Dermatological Test Report
Semi-Open Test

Test Reference	21/04685/002
Customer	Wipertec Ltd
Contact	Andy Abraham (andy@wipertecltd.co.uk)
Address	Unit 33/Peel Ind Est/Chamberhall St, Bury BL9 0LU

Product Name	Mili Pad Baby Wipes	**Test Date**	20/08/2021
Batch Code	N/A	**Report Date**	29/09/2021

Scope of Tests Compliant With:

- Regulation of the European Parliament and of the Council (EC) No. 1223/2009 of 30 November 2009 on cosmetic products.
- Cosmetics Europe – The Personal Care Association (previously COLIPA) Guidelines Product Test Guidelines for the Assessment of Human Skin Compatibility 1997.
- Cosmetics Europe – The Personal Care Association (previously COLIPA) Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008.

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1. The Basis of the Study

- Test sample delivered by the Client.
- The qualitative composition of the product delivered by the Client.
- The result of microbiology delivered by the Client.

The Client is responsible for compliance with the declared qualitative composition and microbiological purity of the product sample sent for testing.

2. Object of Study:

Parameter	Description
Appearance	Impregnated Wipe
Colour	White
Fragrance	Characteristic for raw materials (or fragrance composition)
Packaging	Replacement packaging containing the name and sample number for testing

3. Qualitative Composition of the Product

The qualitative composition was delivered to the Laboratory by the Client before the start of the study.

4. Purpose of the Study

The aim of the study was to assess the irritating properties (skin tolerance) of the cosmetic product on a healthy adult skin, with applied patch test.

5. Description of Volunteers

The volunteers (50 people) were healthy, 25 people with negative and 25 people with positive allergy history. The selection of the group included the criteria of inclusion and exclusion. General inclusion criteria: healthy men and women over 18 years old, phototype: I-IV on Fitzpatrick scale, Caucasians, skin without irritations and changes requiring pharmacological treatment. General exclusion criteria: volunteers who use any treatment on the skin area subject to the study, volunteers exhibiting or having a known history of acute or chronic dermatological, medical and/or physical conditions that could influence the outcome of the study, pregnant or breastfeeding women or women planning a pregnancy during the study. None of the volunteers reported documented oversensitivity or history of adverse reactions to individual ingredients of the product tested. All the volunteers fulfilled the requirements of inclusion for tests and signed the Informed Consent Form (ICF). Additionally, they were informed on the purpose, methodology of the study and possible adverse effects. The skin at the application spot (arms or interscapular area) was healthy, without lesions. The volunteers were advised to exercise caution in handling the applied contact tests.

6. Testing Methodology

The preparation in the appropriate concentration is applied onto filter paper discs of 12 mm diameter, manufactured by SmartPractice® and then fixed to the arm or interscapular area with the use of a sticking patch. Simultaneously, to objectify the results of the study and in order to exclude possible reading errors connected with dermal irritations two control samples (control sample called "blind" and control sample with water) are used.The purpose of this study is to exclude possible reading errors connected with dermal irritations. The results of the study are presented in section 10 of this report. The dermatologist removes the patch 48h after the application and examines the skin response 30 minutes after removal. 72h after the application, the dermatologist examines the skin again for a response. If irritations appear or persist 72h after the application, an additional examination takes place after 96 hours. Determining the response of the skin, the dermatologist assesses the irritating and sensitising effects of the tested product. The study results may be influenced by factors such as lifestyle, stress, diet and environmental conditions, etc.

7. Date of Performance of the Study

17.08.2021 – 20.08.2021

8. Evaluation Parameters

Evaluation Parameters of Skin Reaction

Erythema	Classification point
No Erythema	0
Light Erythema	0.5
Erythema and/or papules	1
Erythema and/or papules and/or vesicles	2
Erythema and/or papules and/or vesicles and/or blisters	3
Erythema Bullous and/or ulcerative reaction and/or papules and/or vesicles and/or blisters	4
Edema	**Classification point**
No Edema	0
Very light Edema (hardy visible)	1
Light Edema	2
Moderate Edema (about 1mm raised skin)	3
Strong Edema (extended swelling even beyond the application area)	4

9. Results

Table 1 - Characteristics of volunteers with a negative history of allergy

No. of subject	Identification of subject	Begining of the study	Age	Sex	Phototype
1	SUC.EW	17.08.2021	56	F	II
2	KRU.JU	17.08.2021	19	F	II
3	KRZ.MA	17.08.2021	32	F	II
4	WIC.DA	17.08.2021	28	M	II
5	CIE.AL	17.08.2021	26	F	II
6	DUR.KR	17.08.2021	30	M	II
7	ROM.KI	17.08.2021	26	F	II
8	WIE.MA	17.08.2021	24	F	II
9	WIE.WI	17.08.2021	21	F	II
10	NOW.DA	17.08.2021	27	M	II
11	MAC.PA	17.08.2021	36	M	II
12	WIE.MA	17.08.2021	52	F	II
13	LIS.AR	17.08.2021	39	M	II
14	IDZ.MA	17.08.2021	30	F	II
15	KRO.DO	17.08.2021	50	F	II
16	NOW.MA	17.08.2021	38	F	II
17	STO.KA	17.08.2021	45	F	II
18	NAP.SV	17.08.2021	40	F	II
19	POL.EL	17.08.2021	57	F	II
20	KRU.NA	17.08.2021	40	F	II
21	PIO.MI	17.08.2021	61	F	II
22	DIE.BE	17.08.2021	47	F	II
23	SIK.NA	17.08.2021	26	F	II
24	MIC.BA	17.08.2021	54	F	II
25	JER.DA	17.08.2021	54	F	II
		Min	19	No. F	Phototype I
		Max	61	20	0
		Average	38	No. M	Phototype II
				5	25
					Phototype III
					0
					Phototype IV
					0

Table 2 - Characteristics of volunteers with a negative history of allergy

No. of subject	Identification of subject	Begining of the study	Age	Sex	Phototype
1	SUC.EW	17.08.2021	56	F	II
2	KRU.JU	17.08.2021	19	F	II
3	KRZ.MA	17.08.2021	32	F	II
4	WIC.DA	17.08.2021	28	M	II
5	CIE.AL	17.08.2021	26	F	II
6	DUR.KR	17.08.2021	30	M	II
7	ROM.KI	17.08.2021	26	F	II
8	WIE.MA	17.08.2021	24	F	II
9	WIE.WI	17.08.2021	21	F	II
10	NOW.DA	17.08.2021	27	M	II
11	MAC.PA	17.08.2021	36	M	II
12	WIE.MA	17.08.2021	52	F	II
13	LIS.AR	17.08.2021	39	M	II
14	IDZ.MA	17.08.2021	30	F	II
15	KRO.DO	17.08.2021	50	F	II
16	NOW.MA	17.08.2021	38	F	II
17	STO.KA	17.08.2021	45	F	II
18	NAP.SV	17.08.2021	40	F	II
19	POL.EL	17.08.2021	57	F	II
20	KRU.NA	17.08.2021	40	F	II
21	PIO.MI	17.08.2021	61	F	II
22	DIE.BE	17.08.2021	47	F	II
23	SIK.NA	17.08.2021	26	F	II
24	MIC.BA	17.08.2021	54	F	II
25	JER.DA	17.08.2021	54	F	II
		Min	23	No. F	Phototype I
		Max	69	25	0
		Average	51	No. M	Phototype II
				0	25
					Phototype III
					0
					Phototype IV
					0

9.2 Table of skin response

Table 3 - Results for volunteers with a positive history of allergy

No.	Evaluation after 48 hours of product application		Evaluation after 72 hours of product application		Evaluation after 96 hours of product application	
Erythema	Edema	Erythema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	Examination skipped	
2	0	0	0	0	Examination skipped	
3	0	0	0	0	Examination skipped	
4	0	0	0	0	Examination skipped	
5	0	0	0	0	Examination skipped	
6	0	0	0	0	Examination skipped	
7	0	0	0	0	Examination skipped	
8	0	0	0	0	Examination skipped	
9	0	0	0	0	Examination skipped	
10	0	0	0	0	Examination skipped	
11	0	0	0	0	Examination skipped	
12	0	0	0	0	Examination skipped	
13	0	0	0	0	Examination skipped	
14	0	0	0	0	Examination skipped	
15	0	0	0	0	Examination skipped	
16	0	0	0	0	Examination skipped	
17	0	0	0	0	Examination skipped	
18	0	0	0	0	Examination skipped	
19	0	0	0	0	Examination skipped	
20	0	0	0	0	Examination skipped	
21	0	0	0	0	Examination skipped	
22	0	0	0	0	Examination skipped	
23	0	0	0	0	Examination skipped	
24	0	0	0	0	Examination skipped	
25	0	0	0	0	Examination skipped	

Table 4 - Results for volunteers with a positive history of allergy

No.	Evaluation after 48 hours of product application		Evaluation after 72 hours of product application		Evaluation after 96 hours of product application	
Erythema	Edema	Erythema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	Examination skipped	
2	0	0	0	0	Examination skipped	
3	0	0	0	0	Examination skipped	
4	0	0	0	0	Examination skipped	
5	0	0	0	0	Examination skipped	
6	0	0	0	0	Examination skipped	
7	0	0	0	0	Examination skipped	
8	0	0	0	0	Examination skipped	
9	0	0	0	0	Examination skipped	
10	0	0	0	0	Examination skipped	
11	0	0	0	0	Examination skipped	
12	0	0	0	0	Examination skipped	
13	0	0	0	0	Examination skipped	
14	0	0	0	0	Examination skipped	
15	0	0	0	0	Examination skipped	
16	0	0	0	0	Examination skipped	
17	0	0	0	0	Examination skipped	
18	0	0	0	0	Examination skipped	
19	0	0	0	0	Examination skipped	
20	0	0	0	0	Examination skipped	
21	0	0	0	0	Examination skipped	
22	0	0	0	0	Examination skipped	
23	0	0	0	0	Examination skipped	
24	0	0	0	0	Examination skipped	
25	0	0	0	0	Examination skipped	

10. Calculated Values

The following calculated values present the sum of negative reaction (erythema and edema) defined as Average Irritation Index (X_{av}).

Table 4

	Evaluation after 48 hours of product application		Evaluation after 72 hours of product application		Evaluation after 96 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema
The sum of negative reaction (the sume of classification points)	0.00	0.00	0.00	0.00	Examination skipped	
X_{av}	0.00					

11. Interpretation

The average irritation index (X_{av}) of the 25 tests was calculated. The product was then classified according to the following table:

Table 5

Average Irritation Index (xav)	Class
$X_{av} < 0.50$	Not Irritating
$0.50 \leq X_{av} < 2.00$	Slightly Irritating
$2.00 \leq X_{av} < 5.00$	Moderately Irritating
$5.00 \leq X_{av}$	Highly Irritating

12. Conclusion

The patch test study was performed under dermatological control on a group of 50 volunteers, including 25 volunteers positive history of allergy/atopy(sensitive skin). The study allows to conclude that product 21/04685/002 – Mili Pad Baby Wipes used by volunteers, that didn't report documented oversensitivity or a history of adverse reactions to individual ingredients of the tested product, is well tolerated by the skin. In the tested group of volunteers there were no irritations or allergic reactions. The product meets the requirements of compatibility test with the skin (Skin Compatibility Test) and can be classified as **NOT IRRITATING**.

Report Authorised by:

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