

**TEST REPORT No. 602217/23/INT/Z1**

Replaces the report no. 602217/23/GDA/INT

Client: <b>AescuBrands UG</b> <b>91093 Hessdorf, Im Gewerbegebiet 5</b>		Description of the sample ( <i>as per Client's declaration</i> )  SomnoSept CPAP-Reinigungstücher (SomnoSept CPAP cleaning wipes)
Sample reception date:	31.10.2023	
Test report date:	26.03.2024	

**Dermatological test - Semi-open test (25 subjects with allergological history, 25 subjects, without allergological history)**

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**THE STUDY IS 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 (formerly COLIPA) Guidelines: "Product Test Guidelines for the Assessment of Human Skin Compatibility 1997";

Cosmetics Europe – The Personal Care Association (formerly COLIPA) Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008.

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**1. BASIS OF THE STUDY**

The test sample was delivered by the Client.

The qualitative composition of the product was delivered by the Client.

The results of microbiological purity of the product provided by the Client (or the Client's declaration concerning microbiological purity) do not apply to low microbiological risk products.

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

**2. OBJECT OF THE STUDY**

<b>Parameter</b>	<b>Description</b>
Appearance	Wet wipes
Color	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 purpose of the study was to assess irritating properties (skin tolerance) of the product on a healthy adult skin, with applied patch test.

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### **5. DESCRIPTION OF VOLUNTEERS**

The volunteers (50 people) were healthy, 25 people with negative and 25 people with positive history of allergies. 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 or 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 product mentioned above in the form of squares cut out from the central part of the tested product, with the dimensions of 0.5 cm x 0.5 cm, are applied directly on the patch. At the same time, in order to guarantee objective results of the study and to exclude possible reading errors connected with dermal irritations, two control samples (control sample called "blind" and control sample containing water) are used. The dermatologist removes the patch 48 hours after the application and examines the skin reaction 30 minutes after the removal. 72 hours after the application, the dermatologist examines the skin again for a reaction. If irritations appear or persist 72 hours after the application, an additional examination takes place after 96 hours. While determining the skin reaction, 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, environmental conditions, etc.

### **7. DATE OF THE STUDY**

14.11.2023 – 17.11.2023

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**8. EVALUATION PARAMETERS**

<b>EVALUATION PARAMETERS OF SKIN REACTION</b>	
<b>Erythema</b>	<b>Classification point</b>
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
<b>Edema</b>	<b>Classification point</b>
No edema	0
Very light edema (hardly visible)	1
Light edema	2
Moderate edema (about 1mm raised skin)	3
Strong edema (extended swelling even beyond the application area)	4

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**9. RESULTS**
**9.1. CHARACTERISTICS OF VOLUNTEERS**
**Table 1**

No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype	
1	JAZ.MA	14.11.2023	43	F	II	
2	PIS.PI	14.11.2023	46	M	II	
3	KLI.JA	14.11.2023	55	F	II	
4	ADA.AN	14.11.2023	39	F	II	
5	KRZ.EW	14.11.2023	37	F	II	
6	ZAM.PA	14.11.2023	32	F	II	
7	GOL.DA	14.11.2023	20	M	II	
8	JAN.AG	14.11.2023	36	F	II	
9	ROS.WI	14.11.2023	47	F	II	
10	FAN.OL	14.11.2023	26	F	II	
11	KOC.KR	14.11.2023	54	M	II	
12	WOJ.JU	14.11.2023	24	F	II	
13	RYD.WI	14.11.2023	64	F	II	
14	PAC.NA	14.11.2023	24	F	II	
15	JAG.KA	14.11.2023	22	F	II	
16	FUS.MO	14.11.2023	28	F	II	
17	MAM.AG	14.11.2023	24	F	II	
18	KIE.MA	14.11.2023	27	F	II	
19	SER.NA	14.11.2023	27	F	II	
20	BOC.AL	14.11.2023	45	F	II	
21	ZAW.AG	14.11.2023	41	F	II	
22	KOT.AN	14.11.2023	63	M	II	
23	GAN.AG	14.11.2023	26	F	II	
24	DAW.NA	14.11.2023	24	F	II	
25	BIE.IZ	14.11.2023	34	F	II	
			<b>Min</b>	20	<b>No. F</b>	<b>phototype I</b>
			<b>Max</b>	64	21	0
			<b>Average</b>	36	<b>No. M</b>	<b>phototype II</b>
					4	25
						<b>phototype III</b>
						0
						<b>phototype IV</b>
						0

Table 1. Characteristics of volunteers with negative history of allergies

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**Table 2**

No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype
1	KIE.OL	14.11.2023	43	F	II
2	BAR.KA	14.11.2023	44	F	II
3	SKU.IW	14.11.2023	45	F	II
4	CIE.MA	14.11.2023	62	F	II
5	JAG.MA	14.11.2023	63	F	II
6	PIA.DA	14.11.2023	59	F	II
7	GAN.MA	14.11.2023	59	F	II
8	SOS.AG	14.11.2023	34	F	II
9	ARB.LU	14.11.2023	45	F	II
10	KWI.BO	14.11.2023	68	F	II
11	WYS.BE	14.11.2023	35	F	II
12	KOR.DO	14.11.2023	48	F	II
13	ROZ.AG	14.11.2023	41	F	II
14	SLE.AG	14.11.2023	46	F	II
15	DUD.IR	14.11.2023	67	F	II
16	ZAL.IZ	14.11.2023	45	F	II
17	TAR.AG	14.11.2023	58	F	II
18	SZY.UR	14.11.2023	37	F	II
19	GAJ.IZ	14.11.2023	43	F	II
20	BOV.TA	14.11.2023	54	F	II
21	GLA.KA	14.11.2023	29	F	II
22	OKU.AG	14.11.2023	51	F	II
23	TRO.MA	14.11.2023	44	F	II
24	MAN.MA	14.11.2023	48	F	II
25	MAR.DO	14.11.2023	66	F	II
		<b>Min</b>	29	<b>No. F</b>	<b>phototype I</b>
		<b>Max</b>	68	25	0
		<b>Average</b>	49	<b>No. M</b>	<b>phototype II</b>
				0	25
					<b>phototype III</b>
					0
					<b>phototype IV</b>
					0

Table 2. Characteristics of volunteers with positive history of allergies



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### 9.2. TABLE OF SKIN RESPONSE

**Table 3**

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	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 3. Results for volunteers with negative history of allergies

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**Table 4**

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	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 positive history of allergies

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### 10. CALCULATED VALUES

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

	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
<b>The sum of negative reaction (the sum of classification points)</b>	0.00	0.00	0.00	0.00	Examination skipped	
<b><math>X_{av}</math></b>	0.00					

### 11. INTERPRETATION

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

<b>Average irritation index (<math>x_{av}</math>)</b>	<b>Class</b>
$X_{av} < 0.50$	Non 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

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**12. CONCLUSION**

The patch test study was performed under dermatological control on a group of 50 volunteers, including 25 volunteers with positive history of allergies/atopy (sensitive skin). The study allows to conclude that product SomnoSept CPAP-Reinigungstücher (SomnoSept CPAP cleaning wipes) used by volunteers, who 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 NON IRRITATING.

**13. IDENTIFICATION OF THE CHANGES**

Dermatological test - Semi-open test (25 subjects with allergological history, 25 subjects, without allergological history)

Identification of the change: customer data

Identification of the change: sample name

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**14. SIGNATURES**

<b>Technician</b>	<b>Natalia Dawidowicz</b>	
<b>Dermatologist - venereologist</b>	<b>Berenika Olszewska (2880077)</b>	
<b>Project Manager</b>	<b>Karolina Milewska</b>	

The Client is responsible for conformity with the declared quality composition as well as microbiological purity of the delivered samples.

**Attention:** The released opinion of dermatological compatibility does not apply to people who are allergic to any ingredient of the tested product.

Prepared by: Natalia Dawidowicz, Technician  
Supervising dermatologist: Berenika Olszewska, MD, 2880077  
Authorized by: Karolina Milewska, Project Manager (qualified electronic signature)

Laboratory: ul. Bajana 3D, 80-463 Gdańsk

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**THE END OF THE REPORT**