

Analytical Report Nr.

AR-21-YL-009469-01

Sample code Nr.

560-2021-00009546

Date

13/09/2021

ANALYTICAL REPORT**Client Information**

APPAREL SUPPLY LIMITED
Azzurri House Kilcohan Waterford City
Waterford UNITED KINGDOM

corinna.dower@apparelsupply.ie

For the attention of CORINNA DOWER

Sample Information

Order Code: EUAA70-00013437
Reception Date: 25-Aug-2021
Analysis Starting Date: 25-Aug-2021
Analysis Ending Date: 13-Sep-2021
Sample code Nr. 560-2021-00009546
Sample described as: Masks

Requirements and decision rule

Customer requirements: EN 14683:2019+AC:2019 TYPE IIR
Decision Rule: Shared risk - Simple acceptance. Probability of False Acceptance <50%

Information provided by the customer(2)

Client Reference: DM050
Sample Description:
Purchase Order Number:

Batch 210800

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SAMPLE PICTURE



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CONCLUSION:

TEST PROPERTY	PASS	FAIL	REMARKS
● Bacterial Filtration Efficiency (BFE) EN 14683:2019+AC:2019 Annex B			
A	X		
● Microbial cleanliness (bioburden) EN ISO 11737-1:2018			
A	X		
Breathability (Differential Pressure) EN 14683:2019+AC:2019 Annex C			
A	X		
Resistance against penetration by synthetic blood ISO 22609:2004			
A	X		
■ Biocompatibility ISO 10993			
A	X		

Remark: Test has been performed as per application request

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COMPONENT LIST:

COMPONENT ID	COMPONENT NAME	MATERIAL DESCRIPTION	COLOR	REMARKS
CUST 01	A	Mask	Blue	---

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MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES
---------------	---------	---------	------	-----	------------

Analyses on:A

• **Microbial cleanliness (bioburden)**

Analysis Ending Date: 13/09/2021

EN ISO 11737-1:2018

Bioburden	<30 cfu/g	-	≤ 30 cfu/g	✓ PASS
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Complete test data reported at Annex.
Test covered by ACCREDIA accreditation scope n° 1827 L

• **Bacterial Filtration Efficiency (BFE)**

Analysis Ending Date: 03/09/2021

EN 14683:2019+AC:2019 Annex B

Bacterial Filtration Efficiency (BFE)	>98 %	-	≥ 98 %	✓ PASS
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Complete test report attached as Annex

Breathability (Differential Pressure)

Analysis Ending Date: 27/08/2021

EN 14683:2019+AC:2019 Annex C

Differential pressure	<60 Pa/cm²	-	<60 Pa/cm²	✓ PASS
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Complete test data reported at Annex.

Resistance against penetration by synthetic blood

Analysis Ending Date: 27/08/2021

ISO 22609:2004

Number of specimens tested	32	-		
Number of specimens failed	0	-		
Number of specimens passed	32	-	≥29	✓ PASS

At least 29 of 32 specimens must pass tested at 16KPa

Complete test data reported at Annex.

AQL information according to ISO 22609:2004:
A single sampling plan providing an AQL of 4,0 % requires 32 test specimens.
An AQL of 4.0 % is met for a single sampling plan when 29 or more specimens show pass results.
AQL= Acceptable Quality Limit.

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MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES
---------------	---------	---------	------	-----	------------

■ Biocompatibility

Analysis Ending Date: 03/09/2021

ISO 10993

Cytotoxicity

Not cytotoxic

-

Not cytotoxic / No citotóxico ✓ PASS

Irritation and skin sensitization

Not irritative

-

Not irritative / No irritativo ✓ PASS

Complete test data reported at Annex.

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Date

13/09/2021

Signed for and on behalf of Eurofins Textile Testing Spain:

Report electronically validated by

Axel Ferrando

Physical-Mechanical Lab Manager

EXPLANATORY NOTE

- ◆ Test not covered by ENAC accreditation scope
 - Test is subcontracted within Eurofins group and is accredited
 - Test is subcontracted within Eurofins group and is not accredited
 - Test is subcontracted outside Eurofins group and is accredited
 - Test is subcontracted outside Eurofins group and is not accredited
- N/A = Not Applicable

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Eurofins General Sales Terms and Conditions Applied.

Results obtained refer only to samples, products or material received in Laboratory, as described in section "Sample information" and tested in conditions shown in present report.

Test uncertainties not reported are at customer disposal, for those tests in which it is possible to evaluate the test uncertainty.

The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%.

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If you happen to have any comments, please do it by sending email to textile_spain@eurofins.com and referring to this report number.

End Of Report**Eurofins Textile Testing Spain, S.L.U.**

Calle Germán Bernácer, 4

03203 Elche

SPAIN

Phone+34 966 299 638**www.eurofins.com/tex**

ENAC is signatory of EA and ILAC Multilateral Agreement for testing

Activities not covered by ENAC accreditation are marked with ◆○●□■*



Cosmetics &
Personal Care



LAB N° 1827 L


Page: 1 of 1

TEST REPORT	Refer to Analytical Report Number																																																																	
SPONSOR	Eurofins Textile & Footwear Testing Spain																																																																	
	C/Germán Bernácer 4																																																																	
	03203 Elche (Alicante)																																																																	
	SPAIN																																																																	
TEST METHOD	Microbial cleanliness (Bioburden) – EN 14683:2019/AC 2019 par. 5.2.5 + App D																																																																	
TEST ITEM - INFORMATION FROM THE SPONSOR																																																																		
PRODUCT NAME	560-2021-00009546 - MASK																																																																	
MATRIX OF THE PRODUCT	Face Mask - Entire Mask																																																																	
BATCH	EUAA70-00013437	CODE	Not provided																																																															
EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION																																																																		
MATERIAL ITEM ALIQUOT	N721AA2912-1																																																																	
PARCEL REGISTRATION N.	IP-N7-2021245-AAB	RECEIVING DATE	02 Sep 2021																																																															
ANALYSIS STARTING DATE	06 Sep 2021	ANALYSIS ENDING DATE	13 Sep 2021																																																															
PHOTO OF THE TEST ITEM																																																																		
RESULTS	<table border="1"> <thead> <tr> <th>RESULTS</th> <th>SPECIFICATION</th> <th>AEROBIC COUNT</th> <th>MYCOTIC COUNT</th> <th>TOTAL BIOBURDEN</th> <th>UNIT</th> </tr> </thead> <tbody> <tr> <td rowspan="2">ALIQUOT 1</td> <td>/</td> <td>153.00</td> <td>6.00</td> <td>159.00</td> <td>CFU/sample</td> </tr> <tr> <td>≤ 30</td> <td>28.71</td> <td>1.13</td> <td>29.84</td> <td>CFU/g</td> </tr> <tr> <td rowspan="2">ALIQUOT 2</td> <td>/</td> <td>51.00</td> <td>15.00</td> <td>66.00</td> <td>CFU/sample</td> </tr> <tr> <td>≤ 30</td> <td>10.04</td> <td>2.95</td> <td>12.99</td> <td>CFU/g</td> </tr> <tr> <td rowspan="2">ALIQUOT 3</td> <td>/</td> <td>36.00</td> <td>6.00</td> <td>42.00</td> <td>CFU/sample</td> </tr> <tr> <td>≤ 30</td> <td>6.83</td> <td>1.14</td> <td>7.97</td> <td>CFU/g</td> </tr> <tr> <td rowspan="2">ALIQUOT 4</td> <td>/</td> <td>39.00</td> <td>12.00</td> <td>51.00</td> <td>CFU/sample</td> </tr> <tr> <td>≤ 30</td> <td>7.66</td> <td>2.36</td> <td>10.02</td> <td>CFU/g</td> </tr> <tr> <td rowspan="2">ALIQUOT 5</td> <td>/</td> <td>51.00</td> <td>9.00</td> <td>60.00</td> <td>CFU/sample</td> </tr> <tr> <td>≤ 30</td> <td>9.60</td> <td>1.69</td> <td>11.29</td> <td>CFU/g</td> </tr> </tbody> </table>					RESULTS	SPECIFICATION	AEROBIC COUNT	MYCOTIC COUNT	TOTAL BIOBURDEN	UNIT	ALIQUOT 1	/	153.00	6.00	159.00	CFU/sample	≤ 30	28.71	1.13	29.84	CFU/g	ALIQUOT 2	/	51.00	15.00	66.00	CFU/sample	≤ 30	10.04	2.95	12.99	CFU/g	ALIQUOT 3	/	36.00	6.00	42.00	CFU/sample	≤ 30	6.83	1.14	7.97	CFU/g	ALIQUOT 4	/	39.00	12.00	51.00	CFU/sample	≤ 30	7.66	2.36	10.02	CFU/g	ALIQUOT 5	/	51.00	9.00	60.00	CFU/sample	≤ 30	9.60	1.69	11.29	CFU/g
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Reviewed and electronically signed for Technical Supervisor Approval by
Martina Casini, Laboratory Manager
for Eurofins Cosmetic & Personal Care Italy Srl, on 13-Sep-2021 15:12:48 UTC+02:00

TEST REPORT	Refer to Analytical Report Number																				
SPONSOR	Eurofins Textile & Footwear Testing Spain																				
	C/Germán Bernácer 4																				
	03203 Elche (Alicante)																				
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TEST METHOD	Bacterial Filtration Efficiency (BFE) – EN 14683:2019+AC:2019 App B																				
TEST ITEM - INFORMATION FROM THE SPONSOR																					
PRODUCT NAME	560-2021-00009546 - MASK																				
MATRIX OF THE PRODUCT	Face Mask – Entire Mask																				
BATCH	EUAA70-00013437	CODE	Not provided																		
EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION																					
MATERIAL ITEM ALIQUOT	N721AA2817-1																				
PARCEL REGISTRATION N.	IP-N7-2021238-AAA	RECEIVING DATE	26 Aug 2021																		
ANALYSIS STARTING DATE	02 Sep 2021	ANALYSIS ENDING DATE	03 Sep 2021																		
EXPERIMENTAL CONDITIONS	Dimension of the test item: 170 mm x 95 mm Dimension of the test specimen (unfolded): 155 mm x 170 mm Size of the area tested: 49 cm ² Flow rate during testing: 28,3 l/min Inner side of the mask to the aerosol challenge.																				
PHOTO OF THE TEST ITEM																					
RESULTS	<table border="1"> <thead> <tr> <th></th> <th>RESULT</th> <th>UNIT</th> </tr> </thead> <tbody> <tr> <td>ALIQUOT 1</td> <td>98,10</td> <td>%</td> </tr> <tr> <td>ALIQUOT 2</td> <td>98,96</td> <td>%</td> </tr> <tr> <td>ALIQUOT 3</td> <td>98,58</td> <td>%</td> </tr> <tr> <td>ALIQUOT 4</td> <td>98,23</td> <td>%</td> </tr> <tr> <td>ALIQUOT 5</td> <td>98,20</td> <td>%</td> </tr> </tbody> </table>				RESULT	UNIT	ALIQUOT 1	98,10	%	ALIQUOT 2	98,96	%	ALIQUOT 3	98,58	%	ALIQUOT 4	98,23	%	ALIQUOT 5	98,20	%
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ALIQUOT 5	98,20	%																			
DETAILED RESULTS	See Addendum N. 1 (1 page)																				

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LAB N° 1827 L

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Addendum N.1

Started on: 02/09/2021

Batch: N721AA2817

Sample description: 560-2021-00009546 - MASK

Lot Number: EUAA70-00013437

Negative Control Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Mean
Negative Control (CFU)	0	0	0	0	0	0	0

*number of colonies adjusted with positive-hole correction table

Positive Controls Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
Size of particle (µm)	7,00	4,70	3,30	2,10	1,10	0,65	
Positive Control N.1 (CFU)	175	335	1093	739	420	289	3051
Positive Control N.2 (CFU)	198	390	1160	779	434	306	3267

*number of colonies adjusted with positive-hole correction table

Mean of the total plate counts of the two positive controls (CFU):

Mean Particle Size (MPS)

	MPS
Positive Control N.1 (µm)	2,82
Positive Control N.2 (µm)	2,86
Mean (µm)	2,84

Test specimens Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
N721AA2817-1 - Aliquot 1	0	0	0	2	26	32	60
N721AA2817-1 - Aliquot 2	0	0	0	0	10	23	33
N721AA2817-1 - Aliquot 3	0	0	0	2	16	27	45
N721AA2817-1 - Aliquot 4	0	0	0	0	22	34	56
N721AA2817-1 - Aliquot 5	0	0	0	0	17	40	57

*number of colonies adjusted with positive-hole correction table

Test specimens Bacterial Filtration Efficiency (BFE)

	BFE (%)
N721AA2817-1 - Aliquot 1	98,10
N721AA2817-1 - Aliquot 2	98,96
N721AA2817-1 - Aliquot 3	98,58
N721AA2817-1 - Aliquot 4	98,23
N721AA2817-1 - Aliquot 5	98,20

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Reviewed and electronically signed for Technical Supervisor Approval by
Martina Barberis Vignola, Lab Analyst
for Eurofins Cosmetic & Personal Care Italy Srl, on 03-Sep-2021 16:18:08 UTC+02:00

METHOD FOR DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

Test Method: EN 14683: 2019+AC: 2019 Annex C

Number of test specimens: 5

Number of test per specimen: 5

Sample area tested: Circular, diameter 2,5 cm

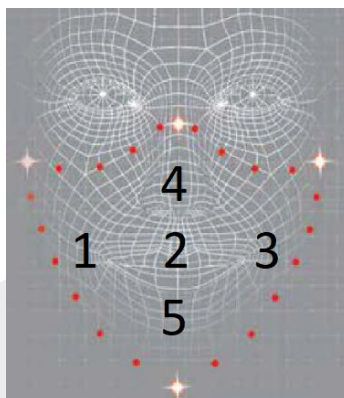
Tested area of the test sample: 4,9 cm²

Flow rate during testing: 8±0,6 l/min

General location of measurement areas: Representative of the overall surface.

Conditioning: T^a between 16,7°C and 26°C. RH between 82,8% and 88% during at least 4 h.

Airflow direction during testing: From the inner layer to the outer layer.



Results

Specimen	Units (Pa)						ΔP (Pa/cm ²)	Uncertainty
	Position 1	Position 2	Position 3	Position 4	Position 5	Mean value (Pa)		
1	250	239	238	243	230	240	49,0	± 1,8
2	237	240	258	247	239	244	49,8	± 2,0
3	247	250	260	231	245	247	50,3	± 2,3
4	223	226	251	222	235	231	47,2	± 2,5
5	249	231	244	214	240	236	48,1	± 2,8

Observation:

For thick and rigid masks the test method may not be suitable as a proper seal cannot be maintained in the sample holder.

DETERMINATION RESISTANCE AGAINST PENETRATION BY SYNTETIC BLOOD

Test Method: ISO 22609:2004; Targeting-plate test method

Number of test specimens: 32

Sample size: Circular, diameter 5,58 cm

Sample area tested: 24,5 cm²

Pressure: 16 kPa (120,0 mm Hg)

Synthetic blood volume: 2 ml

Stream velocity of synthetic blood: 550±10 cm/s

Distance of the face mask target area surface from the tip of the cannula: 30,5 cm

Angle of the pneumatic valve with respect to the face mask target area: 90°

Technique used to enhance visual detection of synthetic blood: Hydrophilic cotton

Conditioning: At least 4 hours. T^a between 16,7°C and 26°C. RH between 82,8% and 88%

Environmental test conditions 22,7°C; 79,1% Hr

Pre-treatment: None

Specimen	Results	
	Pass	Fail
1	X	
2	X	
3	X	
4	X	
5	X	
6	X	
7	X	
8	X	
9	X	
10	X	
11	X	
12	X	
13	X	
14	X	
15	X	
16	X	
17	X	
18	X	
19	X	
20	X	
21	X	
22	X	
23	X	
24	X	
25	X	
26	X	
27	X	
28	X	
29	X	
30	X	
31	X	
32	X	

Conclusion	PASS
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Operating requirements for surgical masks based on EN 14683: 2019+AC: 2019 standard

TEST	TYPE I	TYPE II	TYPE IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm ²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16
Microbial cleanliness (CFU/g)	≤ 30	≤ 30	≤ 30

APPAREL SUPPLY LIMITED

Azzurri House

Kilcohan

X91P667

Ireland

Akkreditierte
Prüfstelle nach
EN ISO/IEC 17025



Bischofshofen, 01.09.2021

Prüfbericht / test report B 28354

Labor-Nr. / <i>identification of the test laboratory:</i>	B 28354
Prüfprodukt / <i>test product:</i>	Mask - 560-2021-00009546 / EUAA70-00013437
Musterbezeichnung / <i>sample designation:</i>	n/a
Chargen-Bez. / <i>batch number:</i>	n/a
Auftraggeber / <i>ordered by:</i>	APPAREL SUPPLY LIMITED
Auftragsdatum / <i>date of order:</i>	2021-08-25
Materialeingang / <i>date of delivery:</i>	2021-08-26
Prüfzeitraum / <i>period of analysis:</i>	2021-08-30 bis / to 2021-09-01
Lagerbedingungen / <i>storage conditions:</i>	erfolgt nach Angabe des Herstellers / <i>according to the manufacturer's specifications</i>
Prüfbedingungen / <i>test conditions:</i>	Die Prüfung erfolgte im Anlieferungszustand. / <i>The test was done in the delivery state.</i>
Prüfmethode / <i>test method:</i>	SOP 09-001 Biologische Beurteilung von Medizinprodukten Zytotoxizität von Eluaten gemäß / <i>Biological evaluation of medical devices testing according to EN ISO 10993-5:2009</i> Teil 5: Prüfung auf Zytotoxizität, Anhang A, Aufnahme von Neutralrot / <i>Part 5: Tests for in vitro cytotoxicity, annex A, neutral red uptake (NRU)</i> Prüfung auf Irritation und Sensibilisierung gemäß / <i>Test for irritation and sensitization according to EN ISO 10993-10:2013</i> Teil 10: Prüfung der Membranintegrität / <i>Part 10: Test of cell membrane integrity</i>

Probenbehandlung / <i>sample processing</i> :	gemäß / <i>according to</i> EN ISO 10993-12:2012 Das Produkt ist während des gesamten Prüfverfahrens aseptisch behandelt worden. / <i>The product was treated under aseptic conditions throughout the complete test procedure.</i>
Probenahme / <i>sampling</i> :	Es wurde ein repräsentatives Teil der Probe zur Überprüfung verwendet. / <i>A representative part of the test sample was used for testing.</i>
Raumtemperatur / <i>room temperature</i> :	21.0 °C
Relative Luftfeuchtigkeit (Raum) / <i>relative humidity (room)</i> :	51 %
Aussehen / <i>appearance</i> :	Fotodokumentation im Anhang / <i>photo documentation in the annex</i>
Bestimmungsgemäße Anwendungsart gemäß Herstellerangaben / <i>Intended use according to the manufacturer</i> :	Medizinische Gesichtsmasken zur Verminderung der Infektionsverbreitung / <i>Medical face masks to minimise the risk of infection spreading.</i>
Extrakt / <i>extract</i>:	
Extraktionsbedingungen / <i>conditions of extraction</i> :	gemäß / <i>according to</i> EN ISO 10993-12:2012
Extraktionsverhältnis / <i>extract ratio</i> :	6 cm ² /ml
Extraktionsmenge und Volumen / <i>sample amount and volume</i> :	60 cm ² Material in 10 ml Extraktionsmedium / <i>60 cm² material in 10 ml extraction medium</i>
Extraktionsmedium / <i>extraction medium</i> :	DMEM + 2% FBS + 1% Pen/Strep + L-Glutamin (Komplettmedium) / <i>DMEM supplemented with 2% FBS and 1% pen/strep + l-glutamine (complete medium)</i>
Extraktionsdauer / <i>duration of extraction</i> :	24 h ± 2h
Extraktionstemperatur / <i>temperature of extraction</i> :	37°C ± 1°C
pH-Wert des Extrakts / <i>pH value from the extract</i> :	B 28354 100% Extrakt / <i>extract</i> 8.46
Farbveränderung / <i>change of colour</i>	nein / <i>no</i>
Präzipitat / <i>precipitate</i> :	ohne / <i>without</i>
Extraktbehandlung / <i>treatment of extraction</i> :	keine / <i>none</i>
Extraktlagerung / <i>storage of extracts</i> :	nicht zutreffend / <i>not applicable</i>
Kommentare / <i>comments</i> :	keine / <i>none</i>

**Beobachtungen Zellreaktion /
notice cell reaction:**

Morphologische Veränderungen /
morphological transformations: nein / no

Prüfanforderung / test requirement:

EN ISO 10993-5, Anhang / *annex A:*

Neutralrot Methode / *neutral red uptake*
Zellvitalität / *cell viability* ≥ 70%

EN ISO 10993-10:

LDHe
Zellschädigung / *cell damage* ≤ 30%

Materialien und Methoden / materials and methods

Zellkultivierung / *cell culture:*

Vero-Zellen (ATCC CCL-81) sind eine adhärenzte Zelllinie des Nierengewebes einer äthiopischen Grünmeerkatze. Zur Testung wurden die Zellen in einer Konzentration von 1×10^5 Zellen/ml in 96-Well Mikrotiterplatten angelegt und 24 h bei 37°C und 5% CO₂ im Brutschrank inkubiert, um eine semikonfluente Einschichtkultur zu bilden.

Stock cultures of Vero cells (ATCC CCL-81), an adherent cell line derived from grivet kidney tissue, were used. Cells with a concentration of 1×10^5 cells/ml were seeded in 96-well microtitre plates and incubated 24 hours at 37°C and 5% CO₂ to form a cell culture monolayer.

Exposition / *treatment:*

Nach 24 Stunden Inkubationszeit der Zellen wurde ein Mediumwechsel mit Testmedium vorgenommen. Dazu wurde das Medium dekantiert und 100 µl pro Vertiefung Prüfmedium hineinpipettiert. Eine Inkubation für 24 Stunden bei 37°C und 5% schließt sich an.

After 24 hours of incubation the medium was exchanged with the test medium by carefully decanting the medium and adding 100 µl of test medium, followed by incubation for an additional period of 24 hours at 37°C and 5% CO₂.

Blindprobe NR Methode /
blank feed NR uptake:

Als Blindprobe wurde Kompletmedium ohne Prüfmedium inkubiert.

As blank feed cells were incubated with complete medium without test medium.

Extrakte / *extracts:*

Extrakte wurden frisch vor der Prüfung gemäß EN ISO 10993-12:2012 hergestellt, sofort für die Prüfung verwendet und nicht gelagert.

Extracts were generally prepared fresh according to EN ISO 10993-12:2012, used immediately for the assay and were not stored.

Prüfmedium / <i>test medium</i> :	<p>Das Prüfmedium ist der Extrakt (100%) oder eine Verdünnung davon, welche mit Kompletmedium hergestellt wurde.</p> <p><i>The test medium is either the neat extract (100%) or a dilution of it, prepared with complete cell culture medium.</i></p>
NR Methode / <i>NR uptake</i> :	<p>Vitale Zellen nehmen den Farbstoff Neutralrot auf. Tote Zellen können den Farbstoff nicht aufnehmen und bleiben ungefärbt. Die Farbintensität der Eluationslösung wurde photometrisch bei 540nm gemessen.</p> <p><i>Viable cells incorporate the dye neutral red. Dead cells do not incorporate the dye and remain unstained. The intensity of the colour of the elution solution was measured by using photometric determination at 540nm.</i></p>
LDHe Methode / <i>LDHe method</i> :	<p>Lactatdehydrogenase (LDH), ein stabiles zytoplasmatisches Enzym, ist in allen Zellen präsent und wird bei Schädigung der Zellmembran oder Zell-Lyse in das Zellmedium freigesetzt. LDH reduziert Pyruvat zu Lactat, indem NADH zu NAD⁺ oxidiert wird. Die Umwandlung von NADH wird durch eine katalytisch gekoppelte gleichzeitige Umwandlung von INT zu einem unlöslichen Formazansalz photometrisch bestimmt.</p> <p><i>Lactate dehydrogenase (LDH), a stable cytoplasmic enzyme, is present in the cytosol, but released into the medium if the cell membrane is damaged or the cells lyse. LDH reduces pyruvate to lactate in the presence of NADH, which is reduced to NAD⁺. Photometric detection follows the consumption of NADH using a catalytically coupled concomitant conversion of INT to an insoluble formazan salt as measurement endpoint</i></p>
Referenzkontrolle NR Methode / <i>reference control NR method</i> :	<p>Als Negativkontrolle wurde sterile Baumwolle in Kompletmedium verwendet. Zusätzlich wurde als Positivkontrolle 0,15mg/ml Natriumdodecylsulfat im Test eingesetzt.</p> <p><i>As negative control, cells were incubated with sterile cotton in complete medium. As positive control, cells were incubated in complete medium containing 0.15 mg/ml sodium dodecyl sulfate.</i></p>
Kontrollen LDH Methode / <i>controls LDH method</i> :	<p>Als Negativkontrolle wurde Zellmedium ohne Prüflösung inkubiert. Zur Überprüfung der maximalen LDH-Freisetzung wurde zusätzlich als Positivkontrolle Triton X eingesetzt.</p> <p><i>As negative control cells were treated with complete culture medium. The positive control for LDHe is Triton X, which results in maximal release of LDH from cells.</i></p>

Ergebnisauswertung Neutralrot Methode / result neutral red uptake:

Abbildung 1 / Figure 1: Boxplot der Zellvitalität / Boxplot of the cell viability B 28354

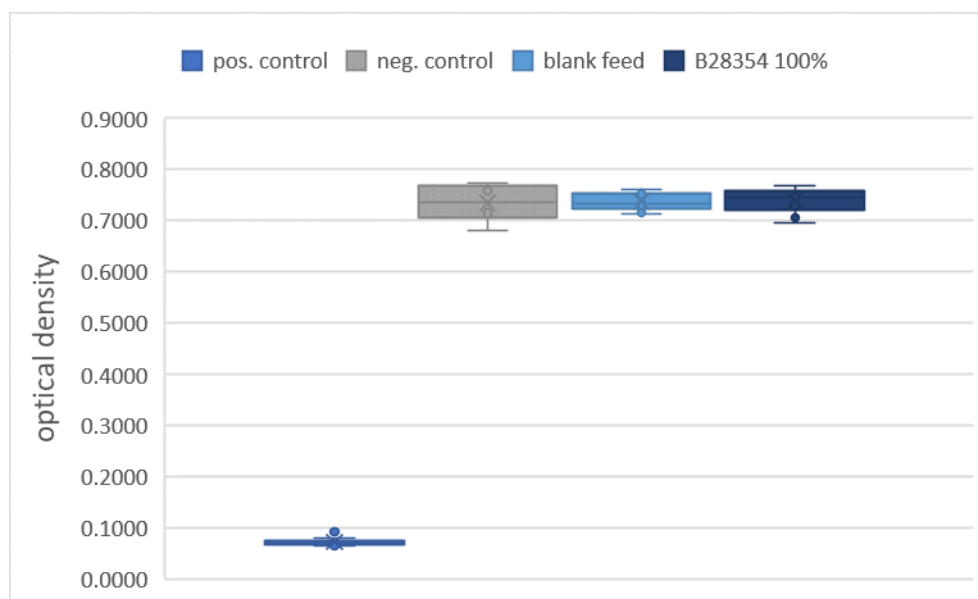


Tabelle 1 / Table 1: Deskriptive Statistik / Descriptive statistics B 28354

	N	Durchschnitt / mean	Zellvitalität / cell viability (%)	Minimum	Maximum	Standardabweichung / standard deviation	p-value ¹
Blindprobe / blank feed	9	0.737	100.00	0.714	0.760	0.017	-
Neg. Kontrolle / neg. control	6	0.735	99.76	0.681	0.772	0.036	-
Pos. Kontrolle / pos. control	9	0.072	9.75	0.065	0.092	0.009	-
B 28354 100%	12	0.740	100.41	0.695	0.767	0.023	0.5538

Ergebnis / result B 28354:

100.41% Zellvitalität in Bezug auf die Blindprobe bei 100% Extrakt / cell viability regarding to the blank feed using the 100% extract solution.

Verifizierung des Verfahrens

OD der Blindprobe $\geq 0,3$

Eine Prüfung erfüllt die Annahmekriterien, wenn der linke und der rechte Mittelwert der Blindproben um nicht mehr als 15% vom Mittelwert aller Blindproben abweichen.

Verification of the process:

OD of blind value ≥ 0.3

Test was considered as positive when the difference of the mean values of the blank feeds on the left and on the right side of the plate do not deviate more than $\pm 15\%$ from all blank feeds together.

¹ U-Test nach Mann-Whitney vs. Kontrolle / U test (Mann-Whitney) vs. Control
Prüfbericht B 28354

Ergebnisauswertung LDH Methode / result LDH method:

Abbildung 2 / Figure 2: Freisetzung / release B 28354

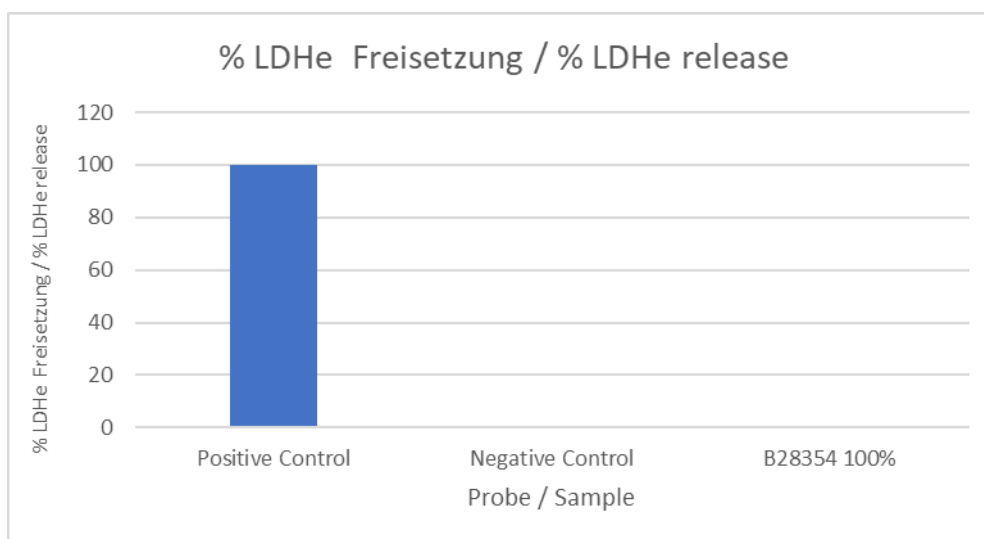


Tabelle 2 / Table 2: Deskriptive Statistik Descriptive statistics B 28354

	N	Standardabweichung / standard deviation	LDH Freisetzung / LDH release (%)
Pos. Kontrolle / pos. control	6	0.09	100
Neg. Kontrolle / neg. control	6	0.01	0.00
B 28354 100%	6	0.01	0.00

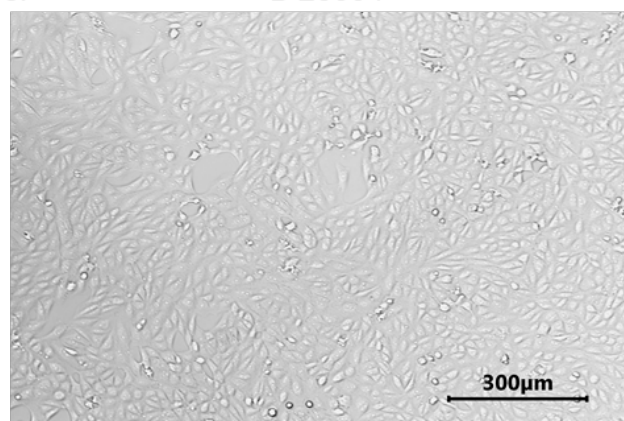
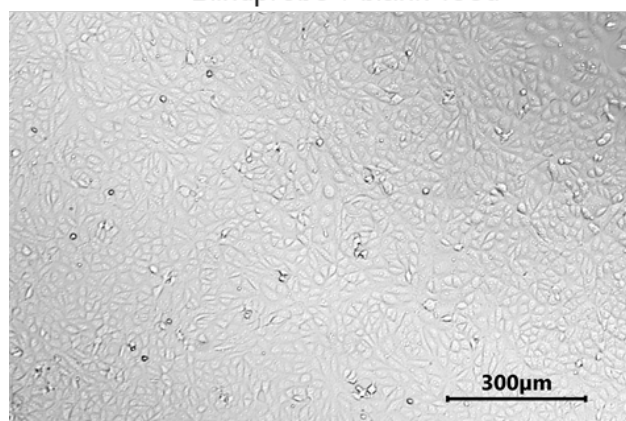
Qualitative morphologiebezogene Gradeinteilung der Zytotoxizität von 100% Extrakten / qualitative scale of cytotoxicity from 100% extracts according to morphological changes

Gradeinteilung / scale	Reaktivität / reactivity	Zustand der Kultur / status of the culture	B 28354
0	Keine / none	Diskrete intrazytoplasmatische Granuli, keine Zellauflösung, keine Verringerung des Zellwachstums / <i>discrete intracytoplasmic granuli, no cell lysis, no reduction of cell growth</i>	✓
1	Gering / low	Nicht mehr als 20% der Zellen sind rund, lose anhaftend und ohne intrazytoplasmatische Granuli oder zeigen Änderungen in der Morphologie, vereinzelt sind aufgelöste Zellen vorhanden, nur geringe Wachstumshemmung bemerkbar / <i>no more than 20% of the cells are round, loose adherent and without intracytoplasmic granuli or show morphological changes, rarely dissolved cells, slight growth inhibition detectable</i>	
2	Leicht / mild	Nicht mehr als 50% der Zellen sind rund, frei von intrazytoplasmatischen Granuli, keine ausgedehnte Zellauflösung; nicht mehr als 50% Wachstumshemmung bemerkbar / <i>no more than 50% of the cells are round, free of intracytoplasmic granuli, no extended cell lysis; no more than 50% growth inhibition detectable</i>	
3	Mäßig / moderate	Nicht mehr als 70% der Zellschichten enthalten runde Zellen oder sind aufgelöst; Zellschichten sind nicht vollständig zerstört, jedoch ist mehr als 50% Wachstumshemmung bemerkbar / <i>no more than 70% of the cells are round or dissolved; cell layers are not completely destroyed, but more than 50% growth inhibition is detectable</i>	
4	Stark / strong	Fast vollständige oder vollständige Zerstörung der Zellschichten / <i>almost complete or complete destruction of cell layers</i>	

Blindprobe / blank feed

vs.

B 28354



**Schlussfolgerung /
conclusion:**

Bei 100% Extrakt des Produktes **Mask - 560-2021-00009546 / EUAA70-00013437** resultierte eine Zellvitalität von mehr als 70% im Vergleich zur Blindprobe und ist deshalb **nicht** als **zytotoxisch** zu bewerten.

*The extract of 100% the product **Mask - 560-2021-00009546 / EUAA70-00013437** resulted in a cell viability of more than 70% in comparison to the blank feed and can therefore be considered **not** as **cytotoxic**.*

Der Extrakt des Produktes **Mask - 560-2021-00009546 / EUAA70-00013437** resultierte in einer LDH-Freisetzung von weniger als 30% im Vergleich zur Kontrolle und ist deshalb **nicht** als **irritativ** zu bewerten.

*The extract of the product **Mask - 560-2021-00009546 / EUAA70-00013437** resulted in a LDH release less than 30% in comparison to the control and is therefore considered **not** to be **irritative**.*

**Archivierung /
Archiving:**

Eine Ausfertigung des Berichtes wird zusammen mit den Rohdaten im Archiv der HygCen Austria GmbH aufbewahrt. / *A copy of this report is kept together with the raw data in the archive of HygCen Austria GmbH.*

Hinweis / Note:

Der vorliegende Prüfbericht bezieht sich ausschließlich auf die dem Labor vorliegenden Prüfgegenstände. Informationen zur Konformitätsbewertung und Messunsicherheit werden auf Wunsch bekanntgegeben. Jede auszugsweise Vervielfältigung bedarf der schriftlichen Genehmigung durch die HygCen Austria GmbH. / *The present test report refers exclusively to the test objects available to the laboratory. Information on conformity assessment and measurement uncertainty will be disclosed upon request. Any duplication in extracts requires the written permission of HygCen Austria GmbH.*



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Technischer Leiter / *technical manager*



Monika Feltgen
Stellvertretender technischer Leiter / *vice technical manager*

Anhang zum Prüfbericht B 28354
attachment to test report B 28354



Abb. 1: Mask - 560-2021-00009546 / EUAA70-00013437