sites, three time points). Primary irritation index is calculated by subtracting the sum of primary irritation scores for the blank sample from the sum of primary irritation scores for the test samples and then dividing this difference by the total number of animals (three). According to the calculated primary irritation index values, the results are presented as the appropriate response category which is given below.

TABLE 1: SCORING SYSTEM FOR SKIN REACTION

| Reaction  | Irritation score |
|---|------------------|
| <b>Erythema and eschar formation</b>  |                  |
| No erythema   | 0                |
| Very slight erythema (barely perceptible)   | 1                |
| Well-defined erythema   | 2                |
| Moderate erythema   | 3                |
| Severe erythema (beet-redness) to eschar formation preventing grading of erythema | 4                |
| <b>Oedema formation</b>   |                  |
| No oedema   | 0                |
| Very slight oedema (barely perceptible)   | 1                |
| Well-defined oedema (edges of area well-defined by definite raising)              | 2                |
| Moderate oedema (raised approximately 1 mm)                                       | 3                |
| Severe oedema (raised more than 1 mm and extending beyond exposure area)          | 4                |
| <b>Maximal possible score for irritation</b>                                      | <b>8</b>         |
| Other adverse changes at the skin sites shall be recorded and reported.           |                  |

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Revizyon No/Tarih: 00/-

Sayfa No: 4/5





# SKIN IRRITATION TEST REPORT FORM



Contract Number: ARGEDS-2016/19A

## RESULT

TABLE 2: MEAN IRRITATION SCORES OF TWO APPLICATION SITES AT 24<sup>th</sup>, 48<sup>th</sup>, 72<sup>th</sup> HOURS

| OBSERVATION TIME POINTS<br>(HOURS) | 1 <sup>ST</sup> RABBIT |           | 2 <sup>ND</sup> RABBIT |           | 3 <sup>RD</sup> RABBIT |           |
|------------------------------------|------------------------|-----------|------------------------|-----------|------------------------|-----------|
|                                    | CONTROL SITE           | TEST SITE | CONTROL SITE           | TEST SITE | CONTROL SITE           | TEST SITE |
| 24 <sup>th</sup>                   | 0                      | 0         | 0                      | 0         | 0                      | 0         |
| 48 <sup>th</sup>                   | 0                      | 0         | 0                      | 0         | 0                      | 0         |
| 72 <sup>nd</sup>                   | 0                      | 0         | 0                      | 0         | 0                      | 0         |
| Primary irritation score           | 0                      | 0         | 0                      | 0         | 0                      | 0         |

Primary irritation index: 0

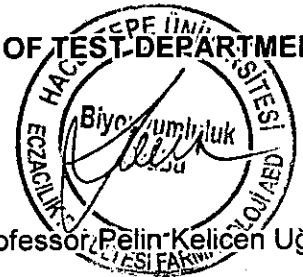
| PRIMARY IRRITATION INDEX | RESPONSE CATEGORY |
|--------------------------|-------------------|
| 0 to 0.4                 | Negligible        |
| 0.5 to 1.9               | Slight            |
| 2 to 4.9                 | Moderate          |
| 5 to 8                   | Severe            |

Response category: Negligible

## CONCLUSION

The test sample with ARGEDS\_2016/19A code does not cause skin irritation.

CHIEF OF TEST DEPARTMENT



Professor Pelin Kelicen Uğur

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