TEST REPORT

LAB LOCATION:TURKEY
LAB NO. : (7220)162-0099 REVISION
SERVICE TYPE: REGULAR
DATE IN: June 10th, 2020
DATE OUT: June 18th, 2020
REVISION DATE: July 14th, 2020

MATERIAL SUBMITTED	:	HAYAT KİMYA SAN. TİC. A.Ş.
SUPPLIER REFERENCE	:	/
BUYER	:	/
MANUFACTURER	:	HAYAT KİMYA SAN. TİC. A.Ş.
COUNTRY OF ORIGIN	:	TURKEY
COUNTRY OF DESTINATION	:	/
SAMPLE DESCRIPTION	:	GOODCARE 175x95 mm MASK
COLOR	:	/
SUBMITTED CARE INSTRUCTION	:	/
GENERAL CONCLUSION	:	**PASS**

SUMMARY OF TEST RESULTS

TESTS REQUIRED	Sample A
Total Viable Count	P
Total Aerobic Mesophilic Bacteria	P
Yeast and Moulds	P
Escherichia coli	P
Staphylococcus aureus	P
Pseudomonas aeruginosa	P
Candida albicans	P
Dermatological Test for Hypoallergenic Product	P
Dermatological Test	P

REMARKS

1	**:**	P: Pass, F: Fail, DATA: No Evaluation
2	**:**	The reported expanded uncertainty is based on the standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95%. Unless otherwise is specified, the uncertainty of measurement has not been taken into account when assessing pass/fail of the sample against the requirements of the standard. In case consideration of measurement uncertainties when assessing pass/ fail limits, some results may be in borderline.
3	**:**	The test result, the uncertainties (if applicable) with confidence probability are given on the following pages which are part of this report.
4	**:**	Test reports without authorised signatures are invalid.
5	**:**	Conclusions are based on the test result from the actual sampling of the received sample(s).

BV CPS TEST LABORATUVARLARI LTD. STI.
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REMARK 1: 72201620099 test report dated June 18th, 2020 is not valid, it is replaced by this report 72201620099 REVISION.

REMARK 2: "Dermatological Test for Hypoallergenic Product and Dermatological Test" analysis have been performed by subcontracted laboratory.

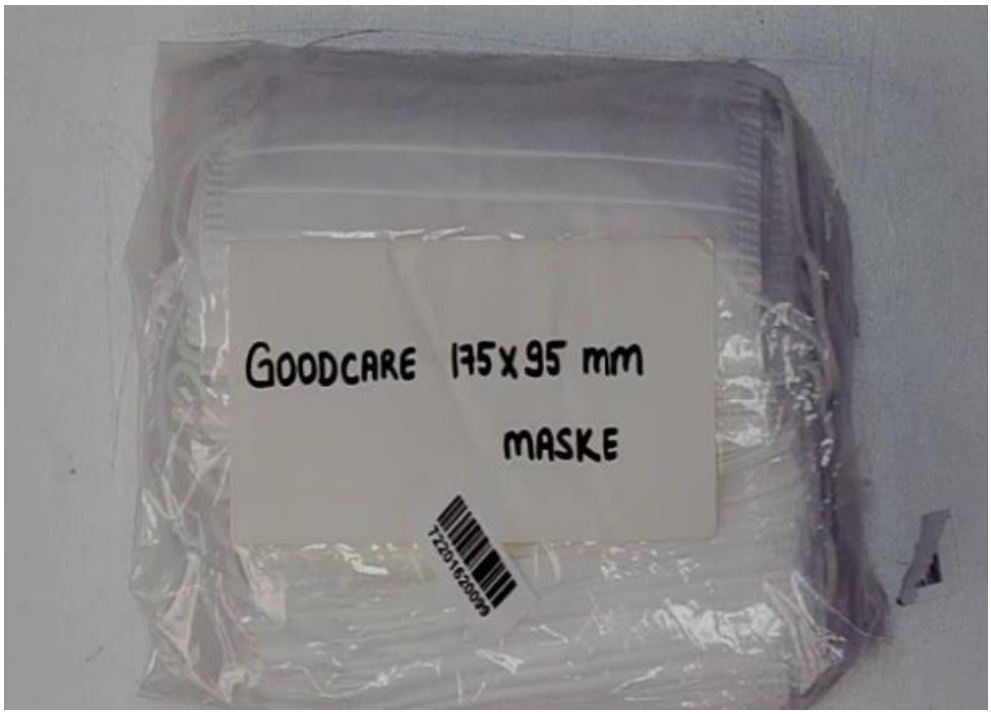
EXECUTIVE SUMMARY: Only vendor selected tests have been performed and submitted samples have been rated as "**PASS**".

Bureau Veritas Consumer Products Services Turkey
BV CPS Test Lab. Ltd. Sti.

Eylem Yaldizli
Senior Client Team Lead -Hardline

Yagiz Barin
Hardline & Pharma Lab. Manager

-Photo of the Submitted Sample-

Sample A


TEST RESULT

Total Viable Count		
Results (cfu/g or cfu/mL)		
I001		
Test Method :	With reference to TS EN ISO 21149:2017	
Tested Item	**Result (cfu/g or cfu/mL)**	
Aerobic Mesophilic Bacteria	<10	
Test Method :	With reference to TS EN ISO 16212:2017	
Tested Item	**Result (cfu/g or cfu/mL)**	
Yeast and Mould	<10	
Total Viable Count (Aerobic Mesophilic Bacteria + Yeast and Mould)	<10	
Permissible Limit(s):	Category I: 10^2 cfu/g or 10^2 cfu/mL for Total Viable Count (Aerobic Mesophilic Bacteria + Yeast and Mould) Category II: 10^3 cfu/g or 10^3 cfu/mL for Total Viable Count (Aerobic Mesophilic Bacteria + Yeast and Mould)	
Conclusion:	**Pass**	
Remark(s):	**1.**	Permissible Limit is according to TURKISH MEDICINES AND MEDICAL DEVICES AGENCY (TMMDA), Guidance on microbiological control of cosmetic products.
	2.	Category I: Products for children under 3 age, for products intended use for eye area and for mucose membrane. Category II: Other products.

Yeast and Mould			
Test Method :	With reference to TS EN ISO 16212:2017		
	Result (cfu/g)		
Tested Item	**A**		**Conclusion**
Yeast and Mould	<10		**Pass**
Permissible Limit(s):	Category I: 10^2 cfu/g or 10^2 cfu/mL Category II: 10^3 cfu/g or 10^3 cfu/mL		
Remark(s):	1.	Permissible Limit is according to TURKISH MEDICINES AND MEDICAL DEVICES AGENCY (TMMDA), Guidance on microbiological control of cosmetic products.	
	2.	Category I defines products for children under 3 age, for products intended use for eye area and for mucose membrane. Category II defines other products.	

Aerobic Mesophilic Bacteria			
Test Method :	With reference to TS EN ISO 21149:2017		
	Result(cfu/g)		
Tested Item	**A**		**Conclusion**
Aerobic Mesophilic Bacteria	<10		**Pass**
Permissible Limit(s):	Category I: 10^2 cfu/g or 10^2 cfu/mL Category II: 10^3 cfu/g or 10^3 cfu/mL		
Remark(s):	1.	Permissible Limit is according to TURKISH MEDICINES AND MEDICAL DEVICES AGENCY (TMMDA), Guidance on microbiological control of cosmetic products.	
	2.	Category I defines products for children under 3 age, for products intended use for eye area and for mucose membrane. Category II defines other products.	

Escherichia coli			
Test Method :	With reference to TS EN ISO 21150:2015		
Result			
Tested Item	**I001**		**Conclusion**
Escherichia coli	Not Detected		**Pass**
Permissible Limit(s):	Category I: Should not be detected. Category II: Should not be detected.		
Remark(s):	**1.**	Permissible Limit is according to TURKISH MEDICINES AND MEDICAL DEVICES AGENCY (TMMDA), Guidance on microbiological control of cosmetic products.	
	2.	Category I: Products for children under 3 age, for products intended use for eye area and for mucose membrane. Category II: Other products.	

Staphylococcus aureus			
Test Method :	With reference to TS EN ISO 22718:2015		
Result			
Tested Item	**I001**		**Conclusion**
Staphylococcus aureus	Not Detected		**Pass**
Permissible Limit(s):	Category I: Should not be detected. Category II: Should not be detected.		
Remark(s):	**1.**	Permissible Limit is according to TURKISH MEDICINES AND MEDICAL DEVICES AGENCY (TMMDA), Guidance on microbiological control of cosmetic products.	
	2.	Category I: Products for children under 3 age, for products intended use for eye area and for mucose membrane. Category II: Other products.	

Pseudomonas aeruginosa			
Test Method :	With reference to TS EN ISO 22717:2015		
Result			
Tested Item	**I001**		**Conclusion**
Pseudomonas aeruginosa	Not Detected		**Pass**
Permissible Limit(s):	Category I: Should not be detected. Category II: Should not be detected.		
Remark(s):	**1.**	Permissible Limit is according to TURKISH MEDICINES AND MEDICAL DEVICES AGENCY (TMMDA), Guidance on microbiological control of cosmetic products.	
	2.	Category I: Products for children under 3 age, for products intended use for eye area and for mucose membrane. Category II: Other products.	

Candida albicans			
Test Method :	With reference to TS EN ISO 18416:2015		
Result			
Tested Item	**I001**		**Conclusion**
Candida albicans	Not Detected		**Pass**
Permissible Limit(s):	Category I: Should not be detected. Category II: Should not be detected.		
Remark(s):	**1.**	Permissible Limit is according to TURKISH MEDICINES AND MEDICAL DEVICES AGENCY (TMMDA), Guidance on microbiological control of cosmetic products.	
	2.	Category I: Products for children under 3 age, for products intended use for eye area and for mucose membrane. Category II: Other products.	

TEST RESULTS

DERMATOLOGICAL TEST for HYPOALLERGENIC PRODUCT

1. BASIS OF TEST IMPLEMENTATION

- Order received on June 15th, 2020 with the assigned number 15/06/20/D/3
- Samples of the product delivered by the Principal
- Confirmation of positive results of microbiological researches – attached by the Principal

Requirements for hypoallergenic products:

- No substances classified by SCCS (or other committee) as sensitizing / causing allergy
- Suitable pH (close to the skin pH)
- No substances identified as sensitizers by the SCCS or former committees assessing the safety of cosmetic ingredients
- No substances identified as skin sensitizers by other official risk assessment committees
- No substances falling under the classification of skin sensitizers of category 1, sub-category 1A or sub-category 1B, on the basis of new criteria set by the CLP Regulation
- No substances identified by the company on the basis of the assessment of consumer complaints
- No substances generally recognized as sensitizers in scientific literature
- No substances for which relevant data on their sensitizing potential are missing

*Responsibility in fulfilling those requirements lies with the Manufacturer

2. PRODUCT DESCRIPTION

- PACKAGING: plactic
- APPEARANCE: fabric
- FRAGRANCE: in accordance with the composition

3. PRODUCT USE

The product is intended for face protection.

4. PURPOSE OF THE RESEARCH

Dermatological safety assessment of the product – evaluation of the potential irritant and sensitizing properties.

5. LEGAL BASE OF THE RESEARCH:

- Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 of November 30, 2009, relating to cosmetic products.
- Cosmetics Europe- The Personal Care Association Guidelines „Product test Guidelines for the Assessment of Human Skin Compatibility 1997"
- WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (1964r. and later changes)

6. PROBAND SELECTION

Probands taking part in the study were selected on the bases of:

- The current Polish and European law
- COLIPA Guidelines
- Declaration of Helsinki (1964) *(with later additions)*

30 women, aged 17 – 53 years, with sensitive, problematic, dry skin were selected for the dermatological tests of the product. All of the probands selected for testing met the requirements for inclusion in the study, signed an agreement to participate in the study and were informed about: the purpose of the study, how it is carried out and what are the possible side effects. During the tests all the probands were under constant dermatological care.

TEST RESULTS

7. METHODS AND DESCRIPTION OF RESEARCH

Dermatological tests were performed in accordance with the COLIPA Guideless for the Assessment of Human Skin Compatibility 1997". Test has been conducted on group of 30 individuals using **h-RIPT (Human Repeated Insult Patch Test)** model. Reading the tests and results registration has been done in accordance with the recommendations of the International Contact Dermatitis Research Group (ICDRG).
A small piece of product was applied to patients forearm using patch test through 3 following days and then removed. Baseline readings were recorded half an hour after removal to let erythema from patches and tape (if any) to settle down. Additional readings was performed after one week for products that may show delayed reactions.. Readings evaluation was done according to graphic scale which was consistent with generally accepted clinical dermatological scale.

8. DURATION OF RESEARCH

All the tests and analysis of their results were conducted from June 22nd, 2020 to July 06th, 2020. Tests were completed by all enrolled people.

RESULTS

No.	Identification number	Sex	Age	Test result			
				after 1-st application	after 2-nd application	after 3-rd application	after one week from 1-st application
1	15/06/20/D/3-1	M	32	(-)	(-)	(-)	(-)
2	15/06/20/D/3-2	F	32	(-)	(-)	(-)	(-)
3	15/06/20/D/3-3	M	51	(-)	(-)	(-)	(-)
4	15/06/20/D/3-4	F	49	(-)	(-)	(-)	(-)
5	15/06/20/D/3-5	F	57	(-)	(-)	(-)	(-)
6	15/06/20/D/3-6	F	36	(-)	(-)	(-)	(-)
7	15/06/20/D/3-7	F	33	(-)	(-)	(-)	(-)
8	15/06/20/D/3-8	F	26	(-)	(-)	(-)	(-)
9	15/06/20/D/3-9	F	51	(-)	(-)	(-)	(-)
10	15/06/20/D/3-10	F	27	(-)	(-)	(-)	(-)
11	15/06/20/D/3-11	F	27	(-)	(-)	(-)	(-)
12	15/06/20/D/3-12	F	27	(-)	(-)	(-)	(-)
13	15/06/20/D/3-13	F	20	(-)	(-)	(-)	(-)
14	15/06/20/D/3-14	F	71	(-)	(-)	(-)	(-)
15	15/06/20/D/3-15	M	26	(-)	(-)	(-)	(-)
16	15/06/20/D/3-16	F	55	(-)	(-)	(-)	(-)
17	15/06/20/D/3-17	F	30	(-)	(-)	(-)	(-)
18	15/06/20/D/3-18	M	30	(-)	(-)	(-)	(-)
19	15/06/20/D/3-19	F	31	(-)	(-)	(-)	(-)
20	15/06/20/D/3-20	F	30	(-)	(-)	(-)	(-)
21	15/06/20/D/3-21	F	29	(-)	(-)	(-)	(-)
22	15/06/20/D/3-22	F	32	(-)	(-)	(-)	(-)
23	15/06/20/D/3-23	F	27	(-)	(-)	(-)	(-)
24	15/06/20/D/3-24	F	54	(-)	(-)	(-)	(-)
25	15/06/20/D/3-25	F	25	(-)	(-)	(-)	(-)
26	15/06/20/D/3-26	F	26	(-)	(-)	(-)	(-)
27	15/06/20/D/3-27	F	24	(-)	(-)	(-)	(-)
28	15/06/20/D/3-28	F	56	(-)	(-)	(-)	(-)
29	15/06/20/D/3-29	F	26	(-)	(-)	(-)	(-)
30	15/06/20/D/3-30	F	60	(-)	(-)	(-)	(-)

F – female
M – male

TEST RESULTS

BEFORE	DURING	AFTER
		

INTERPRETATION OF PATCH TEST

Reading the test and writing their results have been done in accordance with the recommendations of the International Contact Dermatitis Research Group (ICDRG).

Record	Diagnosis	Interpretation
-	Negative reaction	No skin lesions
?	Doubtful reaction	Faint erythema only
+	Weak positive reaction	Palpable erythema, infiltration, possibly papules
++	Strong positive reaction	Erythema, infiltration, papules, vesicles
+++	Extreme positive reaction	Intense erythema, infiltration and coalescing vesicles , bullous or ulcerative reaction
IR	Irritant reaction of different types	Discrete patchy erythema without infiltration.

?	+	++	+++	IR
				
Doubtful reaction	Weak positive reaction	Strong positive reaction	Extreme positive reaction	Irritant reaction of different types

TEST RESULTS

RESULT:

None of 30 people, who were exposed to Patch Testing have shown positive reactions during the test reading.

CONCLUSION:

Tested product

FACE MASK - 72201620099

does not exhibit any allergic or/and irritating properties.

Published opinion does not concern people who are allergic to ingredients of the tested product.

TEST RESULTS

DERMATOLOGICAL TEST

1. BASIS OF TEST IMPLEMENTATION

- Order received on June 15th, 2020 with the assigned number 15/06/20/D/3
- Samples of the product delivered by the Principal
- Confirmation of positive results of microbiological researches – attached by the Principal

2. PRODUCT DESCRIPTION

- PACKAGING: plastic packaging
- APPEARANCE: fabric
- FRAGRANCE: in accordance with the composition

3. PRODUCT USE

The product is intended for face protection.

4. PURPOSE OF THE RESEARCH

Dermatological safety assessment of the product – evaluation of the potential irritant and sensitizing properties.

5. LEGAL BASE OF THE RESEARCH:

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6. PROBAND SELECTION

Probands taking part in the study were selected on the bases of:

- The current Polish and European law
- COLIPA Guidelines
- Declaration of Helsinki (1964) *(with later additions)*

30 women and 5 men, aged 20 – 80 years with dry, sensitive and problematic skin were selected for the dermatological tests of the product. All of the probands selected for testing met the requirements for inclusion in the study, signed an agreement to participate in the study and were informed about: the purpose of the study, how it is carried out and what are the possible side effects. During the tests all the probands were under constant dermatological care.

7. METHODS AND DESCRIPTION OF RESEARCH

Dermatological tests were performed in accordance with the COLIPA Guideless for the Assessment of Human Skin Compatibility 1997". Test has been conducted on group of 30 individuals using Jodassohn-Bloch model (with Rudzki modifications). Reading the tests and results registration has been done in accordance with the recommendations of the International Contact Dermatitis Research Group (ICDRG).

Standard IQ chambers were used for patch testing. A small piece of product was applied to patients forearm for 48 hours and then removed. Baseline readings were recorded 30 minutes after removal of product from skin. Additional readings were performed after 72, 96 hours and one week after test application for product to show delayed reactions. Readings evaluation was done according to graphic scale which was consistent with generally accepted clinical dermatological scale.

TEST RESULTS

8. DURATION OF RESEARCH

All the tests and analysis of their results were conducted from June 22nd, 2020 to July 06th, 2020. Tests were completed by all enrolled people.

RESULTS

No.	Identification number	Sex	Age	Test result			
				48 h	72 h	96 h	one week
1	15/06/20/D/3-1	F	29	(-)	(-)	(-)	(-)
2	15/06/20/D/3-2	F	56	(-)	(-)	(-)	(-)
3	15/06/20/D/3-3	F	80	(-)	(-)	(-)	(-)
4	15/06/20/D/3-4	F	56	(-)	(-)	(-)	(-)
5	15/06/20/D/3-5	F	30	(-)	(-)	(-)	(-)
6	15/06/20/D/3-6	M	32	(-)	(-)	(-)	(-)
7	15/06/20/D/3-7	M	58	(-)	(-)	(-)	(-)
8	15/06/20/D/3-8	F	56	(-)	(-)	(-)	(-)
9	15/06/20/D/3-9	F	31	(-)	(-)	(-)	(-)
10	15/06/20/D/3-10	M	30	(-)	(-)	(-)	(-)
11	15/06/20/D/3-11	F	30	(-)	(-)	(-)	(-)
12	15/06/20/D/3-12	M	27	(-)	(-)	(-)	(-)
13	15/06/20/D/3-13	F	24	(-)	(-)	(-)	(-)
14	15/06/20/D/3-14	F	54	(-)	(-)	(-)	(-)
15	15/06/20/D/3-15	F	51	(-)	(-)	(-)	(-)
16	15/06/20/D/3-16	F	20	(-)	(-)	(-)	(-)
17	15/06/20/D/3-17	F	26	(-)	(-)	(-)	(-)
18	15/06/20/D/3-18	F	26	(-)	(-)	(-)	(-)
19	15/06/20/D/3-19	F	24	(-)	(-)	(-)	(-)
20	15/06/20/D/3-20	M	51	(-)	(-)	(-)	(-)
21	15/06/20/D/3-21	F	49	(-)	(-)	(-)	(-)
22	15/06/20/D/3-22	F	24	(-)	(-)	(-)	(-)
23	15/06/20/D/3-23	F	55	(-)	(-)	(-)	(-)
24	15/06/20/D/3-24	F	51	(-)	(-)	(-)	(-)
25	15/06/20/D/3-25	F	26	(-)	(-)	(-)	(-)
26	15/06/20/D/3-26	F	26	(-)	(-)	(-)	(-)
27	15/06/20/D/3-27	F	27	(-)	(-)	(-)	(-)
28	15/06/20/D/3-28	F	27	(-)	(-)	(-)	(-)
29	15/06/20/D/3-29	F	27	(-)	(-)	(-)	(-)
30	15/06/20/D/3-30	F	27	(-)	(-)	(-)	(-)

F – female
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TEST RESULTS

BEFORE	DURING	AFTER
		

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FACE MASK - 72201620099

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-END OF REPORT-