NATIONAL INSTITUTE OF PUBLIC HEALTH
Šrobárova 48
Praha 10
100 42
Czech Republic

YOUR REFERENCE:
DATE: **9.4.2020**
OUR REFERENCE: **SZÚ4399/2020**
CTZB 187-4399/20-131
EX 200477

CityZen s.r.o.

Resselovo náměstí 4
537 01 Chrudim

PHONE/FAX:
E-MAIL: **RNDr. M. Rucki, PhD.**
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Date: **30.4.2020**

Subject: EXPERT OPINION on health safety of Antibacterial Medical Face Masks Blanka and Hanka.

SUBJECT OF APPLICATION:
Regarding your application from 9.4.2020 for evaluation of health safety of Antibacterial Medical Face Masks Blanka and Hanka according to the requirements of Act No.102/2001 Coll., on general safety of products, in current wording, we hereby notify:

SUBMITTED SAMPLE: **1. Antibacterial Medical Face Masks Blanka**
2. Antibacterial Medical Face Masks Hanka

Manufacturer: CityZen s.r.o., Resselovo náměstí 4, 537 01 Chrudim, Czech Republic

SUBMITTED DOCUMENTATION:
Warning for consumers: WASH AND IRON BEFORE FIRST USE!

PERFORMED TESTS:
Chemical analyses (Determination of pH of aqueous extracts according to ČSN EN ISO 3071, Determination of free and hydrolysed formaldehyde ČSN EN ISO 14184-1, Determination of aromatic amines derived from azo colorants ČSN 621156) and the Tests for human skin compatibility (Cosmetic Product Test Guidelines for Assessment of Human Skin Compatibility, Colipa, Bruxelles 1997, COLIPA = The European Cosmetic, Toiletry and Perfumery Association) were performed by the Accredited Laboratory No. 1206, accredited by ČIA, Centre of Toxicology and Health Safety. The analyses were performed in the scope of the Method Guideline SZÚ No. 1/200 for the evaluation of products coming into direct contact with human skin and/or mucous membranes (AHEM No. 3/2000).

The submitted sample was used up for the purpose of testing.

EXPERT OPINION:
The subject of evaluation was the determination of possible adverse biological effects of the material when coming into contact with human skin.
The value of pH is in the range safe for direct contact with human skin.

The amount of free and hydrolysed formaldehyde is under the detection limit of used method.
The amount of primary aromatic amines is under the detection limit of used method.
Evaluation of the human skin compatibility showed no evidence of primary skin irritation.

CONCLUSION:
Based on the analysis of submitted documentation, on the results of chemical analyses, microbiological testing of SCU and human skin compatibility, we come to the conclusion that the above mentioned **Antibacterial Medical Face Masks** are safe for human health when coming into contact with skin (after washing). The products comply with the safety requirements of Act No. 102/2001 Coll., on general safety of products, and Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment on general safety of products, in current wording.
The function of the product was not the aim of our testing.

This opinion refers solely to the submitted samples and the conclusions from its evaluation may be applied only to other products of the same type, which have identical composition and parameters as the samples tested in our laboratories.

National Institute of Public Health
Centre of Toxicology and Health Safety
Šrobárova 49/48, 100 00 Praha 10
Czech Republic

Dagmar Jírová, M.D.Ph.D.
Head of the Centre of Toxicology and Health Safety

ANNEXES:
Test Report on chemical analysis No. CTZB 187-4399/20-131
Test Report on evaluation of human skin compatibility No. CTZB 187-4399/20-131

TEST REPORT
CHEMICAL ANALYSES

National Reference Centre for Cosmetics
Testing Laboratory No. 1206, accredited by Czech Accreditation Institute
National Institute of Public Health, Centre of Health and Living Conditions
Šrobárova 48, 100 42 Prague 10

Sponsor: **CityZen s.r.o., Resselovo náměstí 4, 537 01 Chrudim, Czech Republic**

No. of study: **CTZB 187-4399/20-131**
Date of study: **20. 4. – 28. 4. 2020**

Samples identification: **1. Antibacterial Medical Face Masks Blanka**
2. Antibacterial Medical Face Masks Hanka

Manufacturer: **CityZen s.r.o., Resselovo náměstí 4, 537 01 Chrudim, Czech Republic**

CHEMICAL ANALYSES

Evaluated parameters:

Determination of pH of aqueous extracts
ČSN EN ISO 3071
Equipment: inoLab pH Level 1

Determination of free and hydrolysed formaldehyde
ČSN EN ISO 14184-1
Equipment: VARIAN CARY 1E

Determination of aromatic amines derived from azo colorants
Extract: 37 °C ±2 °C. 24 h., 100 cm^2 to 100 ml (2 g to 100 ml for foam material)
ČSN EN ISO 14184-1
Equipment: VARIAN CARY 1E

Results:

No. of sample: 1. Antibacterial Medical Face Masks Blanka white part				
test	**measured value**	**unit**	**uncertainty**	**limit**
chemical analyses				
pH extractant	5.3	-	± 0.1	5.0 - 7.5
pH	6.2	-	± 0.1	4.0 – 7.5
formaldehyd	<20*	$mg.kg^{-1}$	± 8 %	75

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No. of sample: 1. Antibacterial Medical Face Masks Blanka green part				
test	**measured value**	**unit**	**uncertainty**	**limit**
chemical analyses				
pH extractant	5.3	-	± 0.1	5.0 - 7.5
pH	6.4	-	± 0.1	4.0 – 7.5
formaldehyd	<20*	$mg.kg^{-1}$	± 8 %	75
primary aromatic amines	< 0,03*	$mg.l^{-1}$(calculated for anilinhydrochloride)	± 15 %	0,05

No. of sample: 2. Antibacterial Medical Face Masks Hanka white part				
test	**measured value**	**unit**	**uncertainty**	**limit**
chemical analyses				
pH extractant	5.3	-	± 0.1	5.0 - 7.5
pH	6.2	-	± 0.1	4.0 – 7.5
formaldehyd	<20*	$mg.kg^{-1}$	± 8 %	75

No. of sample: 2. Antibacterial Medical Face Masks Hanka green part				
test	**measured value**	**unit**	**uncertainty**	**limit**
chemical analyses				
pH extractant	5.3	-	± 0.1	5.0 - 7.5
pH	6.4	-	± 0.1	4.0 – 7.5
formaldehyd	<20*	$mg.kg^{-1}$	± 8 %	75
primary aromatic amines	< 0,03*	$mg.l^{-1}$(calculated for anilinhydrochloride)	± 15 %	0,05

* values lower than limit of detection

The analyses were performed in the scope of the Method Guideline SZÚ No. 1/200 for the evaluation of products coming into direct contact with human skin and/or mucous membranes (AHEM No. 3/2000).

Date: 28.4.2020
Principal investigator: RNDr. Marian Rucki, PhD.

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TEST REPORT
EVALUATION OF HUMAN SKIN COMPATIBILITY

Testing facility: National Reference Center for Cosmetics, National Institute of Public Health, Šrobárova 49/48, 100 00 Prague 10, Czech Republic.

Date of study: 28.4. - 30.4.2020
Study performance: Hana Bendová, M.Sc., Ph.D.
Reference Number: CTZB 187-4399/20-131

The test was carried out in compliance with: Tests for human skin compatibility (Cosmetic Product Test Guidelines for Assessment of Human Skin Compatibility, Colipa, Bruxelles 1997, COLIPA = The European Cosmetic, Toiletry and Perfumery Association).

Aim of the study: Assessment of the potential of the test material to produce dermal irritation.

MATERIALS AND METHODS

TM 1: Textile material - green colour
Antibacterial Medical Face Masks Blanka
Antibacterial Medical Face Masks Hanka

TM 2: Textile material - white colour
Antibacterial Medical Face Masks Blanka
Antibacterial Medical Face Masks Hanka

Sponsor: **CityZen s.r.o.,**
Resselovo náměstí 4
537 01 Chrudim
Czech Republic

REPARATION OF MATERIALS FOR TESTING

TM 1: Applied directly on skin (2.5 x 2.5 cm).
TM 2: Applied directly on skin (2.5 x 2.5 cm).

PARTICIPANTS IN THE STUDY

The selection of volunteers and the test methods complied with the Declaration of Helsinki (1964) and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS, 2002). The study was approved by the Ethical Review Committee of the National Institute of Public Health.

The volunteers were selected on the basis of inclusion and non-inclusion criteria and for this purpose filled in a special form. The volunteers were clearly informed regarding the nature of the study, timetable, constraints and possible risks. They gave their written informed consent before participation in the study. All the

documentation is strictly confidential. 15 healthy volunteers with sensitive skin took part in the study.

Table 1: Demographic data

Subject Number	Subject Initials	Age	Gender
1	PJ	29	M
2	AT	57	M
3	SM	48	F
4	PM	53	F
5	LT	53	F
6	HI	42	F
7	VK	56	F
8	UJ	52	F
9	LJ	42	F
10	VA	53	F
11	TJ	56	F
12	JL	59	F
13	ŠE	61	F
14	NI	59	F
15	HM	52	F

Test procedure
single application closed patch epicutaneous test under semiocclusion

Single application closed patch epicutaneous test

The test materials TM 1 and TM 2 were applied in semiocclusion on the upper back. The duration of treatment was 4 h. The test substances were removed by rinsing and gentle swabbing. The reactions were assessed 30 min. after patch removal, then after 24 h and 48 h.
Semi-occlusive: Curatest (Lohmann / Rauscher)

Table 2: Classification system for skin reactions

Reaction	Numerical grading
Erythema	0
No evidence of erythema	0.5
Minimal or doubtful erythema	1
Slight redness, spotty and diffuse	2
Moderate, uniform redness	3
Strong uniform redness	4
Fiery redness	

Dryness (Scaling)	
No evidence of scaling	0
Dry without scaling; appears smooth and taunt	0.5
Fine/mild scaling	1
Moderate scaling	2
Severe scaling with large flakes	3
Oedema	
absence of oedema	-
presence of oedema	+

RESULTS

No erythema, oedema, dryness or any other adverse skin reactions were detected in any of the reading intervals.

Skin reaction are recorded in the Annex I.

ASSESSMENT OF RESULTS

Textile material - green colour
Antibacterial Medical Face Masks Blanka
Antibacterial Medical Face Masks Hanka

The product was dermatologically tested evaluating the human skin compatibility. It is our considered opinion that results of the patch test study showed no evidence of primary skin irritation for healthy skin.

Textile material - white colour
Antibacterial Medical Face Masks Blanka
Antibacterial Medical Face Masks Hanka

The product was dermatologically tested evaluating the human skin compatibility. It is our considered opinion that results of the patch test study showed no evidence of primary skin irritation for healthy skin.

Date of report: 30.4.2020

Study performance: Hana Bendová, M.Sc., Ph.D.

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Annex I

Table 3: TM 1

Subject No.	Observation time/Skin reaction								
	30 min. after patch removal			24 h after patch removal			48 h after patch removal		
	Erythema	Dryness	Oedema	Erythema	Dryness	Oedema	Erythema	Dryness	Oedema
1	0	0	-	0	0	-	0	0	-
2	0	0	-	0	0	-	0	0	-
3	0	0	-	0	0	-	0	0	-
4	0	0	-	0	0	-	0	0	-
5	0	0	-	0	0	-	0	0	-
6	0	0	-	0	0	-	0	0	-
7	0	0	-	0	0	-	0	0	-
8	0	0	-	0	0	-	0	0	-
9	0	0	-	0	0	-	0	0	-
10	0	0	-	0	0	-	0	0	-
11	0	0	-	0	0	-	0	0	-
12	0	0	-	0	0	-	0	0	-
13	0	0	-	0	0	-	0	0	-
14	0	0	-	0	0	-	0	0	-
15	0	0	-	0	0	-	0	0	-

Table 4: TM 2

Subject No.	Observation time/Skin reaction								
	30 min. after patch removal			24 h after patch removal			48 h after patch removal		
	Erythema	Dryness	Oedema	Erythema	Dryness	Oedema	Erythema	Dryness	Oedema
1	0	0	-	0	0	-	0	0	-
2	0	0	-	0	0	-	0	0	-
3	0	0	-	0	0	-	0	0	-
4	0	0	-	0	0	-	0	0	-
5	0	0	-	0	0	-	0	0	-
6	0	0	-	0	0	-	0	0	-
7	0	0	-	0	0	-	0	0	-
8	0	0	-	0	0	-	0	0	-
9	0	0	-	0	0	-	0	0	-
10	0	0	-	0	0	-	0	0	-
11	0	0	-	0	0	-	0	0	-
12	0	0	-	0	0	-	0	0	-
13	0	0	-	0	0	-	0	0	-
14	0	0	-	0	0	-	0	0	-
15	0	0	-	0	0	-	0	0	-