

**Test Report 5533401-01  
26.10.2020****Epicutaneous Test for the  
Assessment of a Skin-Irritation  
Potential**

**Sponsor:**  
**Xiamen Mk Health Care Product Co.,  
LTD**  
**HuLi Area, XiaMen  
China**

# Test Report 5533401-01

**Test Description:** Assessment of a skin-irritating potential in an epicutaneous test.

**Sponsor:** Xiamen Mk Health Care Product Co., LTD  
 No. 704, DFC, GaoLin Middle Road  
 HuLi Area, XiaMen - China

**Date of Order:** 13.10.2020

**Sample entry:** 15.10.2020

**Date of Report:** 26.10.2020

**Order Number.:** 5533401

**Number of volunteers:** Number : 30 volunteers  
 : 22 sensitive skin  
 : 3 atopic diatheses

Age : 22 – 61 Years  
 Sex : male (6 volunteers)  
 female (24 volunteers)

**Testarea:** back

**Testing period:** 19.10. – 22.10.2020 (control times: 24 & 48 hours)

**Applied Quantity:** 1 x 1 cm

**Test Concentration:** pure

**Labor:** Taunusstein (Germany)

**Dermatologist:** Mrs. Dr. Schorling

**Test Items:**

**2001038600**  
 ECO BOOM Bamboo Diaper XL

## Study Objective

The epicutaneous test is used for the assessment of primary skin irritation as well as localized and temporary contact allergies for test items.

## Summary

Under the chosen test conditions, 22 subjects showed a clear reaction on the positive control '0,5 % SDS'. No subject showed a reaction on the negative control 'distilled water'. No subject showed a clear reaction on the test product.

The claim "**dermatologically tested**" was substantiated by dermatological supervision of the study by a dermatologist and the confirmation of skin tolerance.

### Conclusion:

**The test product can be classified as very well tolerated by the skin.**

We hope to have served you satisfactorily with our investigations. We are at your disposal for any further requests.

Yours sincerely,

**SGS INSTITUT FRESENIUS GmbH**

i.V. Dr. Ines Sellami  
(Leader Hair and Skin Care - Performance Testing Lab)

i. A. Selina Renner  
(Customer Service Assistant)

### Attachments:

- Test Method
- Results

## ATTACHMENTS

### Test Method:

A panel of 22 persons with sensitive skin and 3 persons with atopic skin diathesis (sensitive panel), 24 female and 6 male subjects aged 22-61 years, participated in the study (see attached list of volunteers in Appendix 1).

For the epicutaneous test the undiluted test item was applied onto the clinically healthy skin on the back of volunteers and fixed with a semi - occlusive test-patch (Leukotest®, Patch area: 1 x 1 cm). The controls were applied occlusive. The patch was removed 24 h later. After another 24 h, potential skin reactions were documented by a dermatologist. After additional 24 h test areas were controlled again. The occurrence of skin irritations was documented regarding intensity and temporal development.

### Classification scale:

Erythema	Score
no impression of erythema	0
Doubtful reactions	0.5
Weak, spotty erythema	1 / 1.5
Moderate erythema, sharply defined	2 / 2.5
Medium strong erythema	3 / 3.5
Strong large-surface erythema with edema	4 / 4.5

## ATTACHEMENTS

### 201038600 ECO BOOM Bamboo Diaper XL

Tab.: Biometric data and study results

no	Sex	Age [years]	Skin diathesis	Erythema Score					
				0,5 % SDS		Distilled water		201038600	
				24 h	48 h	24 h	48 h	24 h	48 h
1	f	33	sensitive	0,5	0,5	0	0	0	0
2	m	26	sensitive	2	1	0	0	0	0
3	f	42	normal	1,5	1	0	0	0	0
4	f	53	sensitive	2	1,5	0	0	0	0
5	f	41	sensitive	1,5	1	0	0	0	0
6	f	22	sensitive	1,5	0,5	0	0	0	0
7	f	35	atopic	1,5	1	0	0	0	0
8	f	31	sensitive	0,5	0,5	0	0	0	0
9	f	42	sensitive	1	0,5	0	0	0	0
10	f	55	sensitive	0	0	0	0	0	0
11	f	38	atopic	0,5	0	0	0	0	0
12	m	52	sensitive	2	2	0	0	0	0
13	m	31	sensitive	1,5	1	0	0	0	0
14	f	39	sensitive	1,5	0,5	0	0	0	0
15	m	55	sensitive	2	1,5	0	0	0	0
16	f	47	sensitive	0	0	0	0	0	0
17	f	49	sensitive	2	2	0	0	0	0
18	m	32	sensitive	1,5	1	0	0	0	0
19	f	57	sensitive	0	0	0	0	0	0
20	f	29	sensitive	2,5	0,5	0	0	0	0
21	f	53	sensitive	1,5	1,5	0	0	0	0
22	m	44	sensitive	2,5	2	0	0	0	0
23	f	53	normal	2	0,5	0	0	0	0
24	f	47	sensitive	0,5	0	0	0	0	0
25	f	59	normal	1,5	1	0	0	0	0
26	f	29	atopic	1	0,5	0	0	0	0
27	f	58	normal	1	0,5	0	0	0	0
28	f	27	normal	1,5	1	0	0	0	0
29	f	28	sensitive	1,5	0,5	0	0	0	0
30	f	61	sensitive	0,5	0	0	0	0	0

## ATTACHEMENTS

### Sample Photos

(only sample 201038600 ECO BOOM Bamboo Diaper XL was tested)



Sample 201038600



Sample 201038598



Sample 201038599

\*end of report\*

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