BẢN DỊCH
TRANSLATION

MINISTRY OF HEALTH
VIETNAM INSTITUTE OF MEDICAL DEVICE AND CONSTRUCTION

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

TEST CERTIFICATE

No.: 022920/VTTB-DGCL

Requesting organization: Han Viet Company Limited

Product name: Anti-epidemic protective suit

Model: Set of 7 pieces (body-suit with hat)

Producer: Han Viet Company Limited

Address: Km 14, National Road 1A, Ngoc Hoi Commune, Thanh Tri District, Hanoi City

Origin: Vietnam

Tester: Le Duc Ha

Testing standards: In accordance with all standards of ANSI/AAMI PB70:2012, TCVN 8389-1:2010, TCVN 3581-81, TCVN 6344:2007

Conclusion: Anti-epidemic protective suit of level 1.

Hanoi, April 01st 2020
INSTITUTE DIRECTOR
(Signed and sealed)

PhD. Le Thanh Hai

Address: 40 Phuong Mai – Dong Da – Hanoi * Tel: (024) 38523065

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PhD. Le Thanh Hai

Address: 40 Phuong Mai – Dong Da – Hanoi * Tel: (024) 38523065

TEST REPORT

Specifications

No.	Content	Requirement	Qualified	Underqualified
1	Face mask	In accordance with the standards of TCVN 8389-1: 2010	X	
2	Glasses	In accordance with the standards of TCVN 3581-81	X	
3	Gloves	In accordance with the standards of TCVN 6344: 2007	X	
4	Covered shoes	Nonwoven fabric with elastic band	X	
5	Body-suit with hat	Level 1: Waterproof in accordance with the standards of AATCC 42. Level 2: Waterproof in accordance with the standards of AATCC 42 and AATCC 127. Level 3: Waterproof in accordance with the standards of AATCC 42 and AATCC 127 (higher test levels than those of level 2). Level 4: Passed the test of level 3 and passed the proof test in accordance with the standards of ASTM F1671.		
5.1	Area A (important area - front)	Level 1	X	
5.2	Area B (important area – sleeves)	Level 1	X	
5.3	Area C (front)	Level 1	X	
5.4	Area D (back)	Level 1	X	
	Seams between protected areas and unprotected areas	Level 1	X	

** This test report is only valid with the samples provided by Han Viet Company Limited to Vietnam Institute of Medical Device and Construction on March 30th 2020.*

** Conclusion: Qualified for Level 1.*

Hanoi, April 01st 2020

SUPERVISOR
(Signed)

Nguyen Van Hung

TESTER
(Signed)

Le Duc Ha

Address: 40 Phuong Mai – Dong Da – Hanoi * Tel: (024) 38523065

LỜI CHỨNG CỦA CÔNG CHỨNG VIÊN
NOTARY TESTIMONY

Hôm nay, ngày 03 tháng 04 năm 2020, tại trụ sở Văn phòng Công chứng Trương Thị Nga, A4 - TT19 Khu đô thị Văn Quán, Yên Phúc, phường Phúc La, quận Hà Đông, thành phố Hà Nội.
Today, April 03, 2020 at Truong Thi Nga Notary Office, A4 – TT19 Van Quan urban area, Yen Phuc, Phuc La Ward, Ha Dong District, Hanoi City
Tôi là Công chứng viên Văn phòng Công chứng Trương Thị Nga, số A4 - TT19 Khu đô thị Văn Quán, Yên Phúc, phường Phúc La, quận Hà Đông, thành phố Hà Nội.
I, the undersigned, Notary Public of Truong Thi Nga Notary Office, A4 – TT19 Van Quan urban area, Yen Phuc, Phuc La Ward, Ha Dong District, Hanoi City.

CHỨNG NHẬN:
CERTIFY THAT:

- Bản dịch này do ông Trương Công Đạt, CMND số: 168410115 cấp ngày 28/04/2009 tại Công an tỉnh Hà Nam, là cộng tác viên phiên dịch của Văn phòng Công chứng Trương Thị Nga, A4 - TT19 Khu đô thị Văn Quán, Yên Phúc, phường Phúc La, quận Hà Đông, thành phố Hà Nội, đã dịch từ tiếng **Việt sang tiếng Anh**.
- This is translation from **Vietnamese to English** by Mr. Truong Cong Dat, ID No. 168410115 issued on 28/04/2009 by Public Security of Ha Nam Province, who is translation collaborator of Truong Thi Nga Notary Office, A4 – TT19 Van Quan urban area, Yen Phuc, Phuc La Ward, Ha Dong District, Hanoi City.
- Chữ ký trong bản dịch đúng là chữ ký của ông Trương Công Đạt;
- Signature in the translation is the true and authentic signature of Mrs. Trương Công Đạt;
- Nội dung của bản dịch chính xác, không vi phạm pháp luật, không trái với đạo đức xã hội;
- The contents of the translation are correct and do not violate the law or social morality.
- Bản dịch gồm 05 tờ, 05 trang, lưu một bản tại Văn phòng Công chứng Trương Thị Nga, A4 - TT19 Khu đô thị Văn Quán, Yên Phúc, phường Phúc La, quận Hà Đông, thành phố Hà Nội.
- The translation includes 05 sheets, 05 pages, one of which is retained in Truong Thi Nga Notary Office, A4 – TT19 Van Quan urban area, Yen Phuc, Phuc La Ward, Ha Dong District, Hanoi City.

Số công chứng: 3788 ; Quyển số: 01 -TP/CC-SCC/BD
Notarized No.: 3788 ; Book No.: 01 -TP/CC-SCC/BD

Người dịch
Translation Collaborator

Trương Công Đạt

CÔNG CHỨNG VIÊN
NOTARY PUBLIC

S.Đ.K.H.Đ: 113-C.T.H.Đ
VĂN PHÒNG CÔNG CHỨNG TRƯƠNG THỊ NGA
Q.HÀ ĐÔNG - T.P HÀ NỘI

CÔNG CHỨNG VIÊN
Vũ Thị Thùy Trang

BỘ Y TẾ
VIỆN TRANG THIẾT BỊ
VÀ CÔNG TRÌNH Y TẾ

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

GIẤY CHỨNG NHẬN
THỬ NGHIỆM

Số: 022910/VTTB-ĐGCL

Cơ quan yêu cầu: Công ty TNHH Hàn Việt.

Tên sản phẩm: Bộ trang phục phòng dịch.

Model: Bộ 7 món áo mũ liền quần.

Đơn vị sản xuất: Công ty TNHH Hàn Việt.

Địa chỉ: Km 14 Quốc lộ 1A, Ngọc Hồi, Thanh Trì, Hà Nội, Việt Nam

Xuất xứ: Việt Nam

Người thử nghiệm: Lê Đức Hà

Tiêu chuẩn thử nghiệm: Theo tiêu chuẩn ANSI/AAMI PB70:2012, TCVN 8389-1:2010, TCVN 3581-81, TCVN 6344:2007

Kết luận: Bộ trang phục phòng dịch đạt cấp độ 1.

Hà Nội, ngày 01 tháng 04 năm 2020

VIỆN TRƯỞNG

VIỆN TRANG THIẾT BỊ VÀ CÔNG TRÌNH Y TẾ

TS. Lê Thanh Hải

Địa chỉ: 40 Phương Mai - Đống Đa - Hà Nội * Điện thoại: (024) 38523065

KẾT QUẢ THỬ NGHIỆM

Thành phần

TT	Nội dung	Yêu cầu	Đạt	K.Đạt
1	Khẩu trang	Theo tiêu chuẩn TCVN 8389-1:2010	X	
2	Kính	Theo tiêu chuẩn TCVN 3581-81	X	
3	Găng tay	Theo tiêu chuẩn TCVN 6344:2007	X	
4	Bao giầy	Vải không dệt có chun	X	
5	Áo, quần, mũ liền bộ	- Cấp độ 1: Chống nước theo AATCC 42. - Cấp độ 2: Chống nước theo AATCC 42 và AATCC 127. - Cấp độ 3: Chống nước theo AATCC 42 và AATCC 127 (đặt các mức thử cao hơn so với cấp 2). - Cấp độ 4: Đạt cấp độ 3 và phép thử ngăn chặn sự xâm nhập theo ASTM F1671.		
5.1	Khu vực A (Khu vực quan trọng - phía trước)	Cấp độ 1	X	
5.2	Khu vực B (Khu vực quan trọng - tay áo)	Cấp độ 1	X	
5.3	Khu vực C (Phía trước)	Cấp độ 1	X	
5.4	Khu vực D (Phía sau)	Cấp độ 1	X	
5.5	Đường may giữa các khu vực bảo vệ và không bảo vệ	Cấp độ 1	X	

**Kết quả thử nghiệm này chỉ có giá trị đối với các mẫu thử Công ty TNHH Hàn Việt cung cấp cho Viện Trang thiết bị và Công trình Y tế ngày 30/03/2020.*

** Kết luận: Đạt cấp độ 1.*

Hà Nội, ngày 01 tháng 04 năm 2020

SOÁT XÉT

Nguyễn Văn Hùng

NGƯỜI THỬ NGHIỆM

Lê Đức Hà

Địa chỉ: 40 Phương Mai - Đống Đa - Hà Nội * Điện thoại: (024) 38523065

HAN VIET CO.,LTD
KM 14,1A HIGHWAY THANH TRI,HANOI VIETNAM

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)woven fabric (B)knitted fabric
Sample Color	:	(A)(dark green) 63" Cotton elastic Imitation linen cloth; (B)(off white) 63" Polyester cotton air layer
Sample Receiving Date	:	Mar 27, 2020
Testing Period	:	Apr 01, 2020 – Apr 23, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).
Test Performed	:	Selected test(s) as requested by applicant

Signed for and on behalf of
SGS-CSTC Standards Technical
Services Co., Ltd. HangZhou Branch

Jack Zhang (Account Executive)

SGS-CSTC Standards Technical Services Co., Ltd. Hangzhou Branch Textile Laboratory.

3-6/F, No.4 Building, Huaye Hi-Tech Zone, No.1180. Bin'an Road, Binjiang District, Hangzhou, Zhejiang, China 310052 t (86-571)86791199 f (86-571)87688901 www.sgsgroup.com.cn
中国·浙江·杭州·滨江区滨安路1180号华业高科技产业园4号楼3-6层 邮编: 310052 t (86-571)86791199 f (86-571)87688901 e sgs.china@sgs.com

Test Result

Ultraviolet Protection Factor (UPF)

(AATCC TM 183-2014; Test Conditions
1) Air temperature: 21±1oC
2) Relative humidity: 65±2% R.H.
3) Orientation of test specimen: Specimens were clamped on sample holder. Fabric face side is facing the incident UV light.
4) Test conducted in wavelength range 280-400 nm
5) Instrument: UV-VIS Spectrophotometer
6) No. of Scans: 6)

(A)	Unit	Dry Evaluation	Wet Evaluation
As Received			
Mean Ultraviolet Protection Factor (UPF)	No Unit	17	29
Standard Deviation	No Unit	1.3	1.7
Standard Error	No Unit	1.6	2.1
UPF Rating	No Unit	15	25
Protection Category	No Unit	Good	Very good
Percent Transmittance, T (UV-A)	%	6.72	4.44
Percent Transmittance, T (UV-B)	%	5.76	3.31
The Percent Blocking, UV-A	%	93.28	95.56
The Percent Blocking, UV-B	%	94.24	96.69

3-6/F, No.4 Building, Huaye Hi-Tech Zone, No.1180, Bin'an Road, Binjiang District, Hangzhou, Zhejiang, China 310052 t (86-571)86791199 f (86-571)87688901 www.sgsgroup.com.cn
中国·浙江·杭州·滨江区滨安路1180号华业高科技产业园4号楼3-6层 邮编: 310052 t (86-571)86791199 f (86-571)87688901 e sgs.china@sgs.com

(B)	Unit	Dry Evaluation	Wet Evaluation
As Received			
Mean Ultraviolet Protection Factor (UPF)	No Unit	1285	889
Standard Deviation	No Unit	10.5	34.2
Standard Error	No Unit	13.1	42.4
UPF Rating	No Unit	50+	50+
Protection Category	No Unit	Excellent	Excellent
Percent Transmittance, T (UV-A)	%	0.67	1.39
Percent Transmittance, T (UV-B)	%	0.05	0.05
The Percent Blocking, UV-A	%	99.33	98.61
The Percent Blocking, UV-B	%	99.95	99.95

Remarks :
1. Refer to ASTM D6603, the UV protection category is determined by the UPF values,
UPF 40 or greater Excellent UV Protection
UPF in between 25 to 39 Very Good UV Protection
UFP in between 15 to 24 Good UV Protection
UPF less than 15 Unclassification

2. Ultraviolet Protection Factor (UPF) is the ratio of the average effective ultraviolet radiation (UV-R) irradiance transmitted and calculated through air to the average effective UV-R irradiance transmitted and calculated through fabric.

3. The limits of the spectral range of ultraviolet radiation are not well defined and may vary according to the user. Committee E-2.12 of the International Commission on Illumination (CIE) distinguishes in the spectral range between 400 and 100 nm :
UV-A : 315 - 400 nm
UV-B : 280 - 315 nm
UV-R : 280 - 400 nm

4. This method can also be used to determine the UPF of the fabrics in a stretched state. However, the techniques for stretching the specimens are not part of this method and are addressed in a separate test procedure. It must be noted that stretching the specimens could change the UPF properties.

5. The listed protection category is for reference only, the market claims for labeling UV-Protection product shall follow "Standard Guide For Labeling UV-Protection Textiles" as stated in ASTM D6603.

3-6/F, No.4 Building, Huaye Hi-Tech Zone, No.1180. Bin'an Road, Binjiang District, Hangzhou, Zhejiang, China 310052 t (86-571)86791199 f (86-571)87688901 www.sgsgroup.com.cn
中国·浙江·杭州·滨江区滨安路1180号华业高科技产业园4号楼3-6层 邮编: 310052 t (86-571)86791199 f (86-571)87688901 e sgs.china@sgs.com

Antimicrobial Activity Test^

Test Method : AATCC 100-2012 Antibacterial Finishes on Textile Material: Assessment of

(A)

Test organism	Klebsiella pneumoniae ATCC 4352
Concentration of bacteria(CFU/mL)	1.9x10^5
Sample -at "0H" contact time (CFU/sample)	1.6x10^5
Control sample- at "0H" contact time (CFU/sample)	1.9x10^5
Sample -at "24H" contact time (CFU/sample)	<100
Control sample- at "24H" contact time (CFU/sample)	1.3x10^8
Reduction(%)	>99.9%

(B)

Test organism	Klebsiella pneumoniae ATCC 4352
Concentration of bacteria(CFU/mL)	1.9x10^5
Sample -at "0H" contact time (CFU/sample)	1.5x10^5
Control sample- at "0H" contact time (CFU/sample)	1.9x10^5
Sample -at "24H" contact time (CFU/sample)	<100
Control sample- at "24H" contact time (CFU/sample)	1.3x10^8
Reduction(%)	>99.9%

Notes :

Test sample was 4 swatches of 4.8 cm diameter circular ,1 mL inoculum per trial.
The sample had been sterilized in the autoclave before the testing.
The control sample was 100% cotton, provided by SGS laboratory.

^This test was carried out by SGS Shanghai Laboratory

End of Report

4/28/2020

FDA | U.S. Food and Drug Administration

Registration Confirmation

Facility: HAN VIET CO., LTD (HANVICO), Thanh Tri District, Ha Noi, thanh pho, VIET NAM

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

As a manufacturer, specification developer, or single-use device reprocessor, you are required to pay an annual fee for medical device facility registration.

You will receive another e-mail providing you with your registration number in approximately 30 to 90 days. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.

Your registration will be valid through Dec 31, 2020. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for Fiscal Year 2020 with instructions on how and when to re-register.

Note: Registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to reglist@cdrh.fda.gov (mailto:reglist@cdrh.fda.gov).

The Owner/Operator Number for this Registration is: 10072350

Facility Information

Initial Importer:	**N**
Facility Name:	**HAN VIET CO., LTD (HANVICO)**
Address:	**Km 14 Road No. 1 A** **Thanh Tri District, Ha Noi, thanh pho, none, VIET NAM**
Foreign Trade Zone:	**N**
Facility URL:	**http://www.hanvico.com**
Other Business Trade Name(s):	1. Hanvico

Owner/Operator Information

Owner/Operator Number:	**10072350**
Contact Name:	**Pham Thanh Tung**
Company:	**HAN VIET CO., LTD (HANVICO)**
Address:	**Km 14 Road No. 1 A Thanh Tri District, HA NOI, THANH PHO, none, VIET NAM**
Telephone:	**084 - 243 - 8618040**
Fax:	**084 - 243 - 8618040**
E-mail:	**tungpham@hanvico.com.vn**

Official Correspondent Information

Contact Name:	**David Lennarz**
Company:	**Registrar Corp**
Address:	**144 Research Drive Hampton, VIRGINIA, 23666, UNITED STATES**
Telephone:	**1 - 757 - 2240177**
Fax:	**1 - 757 - 2240179**
E-mail:	**david.lennarz@registrarcorp.com**
DUNS Number:	**139242874**

United States Agent Information

Contact Name:	**David Lennarz**
Contact Title:	**Mr**
Business Name:	**Registrar Corp**
Address:	**144 Research Drive Hampton, Virginia, 23666, UNITED STATES**
Phone:	**757 - 2240177**
Fax:	**757 -2240179**
DUNS Number:	**139242874**
E-mail:	**david.lennarz@registrarcorp.com**

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D397760	Enforcement Discretion	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance	Manufacturer Contract Manufacturer Reprocessor of Single Use Devices Repackager/Relabeler Remanufacturer Complaint File Establishment	

Date of Initial Registration: Tue Apr 28 12:53:37 EDT 2020

HAN VIET CO., LTD (HANVICO)

Km14, National Highway 1A, Thanh Tri, Hanoi

Tel: +84-24 – 38617978 Fax: +84-24 – 3861 8040

SOCIALIST REPUBLIC OF VIETNAM

Independence - Freedom - Happiness

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LETTER OF CONFIRMATION

Our Company: Han Viet Co.,LTD (Hanvico)

Add: Km14, National Highway 1A, Ngoc Hoi Commune, Thanh Tri District, Hanoi City, Vietnam

Tel: +84-2438617978 - fax: +842438618040

Email: hanvico@hanvico.com.vn ; website: hanvico.com.vn

Since the outbreak of Covid-19 in Vietnam and around the world, Hanvico with its experience as a manufacturer of antibacterial Nano Silver Polyester padding products, we has developed shoulder face mask for the Vietnam market and export. In Europe, ITUL GmbH Company is the exclusive distributor of Hanvico face mask including the following products:

1. Fabric Nano Silver Face Mask
2. Fabric Nano Silver 3D Plus
3. Fabric Nano Silver 3D Max
4. Fabric Fresh Ever 3D Plus
5. Fabric Fresh Ever 3D Max
6. Fabric Fresh Ever 870

The materials and our finished products have the following standards of conformity certificates:

1 . Certificate Antibacterial Nano Silver fiber

2. Certificate Fabric Antibacterial Nano Silver Face Mask

3. Certificate Fabric Fresh Ever 870

4. TORAY, SGS, TQC, FRESH EVER, CE,.., and others certificate.

In the context of widespread of covid-19 epidemic / Our face mask are manufactured and supplied to ITUL GmbH Company. These products are personal protective equipment products and suitable to the epidemic situation as well as European and American PPE standards

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=uriserv:OJ.C_.2017.118.01.0011.01.ENG

https://www.fda.gov/media/136449/download

Hanoi, May 4, 2020

HAN VIET COMPANY

CÔNG TY HÀN VIỆT

TỔNG GIÁM ĐỐC

Trần Chí Thanh

2020

CERTIFICATE OF REGISTRATION

This certifies that:

HAN VIET CO., LTD (HANVICO)
Km 14 Road No. 1 A
Thanh Tri District Ha Noi, Thanh Pho, VN

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**3016790408**
Device Classification Name:	**FACE MASK (EXCEPT N95 RESPIRATOR) FOR GENERAL PUBLIC/HEALTHCARE PERSONNEL PER IIE GUIDANCE**
Product Code:	**QKR**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp

144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: May 4, 2020

MINISTRY OF HEALTH
NATIONAL INSTITUTE OF MEDICAL DEVICE AND CONSTRUCTION

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

CERTIFICATE OF TEST RESULT

No.: 0214020/VTTB-DGCL

Requesting organization: Han Viet Company Limited

Address: Km14, National Road 1A, Ngoc Hoi, Thanh Tri District, Hanoi City, Vietnam

Product name: Medical face mask

Model: HV01

Manufacturer: Han Viet Company Limited

Origin: Vietnam

Tester: Le Duc Ha

Test standard: Vietnamese Standard TCVN 8389-1:2010

Test method: Vietnamese Standard TCVN 8389-1-2010

Conclusion: The face mask is satisfied with the Vietnamese Standard TCVN 8389-1-2010-normal medical face mask

SAO Y BẢN CHÍNH
Ngày... tháng... năm 20...

Hanoi, May 08th 2020

DIRECTOR

(Signed and sealed)

PhD. Le Thanh Hai

GIÁM ĐỐC
Phạm Văn Tuân

Address: 40 Phuong Mai – Dong Da – Hanoi * Tel: (024)3 8523065

TEST REPORT

(In accordance with the Vietnamese Standard TCVN 8389-1:2010)

Specifications

No.	Content	Requirement			Qualified	Underqualified
1	Structure and material	Nonwoven fabric, smooth surface, microfiltration layer, nose clip and strap; no appearance defects.			X	
2	Filtration efficiency with oil droplet (%)	Measured value				
		The first	The second	The third		
2.1	Particle size 0.3µm	96.96%	96.94%	96.95%	X	
2.2	Particle size 0.5µm	99.91%	99.89%	99.91%	X	
2.3	Particle size 1.0µm	99.95%	99.92%	99.94%	X	
3	Airway resistance (mmH_2O)	Airway resistance is no more than 9 mmH_2O			X	
4	Limit of view (%)	Limit of view is no more than 6%			X	
5	Weight (g)	Weight is no more than 10 g			X	
6	Permissible limit of heavy metal content					
6.1	Arsenic content (As)	0.17 mg/kg			X	
6.2	Lead content (Pb)	1.00 mg/kg			X	
6.3	Mercury content (Hg)	0.12 mg/kg			X	
6.4	Antimony content (Sb)	0.10 mg/kg			X	
6.5	Cadmium content (Cd)	0.10 mg/kg			X	

** This test report is only valid with the samples provided by Han Viet Company Limited to National Institute of Medical Device and Construction on May 6th 2020.*

Hanoi, May 8th 2020

SUPERVISOR
(Signed)

Ha Quang Thanh

TESTER
(Signed)

Pham Thanh Tung

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D o s s i e r

Antiviral efficacy of nanosilver

last modified: May 2020

Biomaterials, 35(13), 4195–4203

Inhibitory effect of silver nanomaterials on transmissible virus-induced host cell infections..

Lv, X., Wang, P., Bai, R., Cong, Y., Suo, S., Ren, X., & Chen, C. (2014).

Coronaviruses belong to the family Coronaviridae, which primarily cause infection of the upper respi- ratory and gastrointestinal tract of hosts. Transmissible gastroenteritis virus (TGEV) is an economically significant coronavirus that can cause severe diarrhea in pigs. Silver nanomaterials (Ag NMs) have attracted great interests in recent years due to their excellent anti-microorganism properties. Herein, four representative Ag NMs including spherical Ag nanoparticles (Ag NPs, NM-300), two kinds of silver nanowires (XFJ011) and silver colloids (XFJ04) were selected to study their inhibitory effect on TGEV- induced host cell infection in vitro. Ag NPs were uniformly distributed, with particle sizes less than 20 nm by characterization of environmental scanning electron microscope and transmission electron microscope. Two types of silver nanowires were 60 nm and 400 nm in diameter, respectively. The average diameter of the silver colloids was approximately 10 nm. TGEV infection induced the occurring of apoptosis in swine testicle (ST) cells, down-regulated the expression of Bcl-2, up-regulated the expres- sion of Bax, altered mitochondrial membrane potential, activated p38 MAPK signal pathway, and increased expression of p53 as evidenced by immunofluorescence assays, real-time PCR, flow cytometry and Western blot. Under non-toxic concentrations, Ag NPs and silver nanowires significantly diminished the infectivity of TGEV in ST cells. Moreover, further results showed that Ag NPs and silver nanowires decreased the number of apoptotic cells induced by TGEV through regulating p38/mitochondria-caspase- 3 signaling pathway. Our data indicate that Ag NMs are effective in prevention of TGEV-mediated cell infection as a virucidal agent or as an inhibitor of viral entry and the present findings may provide new insights into antiviral therapy of coronaviruses.

- In the present study, four different types of Ag NMs were used to study the antiviral activity of silver against coronaviruses. One of them was NM-300 K which is synonymous to agpure® W10, made by RAS AG.
- Among these Ag NMs, Ag NPs and two types of silver nanowires could significantly cause an inhibitory effect on TGEV (a type of coronavirus)-induced host cell infection and TGEV multiplication.
- Moreover, these three Ag NMs decreased cell apoptosis which was caused by TGEV infection through activation of p38/mitochondriacaspase-3 signaling in ST cells.

LWT - Food Science and Technology, 79, 503–510

Antiviral properties of silver nanoparticles against norovirus surrogates and their efficacy in coated polyhydroxyalkanoates systems.

Castro-Mayorga, J. L., Randazzo, W., Fabra, M. J., Lagaron, J. M., Aznar, R., & Sánchez, G. (2017)

Silver nanoparticles (AgNP) have strong broad-spectrum antimicrobial activity and gained increased attention for the development of AgNP based products, including medical and food applications. Initially, the efficacy of AgNP and silver nitrate (AgNO3) was evaluated for inactivating norovirus surrogates, the feline calicivirus (FCV) and the murine norovirus (MNV). These norovirus surrogates were exposed to AgNO3 and AgNP solutions for 24 h at 25°C and then analyzed by cell-culture assays. Both AgNP and silver ions significantly decreased FCV and MNV infectivity in a dose-dependent manner between concentrations of 2.1 and 21 mg/L. Furthermore, poly (3-hydroxybutyrate-co-3-hydroxyvalerate) (PHBV) films were prepared by depositing a coating of thermally post-processed electrospun PHBV18/AgNP fiber mats over compression moulded PHBV3 films. After 24 h exposure at 37°C and 100% RH, no infectious FCV were recovered when in contact with the AgNP films while MNV titers decreased by 0.86 log. The morphology of the PHBV18 and PHBV18/AgNP fibers studied by SEM showed smooth and continuous fibers in both cases and the EDAX analysis confirmed the homogeneously distribution of AgNP into the coating and onto the PHBV3/PHBV18 layer. This study showed, for the first time, the suitability of the PHBV18/AgNP electrospun coating for antiviral surfaces.

- Both AgNP and silver ions significantly decreased FCV and MNV infectivity in a dose-dependent manner between concentrations of 2.1 and 21 mg/L.

Foodborne Pathogens and Disease, 13(5), 239–244.

Dose and Size-Dependent Antiviral Effects of Silver Nanoparticles on Feline Calicivirus, a Human Norovirus Surrogate.

Bekele, A. Z., Gokulan, K., Williams, K. M., & Khare, S. (2016).

Objectives: Silver nanoparticles (AgNPs) as antibacterial agents are incorporated in many consumer products, while the use as antiviral agents is an ongoing area of research. We evaluated the antiviral properties of AgNPs of variable sizes (10, 75, and 110 nm) and doses (25, 50, and 100 lg/mL) at different contact time points against feline calicivirus (FCV), a surrogate for norovirus.
Materials and Methods: Antiviral effects of the AgNPs were determined by comparing the infectivity of FCV, the appearance of cytopathic effects (CPEs), and the integrity of the viral capsid protein in viral suspension treated with AgNPs with the untreated controls.
Results: The 10nm AgNPs at 50 and 100 lg/mL concentrations inactivated the FCV beyond the limit of detection, resulting in a decrease of up to 6.5 log10 viral titer, prevented development of CPEs, and reduction in the western blot band signal of the viral capsid protein. No significant antiviral effect was observed for the 75 and 110nm AgNPs.

- The 10nm AgNPs at 50 and 100 lg/mL concentrations inactivated the FCV beyond the limit of detection
- The results demonstrate that the antiviral effects of AgNPs are both size and dose dependent, thus potential applications of AgNPs as antiviral agents to prevent contamination of foodborne viruses need to consider size and dose effects.

International Journal of Nanomedicine, 7, 5007–18 (2012).

Inactivation of microbial infectiousness by silver nanoparticles-coated condom: a new approach to inhibit HIV- and HSV-transmitted infection.

Mohammed Fayaz, a, Ao, Z., Girilal, M., Chen, L., Xiao, X., Kalaichelvan, P., & Yao, X.

Recent research suggests that today's condoms are only 85% effective in preventing human immunodeficiency virus (HIV) and other sexually transmitted diseases. In response, there has been a push to develop more effective ways of decreasing the spread of the disease. The new nanotechnology-based condom holds the promise of being more potent than the first-generation products. The preliminary goal of this study was to develop a silver nanoparticles (Ag-NPs)-coated polyurethane condom (PUC) and to investigate its antimicrobial potential including the inactivation of HIV and herpes simplex virus (HSV) infectiousness. The Ag-NPs-coated PUC was characterized by using ultraviolet-visible spectrophotometry, Fourier transform-infrared spectroscopy, high-resolution scanning electron microscopy, and energy-dispersive analysis of X-ray spectroscopy. Nanoparticles were stable on the PUC and not washed away by water. Morphology of the PUC was retained after coating. The NP binding is due to its interaction with the nitrogen atom of the PUC. No significant toxic effects was observed when human HeLa cells, 293T and C8166 T cells were contacted to Ag-NPs-coated PUC for three hours. Interestingly, our results demonstrated that the contact of the Ag-NPs-coated PUC with HIV-1 and HSV-1/2 was able to efficiently inactivate their infectiousness. In an attempt to elucidate the antiviral action of the Ag-NPs, we have demonstrated that the anti-HIV activity was primarily mediated by the Ag-NPs, which are associated with the PUC. In addition, the data showed that both macrophage (M)-tropic and T lymphocyte (T)-tropic strains of HIV-1 were highly sensitive to the Ag-NPs-coated PUC. Furthermore, we also showed that the Ag-NPs-coated PUC was able to inhibit the growth of bacteria and fungi. These results demonstrated that the Ag-NPs-coated PUC is able to directly inactivate the microbe's infectious ability and provides another defense line against these sexually transmitted microbial infections.

Conclusion:

- AgNP-coated condom showed activity against HIV-1 and HSV-1/-2 (inactivate the virus' infectivity)
- AgNPs tightly bound to PUC, release of ions in supernatant below detection limit
- HIV-1: direct transfer of silver ions from oxidized NPs to virus membrane particles (gp120 and gp41)
- HSV: inactivation of HSV-1/-2 infectivity on VeroE6 cells, prevention of infection

Molecules (Basel, Switzerland) (2011)

Silver nanoparticles as potential antiviral agents.

Galdiero, S., Falanga, A., Vitiello, M., Cantisani, M., Marra, V., & Galdiero, M.

Virus infections pose significant global health challenges, especially in view of the fact that the emergence of resistant viral strains and the adverse side effects associated with prolonged use continue to slow down the application of effective antiviral therapies. This makes imperative the need for the development of safe and potent alternatives to conventional antiviral drugs. In the present scenario, nanoscale materials have emerged as novel antiviral agents for the possibilities offered by their unique chemical and physical properties. Silver nanoparticles have mainly been studied for their antimicrobial potential against bacteria, but have also proven to be active against several types of viruses including human imunodeficiency virus, hepatitis B virus, herpes simplex virus, respiratory syncytial virus, and monkey pox virus.

The use of metal nanoparticles provides an interesting opportunity for novel antiviral therapies. Since metals may attack a broad range of targets in the virus there is a lower possibility to develop resistance as compared to conventional antivirals. The present review focuses on the development of methods for the production of silver nanoparticles and on their use as antiviral therapeutics against pathogenic viruses.

Conclusion:

- Metal nanoparticles (especially gold and silver) have proven to exhibit virucidal activity against many viruses (Pox-, Hepadna-, Orthomyxo-, Paramyxo-, Herpes- and Retroviridae) and reduce the viral infectivity of cultured cells
- Nanoparticles interact with viral surface glycoproteins or may gain access to cells and exert their antiviral activity through interactions with the viral genome

Journal of Nanobiotechnology (2010), 8:1

Mode of antiviral action of silver nanoparticles against HIV-1

Humberto H Lara, Nilda V Ayala-Nuñez, Liliana Ixtepan-Turrent, Cristina Rodriguez-Padilla

In this study, silver nanoparticles are evaluated to elucidate their mode of antiviral action against HIV-1 using a panel of different in vitro assays. Our data suggest that silver nanoparticles exert anti-HIV activity at an early stage of viral replication, most likely as a virucidal agent or as an inhibitor of viral entry. Silver nanoparticles bind to gp120 in a manner that prevents CD4-dependent virion binding, fusion, and infectivity, acting as an effective virucidal agent against cellfree virus (laboratory strains, clinical isolates, T and M tropic strains, and resistant strains) and cell-associated virus. Besides, silver nanoparticles inhibit post-entry stages of the HIV-1 life cycle.

Conclusions: Free silver nanoparticles bind to gp120 in a manner that prevents CD4-dependent virion binding, fusion, and infectivity.

DARU Vol 17, No. 2 (2009), 88

In Vitro Antiviral Effect of "Nanosilver" on Influenza Virus

Kheiri et al

The aim of this study was to determine antiviral effects of Nanosilver against influenza virus. TCID50 (50% Tissue Culture Infectious Dose) of the virus as well as CC_{50} (50% Cytotoxic Concentration) of Nanosilver was obtained by MTT (3- [4, 5-dimethylthiazol-2-yl]-2, 5-diphenyl-tetrazolium bromide, Sigma) method. This compound was non-toxic to MDCK (Madin-Darbey Canin Kidney) cells at concentration up to 1 µg/ml. Effective minimal cytotoxic concentration and 100 $TCID_{50}$ of the virus were added to the confluent cells. Inhibitory effects of Nanosilver on the virus and its cytotoxicity were assessed at different temperatures using Hemagglutination (HA) assay, RT-PCR and DIF. RT-PCR and free band densitometry software were used to compare the volume of the PCR product bands on the gel.

Conclusions: In this study it was found that Nanosilver has destructive effect on the virus membrane glycoprotein knobs as well as the viral cells.

Antivir Ther. (2008);13(2):253-62.

Silver nanoparticles inhibit hepatitis B virus replication.

Lu L, Sun RW, Chen R, Hui CK, Ho CM, Luk JM, Lau GK, Che CM

The aim of the present study was to investigate the effects of silver nanoparticles on hepatitis B virus (HBV). The in vitro anti-HBV activities of these particles were determined using the HepAD38 cell line as infection model. Results: Ag10Ns and Ag50Ns were able to reduce the extracellular HBV DNA formation of HepAD38 cells by >50% compared with the vehicle control. As both the viral and Ag10Ns systems are in the nanometer size range, we found that Ag10Ns could directly interact with the HBV viral particles as revealed by transmission electronic microscopy.

Conclusions: Silver nanoparticles could inhibit the in vitro production of HBV RNA and extracellular virions. The direct interaction between these nanoparticles and HBV double-stranded DNA or viral particles might be responsible for their antiviral mechanism.

Journal of Science of Healing Outcomes, (2008),1(1))

Effect of Prophylactic Treatment with ASAP-AGX-32 and ASAP Solutions on an Avian Influenza A (H5N1) Virus Infection in Mice

Pedersen G, Sidwell RW, Moloff A, Saum RW

Mice infected with avian influenza A/Duck/MN/1525/81 (H5N1) virus were treated with the Silver Sol-containing formulations ASAP-AGX-32 and ASAP provided by American Biotech Labs. Oral gavage treatment began 7 days prior to virus exposure and continued twice daily for a total of 17 days. Treatments with both formulations provided a suggested inhibitory and preventive effect on this virus infection as seen by either less animals dying in the treated groups than in the placebo-treated controls, delay in mean day to death, lessened SaO2 decline, modest inhibition of lung consolidation, and/or lessened virus titers in the lungs. Ribavirin was included as a positive control drug, used orally at a dose of 75 mg/kg/day twice daily for 5 days beginning 4 h pre-virus exposure, and this treatment was markedly inhibitory to the infection as expected.

Conclusions: Treatments with both formulations provided a suggested inhibitory and preventive effect on this virus infection:

- less animals dying in the treated groups than in the placebo-treated controls
- delay in mean day to death
- lessened SaO2 decline
- modest inhibition of lung consolidation
- and/or lessened virus titers in the lungs

Chem Commun (Camb). (2005) Oct 28;(40):5059-61)

Silver nanoparticles fabricated in Hepes buffer exhibit cytoprotective activities toward HIV-1 infected cells

Sun RW, Chen R, Chung NP, Ho CM, Lin CL, Che CM

In summary, the cytoprotective and the post-infected anti-HIV activities of metal nanoparticles have been demonstrated. These nanoparticles were found to interact with human serum albumin, but meanwhile, their anti-viral properties were retained.

Conclusions: Free silver nanoparticles protect human cells against HIV by inhibiting HIV replication.

J.Nanobiotechnol. (2005) 3, 6

Interaction of silver nanoparticles with HIV-1

Elechiguerra JL, Burt JL, Morones JR, Camacho-Bragado A, Gao X, Lara HH, Yacaman MJ

The interaction of nanoparticles with biomolecules and microorganisms is an expanding field of research. Within this field, an area that has been largely unexplored is the interaction of metal nanoparticles with viruses. In this work, we demonstrate that silver nanoparticles undergo a sizedependent interaction with HIV-1, with nanoparticles exclusively in the range of 1–10 nm attached to the virus. The regular spatial arrangement of the attached nanoparticles, the center-to-center distance between nanoparticles, and the fact that the exposed sulfur-bearing residues of the glycoprotein knobs would be attractive sites for nanoparticle interaction suggest that silver nanoparticles interact with the HIV-1 virus via preferential binding to the gp120 glycoprotein knobs. Due to this interaction, silver nanoparticles inhibit the virus from binding to host cells, as demonstrated in vitro.

Conclusions: Free silver nanoparticles (1-10 nm) inhibit the virus from binding to host cells via interaction with the sulfur bearing residues of the gp120 glycoprotein knobs.

QSA INTERNATIONAL

Certificate OF REGISTRATION

HAN VIET COMPANY LIMITED (HANVICO)

KM 14 HIGHWAY 1A. NGOC HOI COMMUNE, THANH TRI DISTRICT, HA NOI CITY, VIETNAM

has submitted declaration of Conformity (Dated: 20-02-2020) according to

Class-1, Medical Devices Directive 93/42 EEC Annexure VII

Organization has been assessed and found to be conforming with the requirements of the stated directive and standards submitted through Declaration of conformity

Hence manufacturer places the CE marking with his own responsibility as follows:

CE

For the Products of

NANO SILVER ANTIBACTERIAL MASK

By QSA International, UK

Registration Number : QSA-20012301
Initial Certification Date: 20 March 2020
Certification Expiry Date: 19 March 2023

Stratford Ray

Certification Manager

QSA INTERNATIONAL LIMITED
27, Old Gloucester Street, London, WC1N3AX, ENGLAND

CGA
Centre for Global Accreditation
Accreditation No. AB-145001

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Prüfbericht / *Test report*
No. 3417722.10-CPA

Prüfgegenstand *Testsubject*	Corona SARS-CoV-2 Atemschutzmaske *Coroan SARS-CoV-2 respiratory protective mask*
Modell *Type*	Nano Silver FFP2
Hersteller *Manufacturer*	Han Viet Silver Limited Km 14, National Road 1A, Ngoc Hoi Commune, Thanh Tri District, Hanoi City, Vietnam
Prüfgrundlage *Test requirement*	Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Rev. 1 vom 26.03.2020 *Testing principle for Corona SARS-CoV-2 pandemic respiratory masks rev. 1 of 2020-03-26*
Prüfergebnis *Test result*	Die Pandemie Atemschutzmaske entspricht **nicht** den Corona SARS-CoV-2 Prüfanforderung *The pandemic respiratory protective mask does **not** meet the Corona SARS-CoV-2 test requirement.*
Datum *Date of issue*	30.04.2020

Dieser Bericht besteht aus 10 Seiten. *This report consists of 10 pages.*

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle *Certification Body*: Dinnendahlstraße 9, 44809 Bochum
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

Veranlassung / *Reason*

Auftragseingang *Date of order*	16/04/2020
Auftraggeber *Applicant*	DEKRA Automobil GmbH Charls-Darwin-Ring 7 18059 Rostock
Importeur *Importer*	STH Handels- & Vertriebs GmbH Damerow Kaserne 19399 Neu Poserin
Eingang der Prüfmuster *Date of receipt of test item*	22/04/2020
Prüfzeitraum *Date (s) of performance of tests*	23/04/2020 – 30/04/2020
Prüfstandort *Test location*	DEKRA Testing and Certification GmbH Persönliche Schutzausrüstungen Adlerstraße 29 45307 Essen, Germany

Zusammenfassung der Prüfung / *Summary of Testing*

Prüfung		**bestanden** *pass*	**nicht bestanden** *fail*	**nicht anwendbar** *not applicable*
2.2	Sichtprüfung / *Visual inspection*	✓		
2.3	Anlegeprüfung / *Donning test*	✓		
2.4	Durchlass des Filtermediums / *Penetration of the filter medium*		✓	
2.5	Ausatemventil(e) / *Exhalation valve(s)*	✓		
2.6	Atemwiderstand / *Breathing resistance*			
2.6.1	CPA ohne Ventil / *CPA without valve*	✓		
2.6.2	CPA mit Ventil / *CPA with valve*			✓
2.7	Kennzeichnung und Informationen des Hersteller / *Marking and manufacturer's information*		✓	

Bemerkung / *Remarks*:

Die Konformitätsaussage ist „Erfüllt", wenn der ermittelte Messwert kleiner oder gleich dem vorgegebenen Grenzwert ist.

The conformity verdict is "Fulfilled" if the measured value is less or equal to the limit.

DEKRA Testing and Certification GmbH

(Stockmann)

Prüfingenieur/ *Test engineer*

Inhaltsverzeichnis / *Table of contents*

1 Bezug der Prüfergebnisse / *Reference of the test results*

Die in diesem Bericht aufgeführten Ergebnisse beziehen sich ausschließlich auf die untersuchten Prüfmuster.
The results listed in this report refer only to the tested samples.
Für die Prüfung wurden folgende Dokumente zugrunde gelegt:
The following documents were taken as a basis for the tests:

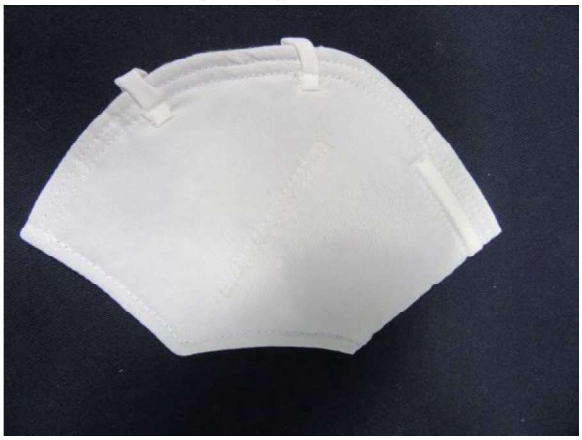
1	Verpackung / *packaging*
2	Gebrauchsanweisung / *user manual*

Die folgende Maske wurde geprüft / *The following mask was tested:*

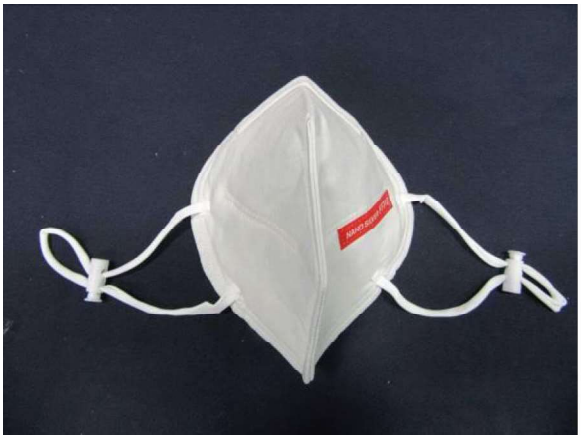
Verpackung / *Packaging*

Verpackung / *Packaging*

Seitenansicht / *Side view*



Seitenansicht / *Side view*



Frontansicht / *Front view*

Innenansicht / *Inner view*

2 Prüfergebnisse / *Test results*

A Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken / *Testing principle for Corona SARS-CoV-2 pandemic respiratory masks*

Die nachfolgenden Ziffern entsprechen den Abschnitten des Prüfgrundsatzes für Corona SARS-Cov-2 Pandemie Atemschutzmasken.

The following numbers correspond to the paragraphs of the testing principle for Corona SARS-CoV-2 pandemic respiratory masks.

2 Anforderungen und Prüfungen / *Requirements and tests*

2.1 Übersicht der Prüfungen / *Overview of tests*

Prüfung *Test*	**Anzahl Muster** *Number samples*	**Konditionieren** *Conditioning*	**Abschnitt** *Section* **EN 149**
Temperaturkonditionierung *Temperature conditioning*	5	--	8.3.2 nur *only* a)
Gebrauchssimulation *Simulation of wearing*	5	--	8.3.1
Sichtprüfung *Visual inspection*	1	--	--
Anlegeprüfung *Donning test*	1	--	8.4.1
Atemwiderstand (Geräte ohne Ventil) *Breathing resistance (valveless devices)*	2	T.C. + S.W. (2)	8.9.2 + 8.9.3
Ausatemventil-Durchströmung *Exhalation valve flow*	2	--	8.3.4
Atemwiderstand (Geräte mit Ventil) *Breathing resistance (valved devices)*	2	T.C. + S.W. + F.C. (2)	8.9.2 + 8.9.3
Durchlass des Filtermediums *Flow rate through the filter medium*	3	T.C. + S.W. (3)	8.11

2.2 **Sichtprüfung** / *Visual inspection*

CPA müssen zum Verkauf so verpackt angeboten werden, dass sie gegen mechanische Beschädigung und Verunreinigung vor dem Gebrauch geschützt sind.
When supplied for purchase, the CPA must be packed in such a way that they are protected against mechanical damage and contamination prior to their use.

Ergebnis: *test result:*	Die Verpackung schützt die Maske vor mechanischer Beschädigung und Verunreinigungen. *The package protects the mask from mechanical damage and contamination.*	**Erfüllt** *Fulfilled* ✓

2.3 **Anlegeprüfung** / *Donning test*

Die CPA muss leicht an- und abgelegt werden können. Die Kopfbänderung muss kräftig genug sein, um die CPA in Position zu halten. Die CPA muss einen Dichtsitz am Gesicht der Testperson gewährleisten. Bei einem Trageversuch dürfen keine offensichtlichen Undichtigkeiten im Bereich der Dichtlinie der Maske erkennbar sein. Bei der Beatmung durch eine Testperson dürfen keine Luftströmungen, die durch Undichtigkeiten in der Dichtlinie (schlechte Anpassung an das Gesicht) entstehen, wahrnehmbar sein.
Putting on and removing the CPA must be done easily. The head straps must be strong enough to keep the CPA in place. The CPA must ensure a close fit at the face of the test person. When carrying the mask in a test, no obvious leakage along the sealing line of the mask shall be recognisable. When the test person uses the mask for breathing, no air flow shall be noticeable which is caused by leakage in the sealing line (poor facial fit).

Ergebnis: *test result:*	Die Kopfbänderung besteht aus dünnen flexiblen Bändern und die CPA konnte leicht angelegt und abgenommen werden. *The headgear consists of thin flexible straps and the CPA was easy to put on and take off.*	**Erfüllt** *Fulfilled* ✓

Ergebnis: *test result:*	Die Kopfbänderung ist kräftig genug, um die CPA in Position zu halten. *The headgear is strong enough to hold the CPA in place.*	**Erfüllt** *Fulfilled* ✓

Ergebnis: *test result:*	Bei einem Trageversuch waren keine offensichtlichen Undichtigkeiten im Bereich der Dichtlinie der CPA erkennbar oder bei einer Beatmung in Form von Luftströmungen wahrnehmbar. *During a wearing test, no obvious leaks were detected in the area of the sealing line of the CPA or were perceptible in the form of air currents during ventilation.*	**Erfüllt** *Fulfilled* ✓

2.4 Durchlass des Filtermediums / *Penetration of the filter medium*

Der Durchlass des Filters der CPA wird mit Paraffinöl mit 95 l/min geprüft. Es müssen insgesamt drei Muster der CPA geprüft werden. Die drei Muster werden wie folgt konditioniert: Temperaturkonditionierung nur bei hoher Temperatur und Gebrauchssimulation mit feuchter Beatmung für 20 Minuten. Die Prüfung erfolgt nach EN 149:2001+A1:2009 Abschnitt 8.11 mit der Prüfung des Durchlasses nach EN 13274-7:2008 Abschnitt 5.1 und 5.2. Der Durchlass der CPA aller drei Muster muss ≤ 6,0 % sein.

The penetration through the filter of the CPA is tested using paraffin oil at 95 l/min. In total, three samples of the CPA have to be tested. The three samples will be conditioned as follows: temperature conditioning only at high temperature, and simulation of wearing with moist respiration for 20 minutes. The test is carried out in accordance with section 8.11 of EN 149:2001+A1:2009 with the filter penetration according to EN 13274-7:2008 clause 5.1 and 5.2. The penetration of the CPA of all three samples must be ≤ 6.0 %.

Tabelle l Ergebnisse beim Kurztest (3 min) / *Table l Results during short test (3 min)*

Probe *Sample*[1]	**Konditionierung** *Conditioning*	**Durchlassgrad bei 95 l/min Paraffinöl** *Penetration at 95 l/min Paraffine oil* **[%]**	
		Anforderung *Requirement*	**Ergebnis** *Test result*
01	T.C. + S.W.	≤ 6,0 %	87,49
02	T.C. + S.W.		86,30
03	T.C. + S.W.		87,32

[1] Vom Prüflabor verwendete Bezeichnung. *Designation used by the testing laboratory.*
T.C.: Temperatur konditioniert / *Temperature conditioned*
S.W.: Gebrauchssimulation / *Usage simulation*

2.5 **Ausatemventil(e)** / *Exhalation valve(s)*

Die CPA darf ein oder mehrere Ausatemventil(e) haben. Sie müssen in jeder Lage richtig funktionieren. Die Prüfung muss nach EN 149:2001+A1:2009 Abschnitt 8.9.1 erfolgen. Falls ein Ausatemventil(e) vorhanden ist, muss es (müssen sie) nach einem 30 s dauernden kontinuierlichen Ausatemstrom von 300 l/min weiter richtig funktionieren. Die Prüfung erfolgt während der Messung des Atemwiderstandes. Wenn das Gehäuse des Ausatemventils am Maskenkörper befestigt ist wird mit einer gefühlten Kraft von 10 N per Hand an dem Ausatemventil bzw. an dessen Gehäuse gezogen. Löst sich das Ventil, gilt die Prüfung als nicht bestanden.
The CPA may have one or more exhalation valves; these must work properly in any position. The test has to be carried out in accordance with section 8.9.1 of EN 149:2001+A1:2009. If one or more exhalation valves are in place, they must continue to work properly after a continuous exhalation flow of 300 l/min for 30 s. The test is carried out during the measurement of the breathing resistance. Once the casing of the exhalation valve has been fastened to the mask body, the exhalation valve or its casing is manually pulled with a felt force of 10 N. If the valve comes loose, the test is deemed as not passed.

Ergebnis: *test result:*	Die CPA beinhaltet kein(e) Ausatemventil(e). *The CPA does not include (an) exhalation valve(s).*	**Erfüllt** *Fulfilled*
		✓

2.6 **Atemwiderstand** / *Breathing resistance*

Die Atemwiderstände gelten für CPA mit und ohne Ventil(e).
The breathing resistance requirements apply to valved and valveless CPA.

2.6.1 **CPA ohne Ventil** / *CPA without valve*

Geprüft werden zwei CPA nach der Temperaturkonditionierung und der Gebrauchssimulation mit feuchter Beatmung für 20 Minuten. Die Prüfung erfolgt in Anlehnung an EN 149:2001+A1:2009 Abschnitt 8.9. Der Ausatemwiderstand wird in der Lage geradeaus sehend geprüft.
Der Atemwiderstand bei der Einatmung bei 95 l/min muss bei allen Mustern ≤ 3,0 mbar sein.
Der Atemwiderstand bei der Ausatmung bei 160 l/min muss bei allen Mustern ≤ 3,0 mbar sein.
2 CPA are tested after the temperature conditioning and the simulation of wearing with moist respiration for 20 minutes. The test is carried out following section 8.9 of EN 149:2001+A1:2009. The exhalation resistance is tested in the position "looking straight ahead".
The breathing resistance for inhalation at 95 l/min must be ≤ 3.0 mbar at all samples.
The breathing resistance for exhalation at 160 l/min must be ≤ 3.0 mbar at all samples.

Tabelle II Ergebnisse der Einatemwiderstandsmessungen bei 95 l/min
Table II Results of inhalation resistance measurements at 95 l/min

Probe *Sample*[1]	**Konditionierung** *Conditioning*	**Einatemwiderstand** *Inhalation resistance* **[mbar]**	
		Anforderung *Requirement*	**Ergebnis** *Test result*
04	T.C. + S.W.	≤ 3,0 mbar	0,69
05	T.C. + S.W.		0,60

[1] Vom Prüflabor verwendete Bezeichnung / *Designation used by the testing laboratory.*
T.C.: Temperaturkonditioniert / *Temperature conditioned*
S.W.: Gebrauchssimulation / *Usage simulation*

Tabelle III Ergebnisse der Ausatemwiderstandsmessungen bei 160 l/min
Table III Results of exhalation resistance measurements at 160 l/min

Probe *Sample*[1]	**Konditionierung** *Conditioning*	**Ausatemmwiderstand** *Exhalation resistance* **[mbar]**	
		Anforderung *Requirement*	**Ergebnis** *Test result*
04	T.C. + S.W.	≤ 3,0 mbar	1,06
05	T.C. + S.W.		1,00

[1] Vom Prüflabor verwendete Bezeichnung. / *Designation used by the testing laboratory.*
T.C.: Temperaturkonditioniert / *Temperature conditioned*
S.W.: Gebrauchssimulation / *Usage simulation*

Gemesen in der ersten definierten Lage des Prüfkopfes / *Measured in the first defined position of the test head:*
geradeaussehend / *facing directly ahead*

2.7 Kennzeichnung und Informationen des Hersteller / *Marking and manufacturer's information*

Die Kennzeichnung der CPA oder der kleinsten Verpackungseinheit soll dokumentiert werden, sodass eindeutig erkennbar ist, welche CPA vorliegt.

The marking of the CPA or the smallest packing unit must be documented so that it becomes unmistakeably clear which CPA is provided.

Ergebnisse / *Test Results*		
	Erfüllt *Fulfilled*	**Nicht erfüllt** *not fulfilled*
Die CPA oder die kleinste Verpackungseinheit muss mit den folgenden Informationen gekennzeichnet sein: *The marking of the CPA or the smallest packing unit must contain the following information:*		
a) Name, Warenzeichen oder andere Angaben zur Identifikation des Herstellers; *a) Name, trademark and/or other details identifying the manufacturer;*		✓ *
b) Typidentische Kennzeichnung (Nummer, Modell oder Ähnliches) *b) Marking identifying the type (number, model or similar)*	✓	
Informationen müssen jeder CPA oder der kleinsten Verpackungseinheit beigelegt sein. Die Informationen können in Textform oder beispielsweise in Piktogrammen dargestellt werden. Die Informationen müssen mindestens Angaben enthalten zu: *Information must be supplied with each CPA or smallest packing unit. This information can be displayed either as text or as pictograms, for example. The information must also provide at least details on:*		
a) Sitz sowie richtiges An- und Ablegen; *a) Fit and correct putting on and removing of the mask;*	✓	
b) Hinweise zur Verwendung *b) Instruction on its use*	✓**	

* Keine Informationen vorhanden. *No information available.*

** Waschbarkeit und Wiederverwendbarkeit wurden vom Prüflabor weder verifiziert noch getestet.

*** Washability and reusability were neither verified nor tested by the test laboratory.*

DERMA TRONNIER

REPORT

EPICUTANEOUS TEST FOR THE ANALYSIS
OF THE IRRITATING EFFECTS
TO SKIN OF HUMANS

Mikrofasergewebe mit Nano-Silberausrüstung

IN THE ORDER OF
Fa. SILANOTEX • 80687 MÜNCHEN •
DT-NR • 16/01/06

DERMATRONNIER GMBH & CO. KG
Institut für experimentelle Dermatologie
Alfred – Herrhausen – Str. 44 • 58455 Witten

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Ordering party:	Fa. Silanotex Landsberger Str. 360 80687 München
Date of order:	2006-01-06
Research assignment number:	16/01/06
Scientific administrator:	Prof. Dr. Hagen Tronnier
Objective:	Determination of irritating effects to the skin
Test product:	**Mikrofasergewebe mit Nano-Silberausrüstung**
Test concentration:	Undiluted/dry
Amount of product tested:	2 mg of the test product per 1 cm^2 of skin
Test area:	Back
Test period:	48 hours and 72 hours
Test subjects:	50
those with allergies	13
or sensitive skin	13
Sex:	female: 37
	male: 13
Age:	19 bis 58 Jahre

Principle:

The epicutaneous test serves as proof of a primary skin irritation, or rather a contact allergy, limited as well as in time with regard to the substance to be tested.

Test Implementation:

A collective of female and male test subjects, ranging in age from 18 to 69, participated in the study (see the enclosed test subject list included in Appendix 1).
Through the utilization of a standard test plaster, the substance to be tested is applied and fixed on the clinically healthy skin. The test plaster is removed after 48 hours, and the test area is assessed. Further assessments take place after 72 hours.

Evaluation Score:

O	no irritation
±	slight or improbable erythema
+	distinct erythema (as well as urticarial)
++	strong erythema and/or papule formation
+++	abundant papules and/or vesicles
++++	blister formation or necrosis

Assessment of the test results and conclusions in view of the future usage of the preparation:

Mikrofasergewebe mit Nano-Silberausrüstung
Test concentration: undiluted / dry

Positive or improbable reactions could be found neither after 48 nor 72 hours to the effect that these test results indicate that the product has no primary irritating effect of the skin. The test also did not set-off any possibly already-existing sensitization by means of the substances contained in the product.

DERMATRONNIER
Institute for Experimental Dermatology

Prof. Dr. med. Hagen Tronnier

Appendix 1

Test product: Mikrofasergewebe mit Nano-Silberausrüstung

Test concentration: undiluted / dry

Lfd. No.	Test person	Age	Sex	Diagnosis	Reaction	
					48 h	72 h
1.	G.K.	48	m	sensitiv skin	0	0
2.	G.O.	21	m	healthy	0	0
3.	G.B.	46	f	sensitiv skin	0	0
4.	G.K.	19	f	atopic	0	0
5.	W.M.	57	f	sensitiv skin	0	0
6.	W.G.	48	m	atopic	0	0
7.	K.M.	41	f	atopic	0	0
8.	St.E.	31	f	atopic	0	0
9.	St.V.	33	m	healthy	0	0
10.	H.L.	38	f	healthy	0	0
11.	H.T.	39	m	healthy	0	0
12.	D.C.	46	f	healthy	0	0
13.	H.M.	51	f	atopic	0	0
14.	Sch.P.	43	m	atopic	0	0
15.	Sch.A.	40	f	atopic	0	0
16.	B.F.K.	29	f	healthy	0	0
17.	F.M.	46	f	atopic	0	0
18.	F.F.	50	m	atopic	0	0
19.	F.M.	19	m	sensitiv skin	0	0
20.	P.R.	49	f	atopic	0	0
21.	P.M.	41	m	atopic	0	0
22.	G.M.	38	f	sensitiv skin	0	0
23.	G.P.	47	m	healthy	0	0
24.	E.R.	57	f	healthy	0	0
25.	K.H.	51	f	healthy	0	0
26.	O.M.	23	f	sensitiv skin	0	0
27.	St.St.	36	f	healthy	0	0
28.	M.H.	58	m	healthy	0	0
29.	M.M.	55	f	sensitiv skin	0	0

Lfd. No.	Test person	Age	Sex	Diagnosis	Reaction	
					48 h	72 h
30.	M.E.	22	w	healthy	0	0
31.	J.M.	30	w	healthy	0	0
32.	St.T.	31	w	healthy	0	0
33.	S.H.	56	w	healthy	0	0
34.	G.G.	47	w	sensitiv skin	0	0
35.	Z.A.	26	w	healthy	0	0
36.	T.M.	41	w	healthy	0	0
37.	K.M.	39	w	sensitiv skin	0	0
38.	R.N.	28	w	healthy	0	0
39.	P.A.	22	w	healthy	0	0
40.	H.S.	54	w	healthy	0	0
41.	K.R.	26	w	sensitiv skin	0	0
42.	K.I.	46	w	sensitiv skin	0	0
43.	Sch.G.	45	w	healthy	0	0
44.	P.A.	27	w	healthy	0	0
45.	Que.I.	34	w	sensitiv skin	0	0
46.	B.Y.	25	w	healthy	0	0
47.	Z.H.	46	m	atopic	0	0
48.	Z.P.	43	w	sensitiv skin	0	0
49.	Z.J.	20	m	atopic	0	0
50.	Z.S.	22	w	sensitiv skin	0	0

VTRI

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Chứng nhận lô hàng:

1. Tên hàng hóa và số lượng/khối lượng theo khai báo : Khẩu trang vải kháng khuẩn 2 lớp người lớn, số lượng: 70.000 sản phẩm *(chi tiết sản phẩm như trong danh mục đính kèm)*
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Hà Nội, ngày 16 tháng 03 năm 2020

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GIÁM ĐỊNH CHỨNG NHẬN SẢN PHẨM
ThS. Trần Thị Hà

Mẫu dấu hợp quy

VTRI

** Giấy chứng nhận chỉ có giá trị với lô hàng được chứng nhận nêu trên*
** Khách hàng chịu trách nhiệm về những thông tin khai báo*
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DANH MỤC SẢN PHẨM CHỨNG NHẬN

(Kèm theo giấy chứng nhận hợp quy số *1472000782* do

Công ty Cổ phần - Viện Nghiên Cứu Dệt May cấp ngày 16/03/2020)

TT	Tên sản phẩm	Mã sản phẩm	Đặc tính sản phẩm	Nơi sản xuất/Xuất xứ	Số lượng (SP)	Nhóm sản phẩm theo QCVN01
1	Khẩu trang vải kháng khuẩn 2 lớp người lớn	QTKT01	Khẩu trang may từ vải kháng khuẩn chất liệu 60% cotton, 40% polyester.	Việt Nam	70.000 chiếc	2

*** HẾT ***

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Research Article

Antimicrobial Active Clothes Display No Adverse Effects on the Ecological Balance of the Healthy Human Skin Microflora

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The progressive public use of antimicrobial clothes has raised issues concerning skin health. A placebo-controlled side-to-side study was run with antimicrobial clothes versus fabrics of similar structure but minus the antimicrobial activity, to evaluate possible adverse effects on the healthy skin microflora. Sixty volunteers were enrolled. Each participant received a set of form-fitting T-shirts constructed in 2 halves: an antibacterial half, displaying activities of 3–5 log-step reductions due to silver-finishes or silver-loaded fibres and a nonantibacterial control side. The microflora of the scapular skin was analyzed weekly for opportunistic and pathogenic microorganisms over six weeks. The antibacterial halves did not disturb the microflora in number or composition, whereas a silver-containing deodorant displayed a short-term disturbance. Furthermore, parameters of skin morphology and function (TEWL, pH, moisture) did not show any significant shifts. In summary, antimicrobial clothes did not show adverse effects on the ecological balance of the healthy skin microflora.

1. Introduction

Originally, antimicrobial substances have been used in textiles to prevent rotting, especially under tropical climate conditions. Nowadays, consumers' attitude towards hygiene and active lifestyle has created a rapidly increasing market for antimicrobial consumer goods; hence, the application of antimicrobial agents is extended to clothes used in outdoor, health care sector, sport, and leisure.

The majority of fabrics use silver ions as the active antimicrobial agent [1]. Beside silver, quaternary ammonium compounds, polyhexamethylene biguanides, triclosan, or chitosan are also used. Antimicrobial agents can be applied to the textile substrates as a finish by exhaust, pad-dry-cure, coating, spray, and foam techniques, or the substances can be applied by directly adding into the fibre spinning dope [2]. Manufacturers claim that the antimicrobial effect is restricted more or less to the fibre surface, but mostly the amount of biocide released onto the skin from each product is unknown.

In dermatology, antimicrobials are mainly used as liquids to eliminate pathogens in skin antisepsis and disinfection. The application of therapy-enhancing antimicrobial fabrics in dermatology came up in 2006, when Gauger et al. used form-fitting antimicrobial textiles, based on silver-coated yarns in the treatment of atopic dermatitis [3]. In this double-blind, placebo-controlled trial with 68 atopic dermatitis patients, they were able to show that antimicrobial fabrics, worn for 2 weeks tightly on the skin, may reduce the nonphysiological colonization of the patients skin with the microorganism *Staphylococcus aureus* [4, 5]. Subsequently similar studies confirmed that antimicrobial cloth at least have influence on the pathological skin flora of atopic dermatitis skin and thus may support or reconstitute physiological functions [6–8]. Whether an influence on the physiological skin flora on skin of healthy subjects occurs has not been addressed so far.

In contrast to therapy-enhancing textiles, which support physiological or healing functions, the public use of antimicrobial cloth as a consumer good should not pose any risk to the human health under normal or foreseeable use [8–13]. The question of such health risks is important for the increasing number of people using antimicrobial cloth especially in sport and leisure activities, who wish

to feel clean and safe or to control malodour. The main concerns with the regular use of topical antimicrobial substances on skin comprise the development of irritant and allergic dermatitis [14] as well as disturbances in the ecological balance between the host (transient) and the normal (resident) microflora. Since most studies on the impact of antimicrobial agents on normal microflora have been carried out on the intestinal flora [15], less is known on the effects on the human skin microflora [16], although the skin microbiota provides an important barrier against the colonization of potentially pathogenic microorganisms and against overgrowth of already present opportunistic microorganisms [15]. Proposed beneficial roles also include further processing of skin proteins, free fatty acids, and sebum [17].

Adverse effects of antimicrobial clothes, especially form-fitting sport and leisure underwear, on the ecological balance of the human skin microflora, are poorly studied. We therefore investigated in this study, whether silver-finished and silver-loaded antimicrobial fabrics lead to changes in the physiological human skin microflora of healthy subjects under usual use. To address this question, a placebo-controlled right/left-intraindividual pre-/post-comparison trial with 60 volunteers was performed over a period of 6 weeks. Antimicrobial fabrics, provided with a strong antimicrobial activity according to ISO 20743, were used in this long-term wear trial and compared with the short-term application of an antibacterial silver-containing deodorant. Furthermore, we evaluated the effect of the antimicrobial fabrics on skin physiological parameters. In particular, transepidermal water loss (TEWL), stratum corneum hydration (corneometry) and skin surface pH (pHmetry) were objectively used to monitor the skin barrier functions, in order to look for the advent of irritations or secondary effects of a changing microbial composition of the skin microflora.

2. Materials and Methods

2.1. Subjects. In all, 60 healthy, Caucasian volunteers, 30 female and 30 male (mean age: 36 years, range: 21–65) participated. The volunteers were asked about infections, skin diseases, and their personal assessment of their skin sensitiveness. Subjects who had used antibiotics or other immune-modulating medications less than 8 weeks prior to the study, or had current abnormal discharges, like itching or irritations, were excluded. Also hospitalised persons or health care workers were excluded. The subjects gave their written consent to inclusion. All participants were under dermatological supervision. The sampling areas were checked for any irritating shift weekly over a period of 6 weeks, starting at the outset and ending 1 week after the wear period.

2.2. Textile Samples. The wear trial was planned as a placebo-controlled right/left-intraindividual pre-/post-comparison with special T-shirts. These were constructed in 2 separate halves, both with the same look. One side consisted of a nonantibacterial 100% polyester knitted fabric (placebo, Interlock 42E, dtex 76 f 128), whereas the other half was knitted with an antibacterial 100% polyester yarn endowed with silver (verum 1, Trevira bioactive, Bobingen, Germany, the mass area per unit was 146 g/m^2). The placebo and verum fabrics were combined using press buttons in the front and back and worn during the night at least for 8 h over a period of 4 weeks. After each week, new T-shirts were used and the worn samples were washed and checked for their antibacterial activities (>3 log step was required). Halves were washed separately (according to DIN EN ISO 6330: 2001–2004 Textiles—Domestic washing and drying procedures for textile testing, at 40°C with 9.5°dH and 78.5 g ECE detergent) in order to avoid antibacterial contamination of the placebo fabrics.

Another antibacterial fabric (verum 2) was made by finishing nonantibacterial single jerseys made of Polyamide-Tactel (dtex 85 f 92/Linel 33, mass area per unit was 147 g/m^2) by a common padding method using a commercially available antibacterial finish (Beisoft-SH, CHT Beitlich, Tübingen, Germany). In addition, an alcohol-free, silver-containing antibacterial deodorant was used for a one-day short-term wear trial (verum 3: deodorant).

To exclude any secondary skin irritation effects, all fabrics and deodorants were checked prior to the wear trial for their cytotoxic and irritating potential according to EN ISO 10993 Biological evaluation of medical devices, Part 5: tests for *in vitro* cytotoxicity and Part 10: tests for irritation and delayed-type hypersensitivity.

2.3. Antimicrobial Activity. The antibacterial activities of all textile samples were evaluated with the suspension test according to the standard ISO 20743:2007 "Textiles—determination of antibacterial activity of antibacterial finished products." The determination of the antibacterial activity was performed by the absorption method, in which a test bacterial suspension is inoculated directly onto samples. In brief, textile swatches were inoculated with a starting suspension of 10^5 of *Staphylococcus aureus* and *Klebsiella pneumoniae*. After 18 h incubation at 37°C, the colony plate count method was used for the enumeration of bacteria colony forming units (CFUs). The specific antibacterial activity was determined by inoculating a negative control material of the same sort of fabric but without the antibacterial activity. The efficiency of the activity was then calculated by the following equation:

$$\begin{aligned} &\mathrm{Log}_{10}\mathrm{CFU}\ (\text{negative control, } 18\,\mathrm{h}) \\ &\quad - \mathrm{Log}_{10}\mathrm{CFU}\ (\text{sample, } 18\,\mathrm{h}) \\ &\quad = \text{specific antibacterial activity.} \end{aligned} \tag{1}$$

The general assessment criteria follow a definition by Hohenstein Institutes, in that a growth reduction efficacy of <0.5 corresponds to no antibacterial activity, whereas ≥0.5 to <1 corresponds to a slight, ≥1 to <3 to a significant, and a growth reduction of ≥3 indicates a strong antibacterial activity, respectively.

2.4. Silver Release. The silver release of the textile swatches (1 gr) was determined by shaking the textiles for 24 h in artificial sweat solution according to DIN EN ISO 105-E04: 1996–2008 Textiles—Tests for colour fastness—Part E04: Colour fastness to perspiration (0.5 g L-Histidine-Hydrochloride monohydrate, 5 g NaCl, 2.2 g Na-dihydrogenphosphate, pH 5.5) at 37°C. Two spray bursts of the deodorant were also collected in sweat solution. The silver release of the sweat solutions was determined by ICP-MS (Elan 9000, Perkin-Elmer, Germany).

2.5. Skin Microflora Examinations. Bacterial solutions were collected weekly from the back of the participants, at the region of their scapula of both body sides, immediately before the wear trial (baseline, T_0), during the trial (T_7, T_{14}, T_{21}, T_{28}) as well as 7 days thereafter (T_{35}). The scapular region was chosen because it ensures that all textiles had a close fit and was permanently covered with the sample. The participants were evaluated always by the same investigator. A standard scrub method developed by Williamson-Kligman [18] was used to collect the skin microflora samples from the two back sides. Sterile glass cylinders (2.0 cm in inner diameter with a contact area of 3.14 cm^2) were placed on the scapula skin. 2 mL of sterile Phosphate-Buffered Saline (containing 137 mM NaCl, 2.7 mM KCl, and 10 mM phosphate, pH 7.4) were poured into the cylinder followed by continuous scrubbing of the surface with a blunt sterile rubber policeman for 20 sec. The liquid was removed with a sterile pipette and emptied into a sterile 15 mL test tube. 100 μL each were plated on blood agar plates.

Plates were incubated at 36°C under aerobic conditions and inspected after 2 days. The number of colony forming units (CFUs)/cm^2 was determined. Using routine bacteriological techniques microorganisms were categorized into coagulase-negative staphylococci (CNS), *Staphylococcus aureus*, *Streptococci* spp., *Micrococcus* spec., Bacilli, enterobacteria, Gram-positive rods (propionibacteria, corynebacteria), yeasts and the total number of aerobic microorganisms. The analytical data were expressed as logarithms for CFU per cm^2 of skin.

2.6. Statistics. The Wilcoxon ranked pair test was applied for comparison of the colonization on antibacterial active verum sides versus the nonantibacterial placebo sides in comparison to baseline at different time points of evaluation. A significance level of $P = .05$ was chosen. Means and standard deviations were calculated by means of SigmaStat 3.5 and the Wilcoxon-Signed-Rank Test.

2.7. Skin Physiology Parameters. To analyse possible influences of antibacterial clothes to the skin, an objective quantification of skin parameters was performed by measuring hydration (skin capacitance), evaporimetry/transepidermal water loss (TEWL), and pHmetry, bilaterally, on the scapular region. Test persons stayed in a conditioned room with 22°C and 40% RH during 15 min to acclimatize the skin. The TEWL, as an indicator of the stratum corneum integrity, was measured with an evaporimeter ($g/m^2 * h$; Tewameter TM 300, Courage and Khazaka Electronics, Köln, Germany). Electrical capacitance, as an indicator of the stratum corneum hydration (corneometry) was measured in triplicate with a capacitance meter. For this purpose, a Multiprobe Adaptor System MPA-9 (Courage and Khazaga, Cologne, Germany) was used, equipped with Corneometer CM 825 and a pH 905 pH-meter. According to the manufacturer, the pHmeter measures with a precision of 0.1 unit and a punctual (pointed) electrode. The probe was preheated to skin temperature, and the measured TEWL values were recorded over a period of 60 sec. In addition the skin temperature was measured with an infrared thermometer (Dostmann Electronic, Wertheim-Reichbolzheim, Germany).

Table 1: Antibacterial activities and silver release of the tested textiles and the deodorant.

	Activity (log cfu) *Staphylococcus aureus*	Activity (log cfu) *Klebsiella pneumoniae*	Ag-release (ppm)
Verum 1	4.25	3.38	2.5
Verum 2	3.03	4.24	1.9
Deo	2.95	4.72	0.25

3. Results

Prior to the wear trials, the antibacterial activities of the textile samples and the deodorant were determined. The polyester verum fabric 1 reduced the starting inoculum of 10^5 germs over 4.25 log steps for *S. aureus* and also showed a very strong activity against *K. pneumoniae* (3.38 log-step reduction). The finished antimicrobial T-shirt half displayed a somewhat lower activity of 3.03 log-step reductions for *S. aureus* and a strong 4.24 log-step reduction for *K. pneumoniae*. Thus, the antibacterial activities of the fabrics were in efficacy levels typical for sport and leisure wear. Silver releases, determined by ICP/MS, showed a release of 2.5 ppm of silver from the verum 1, whereas the finished verum 2 released 1.9 ppm of silver. In contrast to this, the silver content of the deodorant amounted 0.25 ppm, although it exhibited strong antibacterial activities versus both test germs. The results are summarized in Table 1.

To evaluate a possible short-term impact on the physiological human skin microflora, a spray burst of an antibacterial silver-containing deodorant was applied on the scapula of the volunteers. Immediately after the application and 8 h later, skin bacteria were recovered, counted, and compared to the number of skin germs before the spray application. The before and after line boxplot is given in Figure 1. A significant drop of microorganisms was observed immediately after the application (0 h), which lasted at least more than 8 h, indicating a short-term impact on the microflora. The microflora recovered to normal values after 24 h (not shown). The spectrum of germs did not change.

The placebo-controlled side-to-side comparison with special T-shirts was run, to evaluate possible long-term effects on the ecological balance of the human skin flora of antimicrobial clothes. For both fabrics, the halves knitted

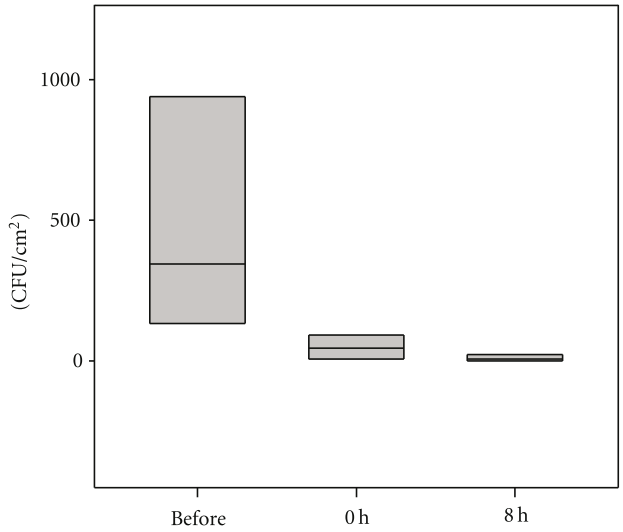

Figure 1: Boxplot diagram showing a short-term impact on the microflora immediately (0 h) and after 8 h following a spray burst of an antibacterial silver-containing deodorant ($n = 8$).

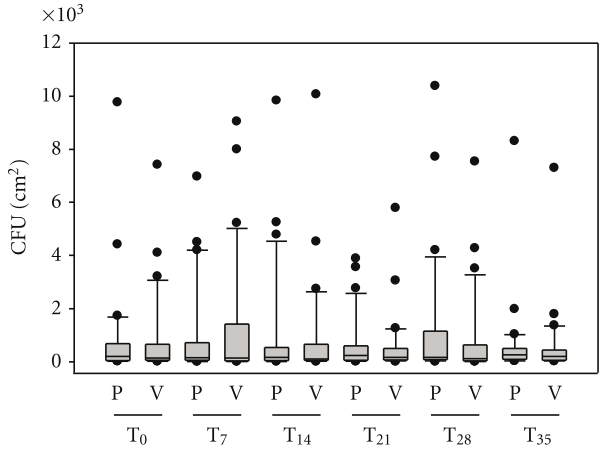

Figure 2: Boxplot diagram showing total germ count after application of fabric 1. PES-silver Verum side (V) and placebo side (P). T_0 = baseline, T_7 = after 1 week wear trial, T_{14} = after 2 weeks, T_{21} = after 3 weeks, T_{28} = after 4 weeks, T_{35} = 1 week after the wearing time ($n = 30$).

with silver-loaded fibres as well as for the halves finished with silver, the effects on the human skin microflora were identical. Figures 2 and 3 summarize the results. At all measuring points we analyzed typical bacteria of the human microflora. No pathogenic germs occurred in the microflora of the subjects during the wear period or afterwards. Furthermore, no significant deviations were found for the total cell counts of the body side covered by the antibacterial half of the T-shirt, or the side covered with the control material of similar structure. In the box-whisker blot, the interquartile ranges (IQRs) of all volunteers were similar. On each body side, the spectrum of microorganisms did not change during the wear trial.

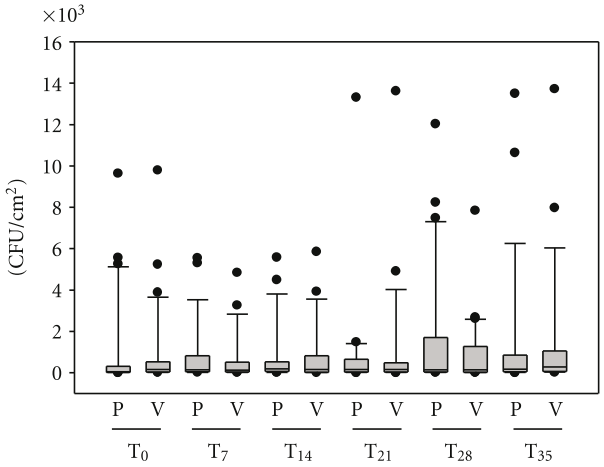

Figure 3: Boxplot diagram showing total germ count after application of fabric 2. Silver-finish Verum side (V), placebo side (P). T_0 = baseline, T_7 = after 1 week wear trial, T_{14} = after 2 weeks, T_{21} =after 3 weeks, T_{28} = after 4 weeks, T_{35} = 1 week after the wear period ($n = 30$).

Possible secondary effects on the skin were determined by measuring the skin physiological parameters pH-value, TEWL and hydration in order to look for a changing microbial composition of the skin microflora or the advent of irritations. Skin parameters were taken prior to each skin scrubbing, that is, before, weekly and a week after the removal of the T-shirts (Figures 4, 5, and 6). Minor individual right/left deviations were observed, which remained in parallel over the wear period. None of the test subjects' skin pH values showed a deviation of more than 0.5 at each weekly measuring point or after the wear trial, when compared to the individual pH value prior to the wear trial. There was also no significant difference for TEWL or the skin moisture over the measuring period as compared to the corresponding placebo sides. Furthermore, over the whole test period of six weeks, the sampling areas were checked weekly by a dermatologist for any irritating shift. None of the test persons showed signs for skin irritations or allergies within the test area.

4. Discussion

Although wearing clothing to protect one's skin is not a new practice, there are limited investigations on physiological responses of skin towards clothes. Parameters like water and water-vapour transport through garments have already been shown to influence microclimate and subsequently the flora of the skin [19], but, to our knowledge, there are only scarce data available on microflora properties, when the skin gets into contact with antibacterial fabrics [20]. Studies are therefore needed to understand the chemical and biological effects of antimicrobial textiles on skin health.

4.1. Antibacterial Activity, Release, and Risks of Silver. Today, metallic silver and silver compounds are predominantly used

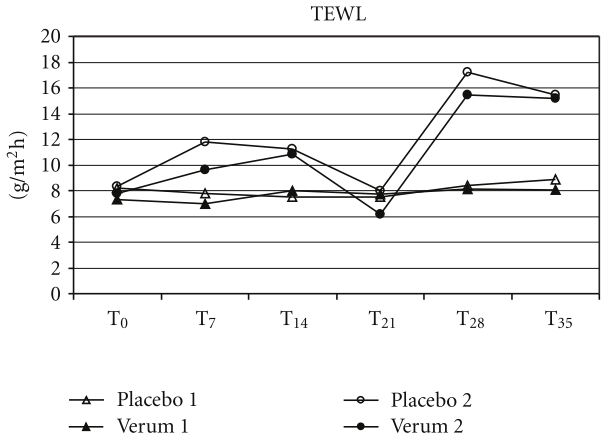

Figure 4: The comparison of the mean values of TEWL between the antibacterial verum and the corresponding placebo shirt halves did not show significant differences between the baseline (T_0), during (T_7–T_{28}) or after the wear trial (T_{35}).

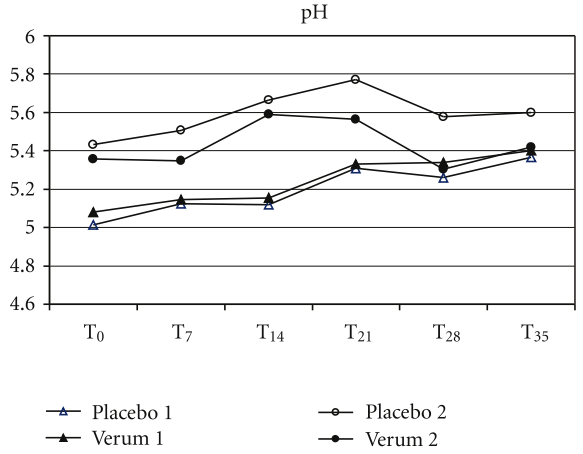

Figure 5: The comparison of the mean values of skin pHmetry between the antibacterial verum and the corresponding placebo shirt halves did not show significant differences between the baseline (T_0), during (T_7–T_{28}) or after the wear trial (T_{35}).

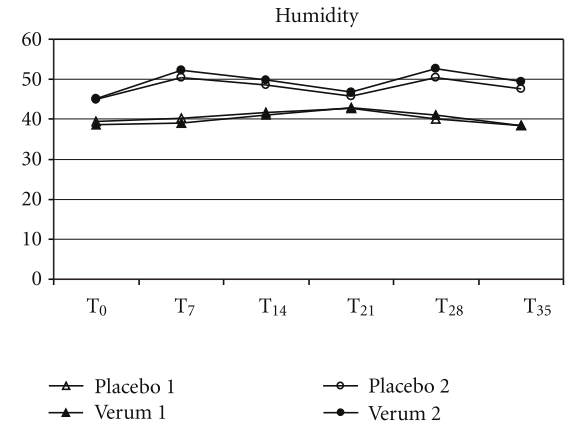

Figure 6: The comparison of the mean values of skin hydration between the antibacterial verum and the corresponding placebo shirt halves did not show significant differences between the baseline (T_0), during (T_7–T_{28}) or after the wear trial (T_{35}).

in antibacterial fabrics by contrast with other biocides, that is, in sport and leisure wear as well as in fabrics for the treatment of atopic dermatitis [3, 6–8, 11]. As the use of silver products increases, it is becoming more important to develop standard procedures to measure the efficacy of each product in order to discuss questions concerning comparability, mechanisms and risks [21]. For example, various dermatological studies propagating the efficacy of silver cloth in lowering *S. aureus* colonization of atopic dermatitis patients failed to use standard procedures to measure the antibacterial efficacy of their samples, neglecting the fact that an industrial key standard (ISO 20743:2007) exists to determine the antibacterial activity of antimycrobially finished products [22]. Technically, the setup of this suspension tests enforces a close proximity and the interaction of test germs with the surface of the antibacterial fibres. Therefore, the resulting log-reduction values, for example, cannot be compared to standardized testing of disinfectants and antiseptics. As a result, the standard ISO 20743 favours high log reductions of antibacterial fabrics, notably when there is only a slight release of biocides. Against this background, we found *strong* activities for the silver-loaded and the silver-finished shirt halves according to the general assessment criteria.

For an alternative assessment of the antibacterial activity, we also measured the silver release of our samples. The total silver release of the silver-loaded fabric was 2.5 ppm, whereas the silver-finished shirt released 1.9 ppm. This is slightly above the minimum of 1 ppm, which is considered to be required for an antimicrobial activity [11] and supports the view that the ISO 20743 favours high log reductions. Nevertheless, compared to silver-loaded wound dressings, which have been shown to release around 10–40 ppm of silver, the silver release of commercially sport and leisure wear is far lower [12, 23]. For many silver-containing products, in contrast to antibiotics, the minimal inhibition concentration (MIC) values and breakpoints of silver still have not been agreed by professional organizations [13, 24, 25]. To complicate matters further, other factors beside the release, for example, the distribution of silver within a product, its chemical and physical forms, also influence its ability to kill microorganisms [21]. Concerning the risk of silver fabrics, the release of approx. 2 ppm of silver exhibits low toxicity in the human body and minimal risk is expected due to dermal application, inhalation, ingestion or through the urological or haematogenous route [10–12]. A further risk factor of silver is its allergenic potential. Silver allergy is discussed as a contraindication for using silver in antibacterial clothes, although the incidence of this rare allergy is still not known [10]. Therefore, despite seldom silver allergies, silver-containing medical devices are evaluated as safe in the use on patients.

4.2. Effects on the Microbiome. The main objective of this pilot study was to investigate whether antibacterial clothes affect the skin microbiome. To prove possible effects on

the ecological balance of the healthy human skin flora, we performed long-term wear trials with form-fitting clothes and also compared the effects to the short-term application of an antibacterial deodorant.

Recent studies employing 16SrRNA gene survey strategies with samples from the inner elbow of healthy human subjects indicate that the human skin microbiome is far more complex and in fact comprises 113 phylotypes that belong to six bacterial divisions [26]. Gene survey analyses are unsuitable for field trials, although it can be assumed that the skin microbiome on the healthy scapular skin and of atopic skin is of similar diversity [27]. *In vivo* studies for testing the efficacy of topical antimicrobial agents require the evaluation of the skin flora by more easy-to-perform methods. Since fabrics may only contact the skin's surface yet for a limited period (due to bending stiffness and drapeability), we used a standard scrub method for the recovery of typical aerobic skin bacteria from the scapula, which allows a satisfying enumeration and identification [18, 28]. The analysis by culture-dependent assays also allowed to distinguish between viable and nonviable bacteria.

Over a wear trial of six weeks, the skin flora was analyzed weekly for opportunistic and pathogenic microorganisms on healthy human skin. No pathogenic germs occurred in the microflora of the subjects during the wear period of four weeks or afterwards. Furthermore, no significant deviations were found for the total cell counts of the body side covered with the antibacterial half of the T-shirts or the side covered with the control material of similar structure. On each body side, the spectrum of microorganisms did not change during the wear trial. Thus, neither the T-shirts with antibacterial silver-finish nor silver-loaded fibres disturbed the skin flora in number or composition. In contrast to this experiment, one single disinfection of the scapula region with an alcohol-free silver-based deodorant of similar strong activity caused a short-term reduction of 2 log-steps in the total germ count.

Our results support the view that the human skin microflora is quite stable towards exogenous destabilisation which is interesting for a risk assessment of antibacterial clothes used for staffs, working in health care institutions (e.g., in nursing homes, intense care units, paramedics), where the antibacterial fibre surface may have beneficial means of controlling life-threatening nosocomial infections including MRSA as well as adding levels of personal hygiene [29]. Lilly et al. concluded that the eradication of the bacterial population of the normal skin flora is impossible *in vivo*, even after repeated applications of skin disinfectants [30]. On the other hand, the constant and excessive use of antimicrobials is known to cause irritant and allergic contact dermatitis [14]. Furthermore, changes in the bacterial flora may occur: they are often associated with skin damages, infections, frequent showering or use of skin care products, hence, hands of health care personnel are often affected [31]. We did not find opportunistic microorganisms on our healthy volunteers, indicating that antibacterial clothes do not impair the colonization resistance of healthy skin. This is in line with Cole et al. [32], who investigated the antibiotic and antibacterial agent cross-resistance in target bacteria from homes of antibacterial product users and nonusers. They showed that the use of antibacterial products does not facilitate the development of antibiotic resistance in bacteria from the home environment.

4.3. Fabrics in Dermatotherapy. Many lines of evidence suggest a role for microorganisms in noninfectious skin diseases, such as atopic dermatitis, rosacea and acne [33, 34] Therefore, antiseptic therapies using liquid skin disinfectants and systemic antimicrobials are essential for the efficient dermatotherapy of affected lesions of atopic dermatitis patients [3]. Hartmann [35] has shown that liquid antimicrobials may have a short-term impact on the ecosystem of the skin flora, a view which is supported by our results taken with the antibacterial silver deodorant. These impacts are of clinical importance, when members of the normal skin flora are involved in the pathogenesis of the disease, for example, *Propionibacterium acnes* in acne vulgaris, *Corynebacterium* species in erythrasma, *S. aureus* in atopic dermatitis and others.

The clinical efficacy of adding an antimicrobial effect to fabrics in the treatment of atopic dermatitis patients has been investigated by many research groups [6–8]. Gauger et al. [3] also used a side-to-side comparative trial by comparing the treatment with silver-coated textiles on one arm to that of cotton on the other arm for 7 days followed by 7 days without the treatment in 15 patients with generalized or localized atopic dermatitis. In contrast to our results taken over 4 weeks, their study demonstrated a highly significant decrease in the nonphysiological *S. aureus* colonization on the side covered by the silver-coated textile already after 2 days. It was furthermore concluded, that overnight wearing might be able to sustain a constant *S. aureus* reduction. Mason already noted that the mechanisms on the eradication of *S. aureus* on atopic skin are unclear [36], in particular against the background of the lack of testing the antibacterial efficacy (see above). In contrast to our study the textiles used by Gauger were form fitting to the skin, and all patients were allowed to use topical steroids. Moreover, atopic dermatitis patients have sensitive and impaired skin barrier functions [37]. We were unable to find *S. aureus* colonization on the skin of our healthy subjects. Nevertheless, despite these differences, antibacterial textiles may play an important clinical role, especially in skin conditions with an increased rate of bacterial or fungal infections like atopic dermatitis and hyperhidrosis, in diabetic patients or aged skin [38].

4.4. Microclimate. The interactions between fabrics and skin climate and their impact on the skin microflora have already been studied by Runeman et al. [19]. The temperature, pH, and total number of microorganisms were significantly lower for users of vapour-permeable panty liners. In this study we monitored skin barrier functions depending on antibacterial cloth by measuring TEWL, stratum corneum hydration and skin surface pH, in order to look for the advent of irritations or secondary effects of a changing microbial composition of the skin microflora. We were unable to find significant difference for TEWL, pH, or skin moisture over the whole measuring period for the antibacterial shirt

halves as compared to the corresponding placebo sides. Since resident microbiota may become pathogenic, sometimes in response to an impaired skin barrier [17], our results speak in favour of no effect on skin barrier and occurrence of pathogenic bacteria. This is also supported by our finding that the sampling areas were checked weekly by a dermatologist for any irritating shift. None of the test persons showed signs for skin irritations or allergies within the test area.

5. Conclusions

Altogether, in our experiments we were not able to see any significant adverse effects of antibacterial clothes on the physiological human skin microflora or the skin barrier of healthy people. Worth of note is that the subject of evaluation was healthy skin that is already in good conditions at the start of the study.

Conflict of Interests

The authors have declared that no competing interests exist.

Acknowledgments

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Report

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LfAS

GLP-Bescheinigung/Statement of GLP Compliance
(gemäß/according to § 19b Abs. 1 Chemikaliengesetz)

Eine GLP-Inspektion zur Überwachung der Einhaltung der GLP-Grundsätze gemäß Chemikaliengesetz bzw. Richtlinie 88/320/EG wurde durchgeführt in:

Assessment of conformity with GLP according to Chemikaliengesetz and Directive 88/320/EEC at:

☒ Prüfeinrichtung/Test facility ☐ Prüfstandort/Test site

BSL Bioservice Scientific Laboratories GmbH
Behringstrasse 6
82152 Planegg
(Unverwechselbare Bezeichnung und Adresse/Unequivocal name and address)

Prüfungen nach Kategorien/Areas of Expertise
(gemäß/according ChemVwV-GLP Nr. 5.3/OECD guidance)

2 Prüfungen auf toxikologische Eigenschaften
3 Prüfungen auf mutagene Eigenschaften (in vitro/in vivo)
9 Sonstige Prüfungen:
a) Mikrobiologische Sicherheitsprüfungen
b) Wirksamkeitsprüfungen an Zellkulturen

Datum der Inspektion/Date of Inspection
(Tag Monat Jahr/day.month year)
11./12.02.2004

Die/Der genannte Prüfeinrichtung/Prüfstandort befindet sich im nationalen GLP-Überwachungsverfahren und wird regelmäßig auf Einhaltung der GLP-Grundsätze überwacht

The above mentioned test facility/test site is included in the national GLP Compliance Programme and is inspected on a regular basis

Auf der Grundlage des Inspektionsberichtes wird hiermit bestätigt, dass in dieser Prüfeinrichtung/diesem Prüfstandort die oben genannten Prüfungen unter Einhaltung der GLP-Grundsätze durchgeführt werden können.

Based on the inspection report it can be confirmed, that this test facility/test site is able to conduct the aforementioned studies in compliance with the Principles of GLP.

München, 21.07.2004

I.V.
Ritter
Leitender Gewerbedirektor

L.S.

CONTENTS

Preface

General

Sponsor:	rent a scientist GmbH Straubinger Straße 81 93055 Regensburg Germany
Study Monitor:	Mr Gregor Schneider
Test Facility:	BSL BIOSERVICE Scientific Laboratories GmbH Behringstraße 6 82152 Planegg Germany
BSL BIOSERVICE-Project No.:	070516
Test Item:	AgPURE W
Title:	Test for Sensitization (Local Lymph Node Assay - LLNA) with AgPURE W

Project Staff

Study Director:	Dr. Ingrid Haist
Deputy Study Directors:	Dr. Achim Albrecht Dr. Daniela Brummer Dipl. Biol. Patricia Schropp
Management:	Dr. Wolfram Riedel Dr. Angela Lutterbach
Quality Assurance Unit:	Dipl. Biol. Uwe Hamann Dr. Margarete Hoechst Dr. Helga Köhn Gwendolyn Pretzsch, B.A.

Schedule

Arrival of Test Item:	February 20, 2007
Date of Project Protocol:	February 22, 2007
Start of Study:	February 27, 2007
End of Study:	March 14, 2007
Date of Report:	March 22, 2007

Project Staff Signatures

Study Director: Dr. Ingrid Haist

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Date: 22.03.2007

Management:

.....

Date: March 22, 2007

Quality Assurance

GLP Compliance

This study was conducted to comply with:

Chemikaliengesetz ("Chemicals Act") of the Federal Republic of Germany, Appendix 1 to § 19a as amended on May 08, 2001. Published May 14, 2001 in Bundesgesetzblatt 2001 part I no. 21, pp. 844 – 854.

OECD Principles of Good Laboratory Practice (as revised in 1997); OECD Environmental Health and Safety Publications; Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 1.
Environment Directorate, Organisation for Economic Co-operation and Development, Paris 1998.

This study was assessed for compliance with the project protocol, the study plan and the Standard Operating Procedures of BSL BIOSERVICE. The study and/or the test facility were periodically inspected by the Quality Assurance Unit and the dates and phases of the inspections and audits are included in this report. These inspections and audits were carried out by the Quality Assurance Unit, personnel independent of staff involved in the study. The final report of the study was audited. A Quality Assurance Statement, signed by the Quality Assurance Unit, is included in this report.

Guidelines

This study followed the procedures indicated by the following internationally accepted guidelines and recommendations:

OECD Guidelines for Testing of Chemicals, number 406 "Skin Sensitization", adopted by the Council on July 17, 1992 (reported Paris, April 29, 1993).

OECD Guidelines for Testing of Chemicals, number 429 "Skin Sensitization: Local Lymph Node Assay" (adopted: 24th April 2002).

EPA Health Effects Test Guidelines, OPPTS 870.2600 "Skin Sensitization".

Archiving

The following records will be stored in the scientific archives of BSL BIOSERVICE Scientific Laboratories GmbH according to the GLP-regulations:

A copy of the final report, the project protocol, the study plan and a documentation of all raw data generated during the conduct of the study (documentation forms as well as any other notes of raw data, printouts of instruments and computers) and the correspondence with the sponsor concerning the project.

If test item is left over a sample will be stored according to the GLP-regulations. Samples that are unstable may be disposed of before that time. No raw data or material relating to the study will be discarded without the sponsor's prior consent. Unless otherwise agreed upon, remaining test item will be discarded three months after release of the report.

Statement of Compliance

BSL BIOSERVICE- Project No.:	070516
Test Item:	AgPURE W
Title:	Test for Sensitization (Local Lymph Node Assay – LLNA) with AgPURE W
Study Director:	Dr. Ingrid Haist

This study performed in the test facility BSL BIOSERVICE Scientific Laboratories GmbH was conducted in compliance with Good Laboratory Practice Regulations:

Chemikaliengesetz ("Chemicals Act") of the Federal Republic of Germany, Appendix 1 to § 19a as amended on May 08, 2001. Published May 14, 2001.

"OECD Principles of Good Laboratory Practice (as revised in 1997) ", Paris 1998.

There were no circumstances that may have affected the quality or integrity of the study.

Study Director: Dr. Ingrid Haist

.....

Date: 03.03.2008

This statement does not include the preliminary test.

Statement of the Quality Assurance Unit

BSL BIOSERVICE-
Project No.: 070516

Test Item: AgPURE W

Title: Test for Sensitization
(Local Lymph Node Assay – LLNA) with
AgPURE W

Study Director: Dr. Ingrid Haist

This report was audited by the Quality Assurance Unit and the conduct of this study was inspected on the following dates:

Phases of QAU Inspections	*Dates of QAU Inspections*	*Dates of Reports to the Study Director and Management*
Audit Study Plan/ Project Protocol:	February 26, 2007	February 26, 2007
Experimental Phase Audit (Method Audit):	October 27, 2006	October 27, 2006
Report Audit:	March 30, 2007	March 30, 2007

This report reflects the raw data.

Member of the
Quality Assurance Unit: .....

Date: 16. April 2007

This statement does not include the preliminary test.

Summary

The test item was assayed at concentrations of 25%, 50% (v/v) and 100%.

The vehicle used was DMSO.

Each mouse was treated by topical application of the prepared test item to the entire dorsal surface of each ear once daily over three consecutive days.

Five days after the first topical application all mice were injected intravenously with ^{3}H-methyl thymidine.

Approximately 5 hours after ^{3}H-methyl thymidine-injection all mice were sacrificed. The draining "auricular lymph nodes" were excised and weighed individually.

A single cell suspension of the lymph node cells for each animal was prepared. The ^{3}H-methyl thymidine – incorporation was measured in a ß-counter and expressed as the number of disintegrations per minute (DPM). Determination of radioactivity was performed individually for each animal.

The proliferative response of lymph node cells was calculated as the ratio of ^{3}H-methyl thymidine - incorporation into lymph node cells of test group animals relative to that recorded for control group animals. A stimulation index, ratio of test item / negative control, was calculated for each concentration.

Summary Results

None of the three tested concentrations of the test item reached the stimulation index of 3.

The stimulation index at a concentration	of	25%	was	**0.6**
The stimulation index at a concentration	of	50%	was	**0.5**
The stimulation index at a concentration	of	100%	was	**0.4**

Weight development of all animals was within the expected range, which includes a weight loss of up to 2 g throughout the study.

At the daily clinical observation the animals did not show any visible clinical symptoms.

Conclusions

The EC3 value (derived by linear interpolation) could not be stated, as all measure points were below the stimulation index of three.

Considering the reported data of this sensitization test it can be stated that the test item AgPURE W causes no reactions identified as sensitization, as the stimulation index was below 3.0 for each concentration tested.

Introduction

The LLNA has been developed as an alternative method for the identification of skin sensitizing test items and measures the proliferation of lymphocytes isolated from lymph nodes (auricular lymph nodes) draining the site of exposure (dorsal aspect of the ears) in mice.

Lymphocyte proliferation is measured by determining the incorporation of ^{3}H-methyl thymidine.

No validated *in vitro* method is available for assessing sensitization potential.

Materials and Methods

Characterisation of the Test Item

The test item and the information concerning the test item were provided by the sponsor.

Name:	AgPURE W
CAS-No.:	7440-22-4
Batch No.:	A7 060724
Chemical name:	colloidal silver
Active components:	0.008%
Purpose:	additive with antimicrobial activity
Colour:	yellow
Physical state at RT:	dispersion
Purity:	± 5 ppm, 19.02.2007
Stability:	3 months
Storage conditions:	at room temperature, protected from light
Safety precautions:	Routine hygienic procedures were sufficient to assure personnel health and safety.

Preparation of the Vehicle

Due to the solubility properties of the test item and after consultation with the sponsor the vehicle was DMSO (Applichem, Lot 6T000072).

Preparation of the Test Item

Due to the results of the preliminary test and after consultation with the sponsor the test item was assayed at three concentrations:

25%, 50%, 100%

The preparations were made immediately prior to each dosing.

Control

The vehicle served as negative control.

Other Materials

^{3}H-methyl thymidine (TRK 300, 25 Ci/mmol; Lot B268; Amersham Pharmacia Biotech), diluted to a working concentration of 80µCi/mL

NaCl 0.9%, Delta-Select, Lot 18511-1B

Trichloroacetic acid (TCA), Sigma GmbH, Lot 014K1176

Phosphate buffered saline (PBS), BSL Bioservice, Lot 26.2.07EA

Test Animals

Mice, CBA/Ca01aHsd, female, age 6 – 12 weeks, 5 mice per test group.

The animals were derived from a controlled full barrier maintained breeding system (SPF).

Source: Harlan Winkelmann GmbH, D-33178 Borchen.

According to Art. 9.2, No.7 of the German Act on Animal Welfare the animals are bred for experimental purposes.

Animal Husbandry

The animals were barrier maintained (semi-barrier) in an air conditioned room

- Temperature: 22 ± 3 °C
- Rel. humidity: 55 ± 10%
- Artificial light, sequence being 12 hours light, 12 hours dark
- Air change: at least 10 x / hour
- Feeding ad libitum, Altromin 1324 maintenance diet for rats and mice, totally-pathogen-free (TPF)
- Free access to tap water (drinking water, municipal residue control, microbiol. controlled periodically)
- The animals were kept in groups in Macrolon-cages on Altromin saw fiber bedding
- Certificates of food, water and bedding are filed at BSL Bioservice
- Adequate acclimatisation period (at least 5 days)

Preparation of the Animals

The animals were randomly selected.

Identification was ensured by cage number and individual marking (tail).

Clinical Observation

Prior to the application and once a day thereafter all animals were observed in order to detect special clinical signs or reactions to treatment.

Weight Assessment

The animals were weighed prior to the application and at the end of the test period.

Dose Groups

3 Test Groups (3 different concentrations) and 1 Negative Control Group (vehicle) were tested.

Test Regime

Topical Application

Each mouse was treated by topical application of 25µL of the selected solution to the entire dorsal surface of each ear.

Topical applications were performed once daily over three consecutive days.

Administration of ^{3}H-methyl thymidine

Five days after the first topical application treatment all mice were dosed with 20µCi ^{3}H-methyl thymidine by intravenous injection (tail vein) of 250µL of ^{3}H-methyl thymidine, diluted to a working concentration of 80µCi/mL.

Preparation of cell suspension

Approximately 5 hours after ^{3}H-methyl thymidine-injection all mice were sacrificed. The draining "auricular lymph nodes" were excised, individually pooled for each animal (2 lymph nodes per animal) and collected in PBS. A single cell suspension of pooled lymph node cells was prepared by gentle mechanical disaggregation through polyamide gauze (200 mesh size). After washing the gauze with PBS the cell suspension was pelleted in a centrifuge. The supernatant was discarded and the pellets were resuspended with PBS. This washing procedure was repeated.

After the final wash each pellet was resuspended in approx. 1 mL 5% TCA at approx. 4 °C overnight for precipitation of macromolecules. Each precipitate was once washed again, resuspended in 1 mL 5% TCA and 10 mL scintillation fluid was added. Then this solution was transferred into scintillation vials and stored at room temperature overnight.

Determination of incorporated ^{3}H-methyl thymidine

The ^{3}H-methyl thymidine – incorporation was measured in a ß-counter and expressed as the number of disintegrations per minute (DPM). Similarly, background ^{3}H-methyl thymidine levels were also measured (5% TCA). Determination of radioactivity was performed individually for each animal.

Evaluation of Results

The proliferative response of lymph node cells was expressed as the number of radioactive disintegrations per minute per lymph node (DPM/NODE) and as the ratio of ^{3}H-methyl thymidine - incorporation into lymph node cells of test group animals relative to that recorded for control group animals (STIMULATION INDEX). Before DPM/NODE values were determined, background values were subtracted.

EC3 values, calculated concentrations which induce stimulation indices of three, are determined by linear interpolation {EC3 = c + [(3-d) / (b-d)] x (a-c)}, between two points of the stimulation indices axis, one above (a,b) and one below (c,d) the stimulation index of three. If all measured points are above or below the stimulation index of three, no EC3 value can be stated.

A substance is regarded as a 'sensitizer' in the LLNA if at least one concentration of the test item results in a 3 fold or greater increase in ^{3}H-methyl thymidine - incorporation into lymph node cells of the lymph nodes of the test group animals, relative to that recorded for the lymph nodes of control group animals **(Stimulation Index equal to or greater than 3.0).**

Deviation from the Project Protocol

There was no deviation from the project protocol.

Results

The test item was assayed at concentrations of 25%, 50% (v/v) and 100%.

The vehicle used was DMSO.

Each mouse was treated by topical application of the prepared test item to the entire dorsal surface of each ear once daily over three consecutive days.

Five days after the first topical application all mice were injected intravenously with ^{3}H-methyl thymidine.

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Considering the reported data of this sensitization test it can be stated that the test item AgPURE W causes no reactions identified as sensitization, as the stimulation index was below 3.0 for each concentration tested.

Table 2: Weight Gain (g)

Group	*Animal No.*	*Start of study*	*End of study*	*Weight gain*
	1	18	17	-1
AgPURE W	2	18	17	-1
25%	3	19	18	-1
in DMSO	4	18	17	-1
	5	21	19	-2
	6	17	18	1
AgPURE W	7	16	16	0
50%	8	18	19	1
in DMSO	9	18	19	1
	10	16	18	2
	11	18	18	0
AgPURE W	12	17	18	1
100%	13	18	18	0
	14	16	16	0
	15	17	17	0
Negative	16	16	16	0
control	17	17	18	1
DMSO	18	16	17	1
	19	17	18	1
	20	18	18	0

Table 3a: Radioactive determination of the test substance groups.
If not noted individually, results include both lymph nodes of an animal.

POS	CPM	Test Item	Conc. [%]	Animal number	DPM	DPM-mean back-ground	DPM/ Node	Stimu-lation Index
61	564.0	**Negative**		16	1354.0	1330.0	665.0	
62	410.0	**Control**		17	999.0	975.0	487.5	
63	497.0			18	1195.0	1171.0	585.5	
64	766.0			19	1834.0	1810.0	905.0	
65	473.0			20	1123.0	1099.0	549.5	
MV	**542.0**			**MV**	**1301.0**	**1277.0**	**638.5**	**1.0**
SD	**122.4**			**SD**	**290.2**	**290.2**	**145.1**	
42	251.0	**AgPURE W**	25	1	597.0	573.0	286.5	0.4
43	111.0			2	270.0	246.0	123.0	0.2
44	340.0			3	825.0	801.0	400.5	0.6
45	532.0			4	1282.0	1258.0	629.0	1.0
46	400.0			5	973.0	949.0	474.5	0.7
MV	**326.8**			**MV**	**789.4**	**765.4**	**382.7**	**0.6**
SD	**141.4**			**SD**	**341.9**	**341.9**	**170.9**	**0.3**
49	335.0	**AgPURE W**	50	6	819.0	795.0	397.5	0.6
50	359.0			7	876.0	852.0	426.0	0.7
51	227.0			8	548.0	524.0	262.0	0.4
52	226.0			9	539.0	515.0	257.5	0.4
53	232.0			10	559.0	535.0	267.5	0.4
MV	**275.8**			**MV**	**668.2**	**644.2**	**322.1**	**0.5**
SD	**58.7**			**SD**	**147.6**	**147.6**	**73.8**	**0.1**
54	123.0	**AgPURE W**	100	11	295.0	271.0	135.5	0.2
55	221.0			12	530.0	506.0	253.0	0.4
56	165.0			13	393.0	369.0	184.5	0.3
57	289.0			14	694.0	670.0	335.0	0.5
58	213.0			15	506.0	482.0	241.0	0.4
MV	**202.2**			**MV**	**483.6**	**459.6**	**229.8**	**0.4**
SD	**56.0**			**SD**	**134.7**	**134.7**	**67.3**	**0.1**
66	11.0	**Background**			25.0			
67	11.0	**Szinti and**			25.0			
68	10.0	**TCA**			24.0			
69	11.0				25.0			
70	9.0				21.0			
MV	**10.4**			**MV**	**24.0**	**0.0**	**0.0**	**0.0**
SD	**0.8**			**SD**	**1.5**			

Szinti = scintillation fluid; TCA = trichloroacetic acid; MV = Mean Value,
SD = Standard Deviation; DPM = disintegrations per minute, CPMA = counts per minute

Distribution of the Report

Sponsor	1x (original)
Study Director	1x (copy)

Nanosilber in Textilien

Ergebnis einer Publikations-Recherche
zum Einsatz von Nanosilber bei Textilien

April 2020

MAE ?

MEDICINA ALTERNATIVA EUROPE

MAE :

- Medicina Alternativa Europe o.s. ist der kontinentale Fachverband für CAM (Complementary & Alternative Medicine) der MAI - Medicina Alternativa International mit Sitz in Sri Lanka

- MAI wurde bereits 1962 während eines WHO-Kongresses in Alma Ata ausgegründet von den damals anwesenden Ländervertretern, mit dem Ziel, bis zum Jahre 2000 eine weltweite Anerkennung der CAM als Teil des öffentlichen Gesundheitswesens zu erreichen

- Gründer war u.a. Prof. Dr. Lama Sir Anton Jayasuriyah aus Sri Lanka (†2005)

- MAE ist eine gemeinnützige Organisation

- MAE wurde 2008 in Prag (CZ) gegründet

- MAE ist die Zentrale nationaler Verbände in der EU

MEDICINA ALTERNATIVA EUROPE

MAE :

- Eine der Hauptaufgaben der internationalen Organisation Medicina Alternativa ist die Förderung des freien Zugangs zu Bildung und Gesundheitssystemen

- Die freie und private Universität der Medicina Alternativa ist die vor allem in Asien bekannte „The Open International University“ (OIU), anfangs OIUCM – The Open International University (for complementary Medicines), mit Sitz in Colombo, Sri Lanka

- MAE ist seit 2010 Host der OIUDC – The Open International University – Digital Campus und der OIUDC-Academy, der Business Schools für berufliche Bildung der MAE

- Die OIUDC ist verbunden mit den Universitäten: OIU, Sri Lanka, UNISS, Cuba, Al Fasher, Sudan und I. Arabaev in Kirgisien

The Open International University
- DIGITAL CAMPUS -

Die Recherche

- MAE wurde im April 2020 von dem deutschen Unternehmen STH GmbH beauftragt mit der Recherche über Publikationen zum Thema „Nanosilber in Textilien" im deutschsprachigen Raum.
- Ziel des Auftrags war die Sichtung von und die Berichterstattung zu Publikationen europäischer Institute und Unternehmen.
- Die hier gemachten Angaben beruhen auf der Sichtung von ca. 40 Publikationen zum o.g. Thema.
- Dabei sind auch die kritischen Berichte der öffentlichen Forschungs-Institute berücksichtigt worden, speziell zum Thema der bioziden Wirkung von Nanosilber.
- Die Recherche soll der Firma STH dazu dienen, die Aussagen des Herstellers der Hanvico-Mundschutzmasken zu verifizieren durch Vergleich von Veröffentlichungen europäischer, anerkannter Institute.
- Die Informationen und uns vorgelegten Prüfberichte des Herstellers der Hanvico-Mundschutzmaske sind diesem Recherche-Bericht ebenfalls beigefügt.
- Folgend sind wesentliche Auszüge aus diesen Publikationen zusammen gefasst worden.

Nanosilber ?

Was ist Nanosilber?

- Das Wort Nano leitet sich vom griechischen Begriff nanos, der Zwerg, ab. Es steht synonym für eine Größenordnung, bzw. Längeneinheit.
- Ein Nanometer ist der milliardste Teil eines Meters (1 nm = 0,000 000 001 m). Ein menschliches Haar hat eine Breite von etwa 80.000 Nanometern (nm).
- Nanosilber bezeichnet Partikel aus metallischem Silber, die im Bereich 1 nm bis 100 nm messbar sind.
- Durch den Nanomaßstab ergibt sich eine Oberflächenvergrößerung pro Volumeneinheit und damit einhergehend eine erhöhte Aktivität. Aufgrund der größeren Oberfläche können mehr reaktive Silberionen freigesetzt werden. Das günstige Oberflächen-Volumen-Verhältnis führt zu einer effektiveren Wirkung bei gleichzeitig geringerem Rohstoffeinsatz.
- Die antimikrobielle Wirkung von Silber, beruhend auf den Silberionen Ag+, wird an der Oberfläche von Silbernanopartikeln gebildet.
- Durch die Nanotechnologie können aktive antimikrobielle Materialien in nahezu jeder Matrix und Beschichtung eingearbeitet werden.

→ effektivere Wirkung bei gleichzeitig geringerem Rohstoffeinsatz von Nanosilber

Wirkmechanismus gegen Bakterien

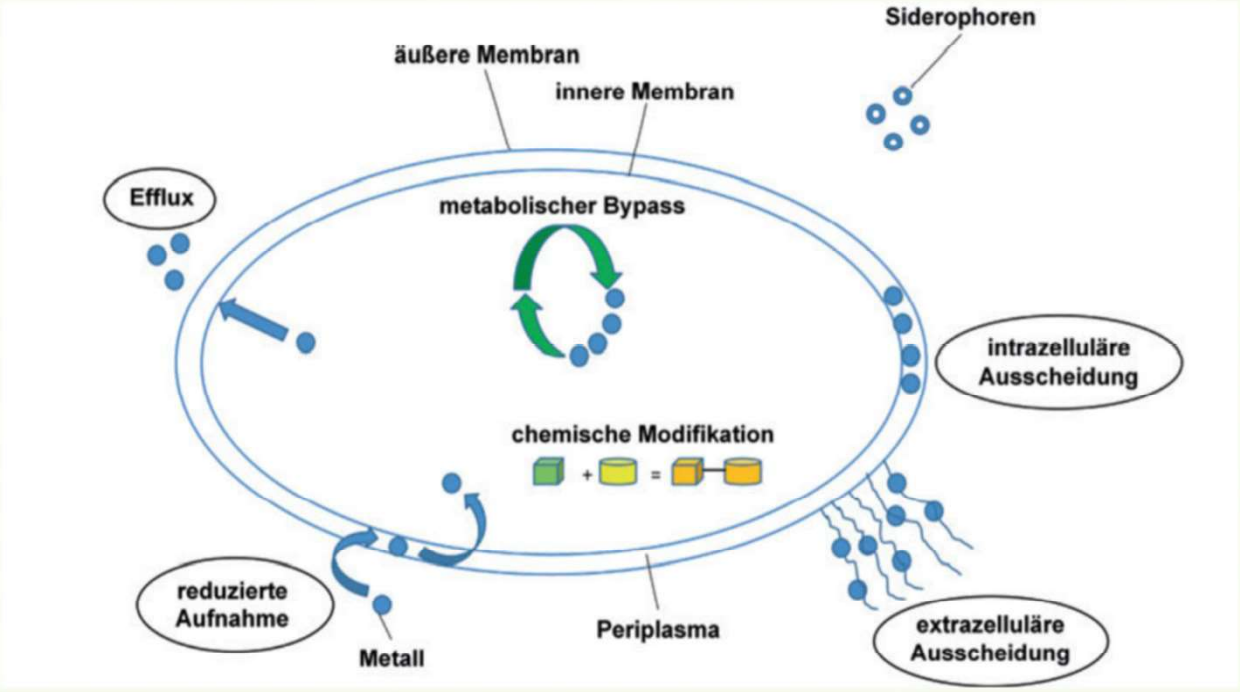

Bild 1: Übersicht zum Abwehrverhalten von Bakterien

- Aufgrund ihres Verhältnisses von Oberfläche zu Volumen haben Nanopartikel besonders aktive Eigenschaften.
- Durch ihre elektro-statischen Ladungen an der Außenmembran können sie Bakterien binden und deren Integrität zerstören.

Wirkmechanismus gegen Bakterien

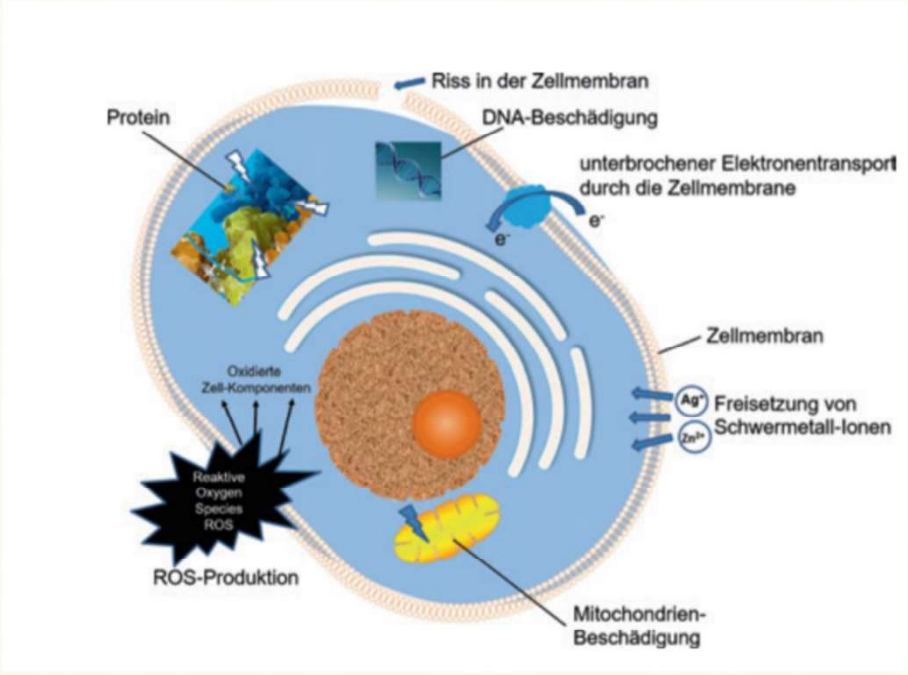

Bild 2: Mechanismen zur Zelltoxizität von Nanopartikeln gegenüber Bakterien

- Interaktionen der Silberionen mit der Zellmembran führen zu einer Verringerung in der Anheftung der Mikroorganismen an ihren Untergrund und dadurch zu schlechten Wachstumsbedingungen
- Durch das Blockieren einiger Schritte im Stoffwechsel verringern sie die Vitalität der Mikroorgansimen
- Ein unumkehrbare Interaktion mit schwefel- und phosphorhaltigen Aminosäuren und Proteinen verursachen eine Schädigung im Zellinneren

Nutzen-bewertung !

Nutzen-Bewertung Textil

- Silberionen sind seit langem wegen ihrer antimikrobiellen Eigenschaften beliebt.
- Seit es Silberpartikel auch in Nanogröße gibt, ist die Diskussion aufgeflammt, wie und wie stark diese Nanopartikel in die Umwelt gelangen.
- Forscher des Technikinstituts Empa der Eidgenössischen Technischen Hochschule in Zürich geben jetzt Entwarnung. Demnach erlaubt sogenanntes Nanosilber nicht nur geringere Dosierungen, zugleich waschen sich diese Nanopartikel auch viel weniger aus als herkömmliche Silberpartikel.
- Vergleich zwischen Nano- und herkömmlicher Silberbeschichtung: Die Empa-Forscher haben silberbeschichtete Kleidung in die Waschmaschine gesteckt und das Abwasser auf Silberpartikel untersucht. Gewaschen wurde Kleidung mit herkömmlichen Silberpartikeln und mit Nanopartikeln.
- Dabei stellten die Forscher fest: Im Unterschied zu herkömmlichen Beschichtungen, aus denen eine Vielzahl verschiedener Silberpartikel im Abwasser nachgewiesen wurden, verlieren nanobeschichtete Silbertextilien laut Empa beim Waschen generell weniger Silber, weil bei einer Nanobeschichtung deutlich weniger Silber ins Textil eingearbeitet wird und dieses für die antibakterielle Wirkung dosierter freigesetzt wird.

Nutzen-Bewertung Textil

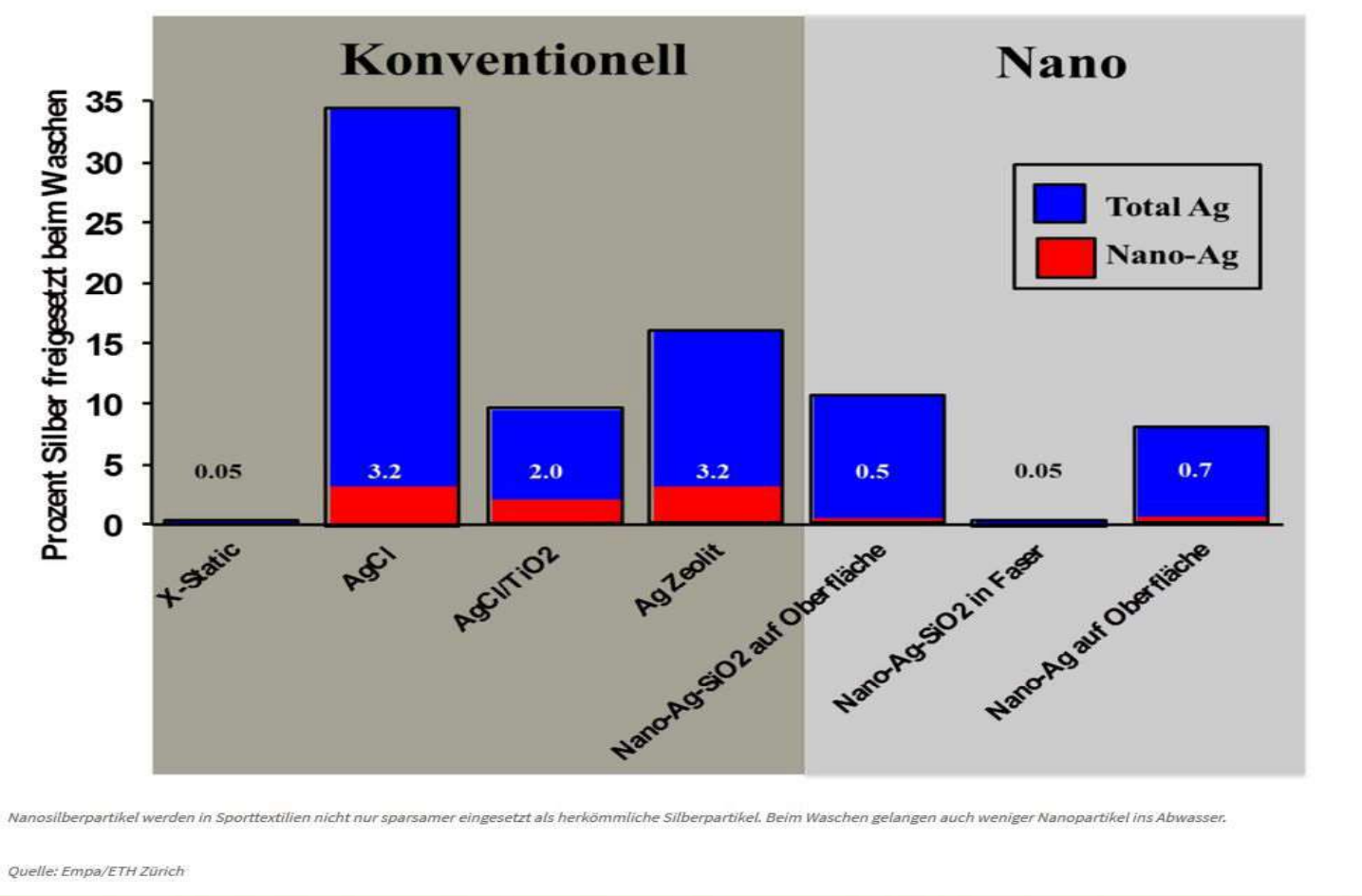

Abbildung: Prozent Silber freigesetzt beim Waschen

Einsatz Nanosilber !

Einsatz von Nanosilber

- Das technische Potential des Nanosilbers gilt als außerordentlich hoch und liegt neben den hervorragenden antimikrobiellen Eigenschaften auch in der ausgezeichneten thermischen und elektrischen Leitfähigkeit, sowie in der Nutzung spezieller optischer Eigenschaften.
- Die antimikrobielle Wirkung des Silbers beruht auf seiner Aktivität gegenüber einem breiten Spektrum von -auch multiresistenten- Bakterien, Hefen, Pilzen und Viren. Die Silberionen wirken, nach bisherigem Kenntnisstand, in verschiedener Weise auf Einzeller, wie Bakterien, Hefen, Pilze und Viren.
- Silber ist das Element mit der höchsten Wärmeleitfähigkeit und elektrischen Leitfähigkeit im Periodensystem. In der Form winzigen Nanosilbers können diese Eigenschaften materialsparend für die Elektronik, z.B. für transparente und gleichzeitig elektrisch-leitfähige Folien genutzt werden.
- Silber-, so wie auch Gold-Nanopartikel haben besondere optische Eigenschaften. Beide Edelmetalle weisen im Nanomaßstab eine hohe Effizienz bei der Lichtabsorption und –streuung auf. Diese Eigenschaften können für Sensoren oder in der Spektroskopie eingesetzt werden.

Einsatz von Nanosilber

- Dadurch eröffnen sich wichtige Anwendungsfelder, die von flexiblen Displays bis hin zu antimikrobieller Ausstattung von Krankenhaustextilien, Wundauflagen und Wandpaneelen reichen.

- Die Anwendungsbereiche gehen von Hygieneartikeln, über Textilien und Lebensmittelkontaktmaterialien, bis zu Arbeitsflächen, Filtern und in medizinischen Geräten.

Einsatz von Nanosilber in Textilien

- Die antimikrobielle Wirkung von Nanosilber wird seit einiger Zeit erfolgreich in auch in Textilien genutzt. Anwendungen für antimikrobiell ausgestattete Textilien sind u.a.:
- Berufsbekleidung (Krankenhaus & Pflege, Lebensmittelverarbeitung), Sportbekleidung und Unterwäsche, sowie technische Textilien (Belüftungsanlagen, Filtration, Wischtücher)
- Um die Nanosilberpartikel mit Fasern zu verbinden, kommen unterschiedliche Herangehensweisen in Betracht:
- Zum einen kann Nanosilber in ein Polymer eingemischt werden (Masterbatch), bevor es zu Fasern versponnen wird. Dies wird z.B. bei Polyester- und Zelluloseacetatfasern angewandt und man erhält eine besonders feste Einbindung in die Faser, die antibakterielle Wirkung hält damit besonders lange an.
- Alternativ kann Nanosilber als Finish auf die Faseroberfläche aufgetragen werden. Hierbei können die Stärke der Anbindung und damit die Wirkungsdauer sehr unterschiedlich ausfallen. Schwach gebundene Partikel werden bereits nach wenigen Waschvorgängen abgelöst.

Einsatz von Nanosilber in Textilien

- Bei sämtlichen Anwendungen wird jeweils die antimikrobielle Wirkung genutzt, die auf der Freisetzung von Silberionen (Ag+) beruht. Bakterien werden durch Ag+-Ionen abgetötet.
- Hierfür sind deutlich geringere Wirkstoffkonzentrationen notwendig als für (metall-)organische Biozide.
- Dies verhindert neben der Übertragung und Ausbreitung von krankheitserregenden Keimen auch die Entstehung von Schweißgeruch, denn Schweiß selbst ist eigentlich nahezu geruchlos. Der typische Geruch entsteht erst durch Bakterien, die natürlicherweise unsere Haut besiedeln und Bestandteile des Schweißes verstoffwechseln.
- Die gesunde Bakterienflora der Haut wird durch nanosilberhaltige Kleidung nicht gestört, respektive werden Nanosilber-Textilien auf der Haut als eher unbedenklich eingestuft von dem Schweizer Institut Empa und dem TVS, dem Textilverband der Schweiz

Einsatz von Nanosilber in Textilien

Abbildung: Einsatz von Nanosilber in der Praxis – Anwendungsbeispiel Textilien

Einsatz von Nanosilber in Textilien

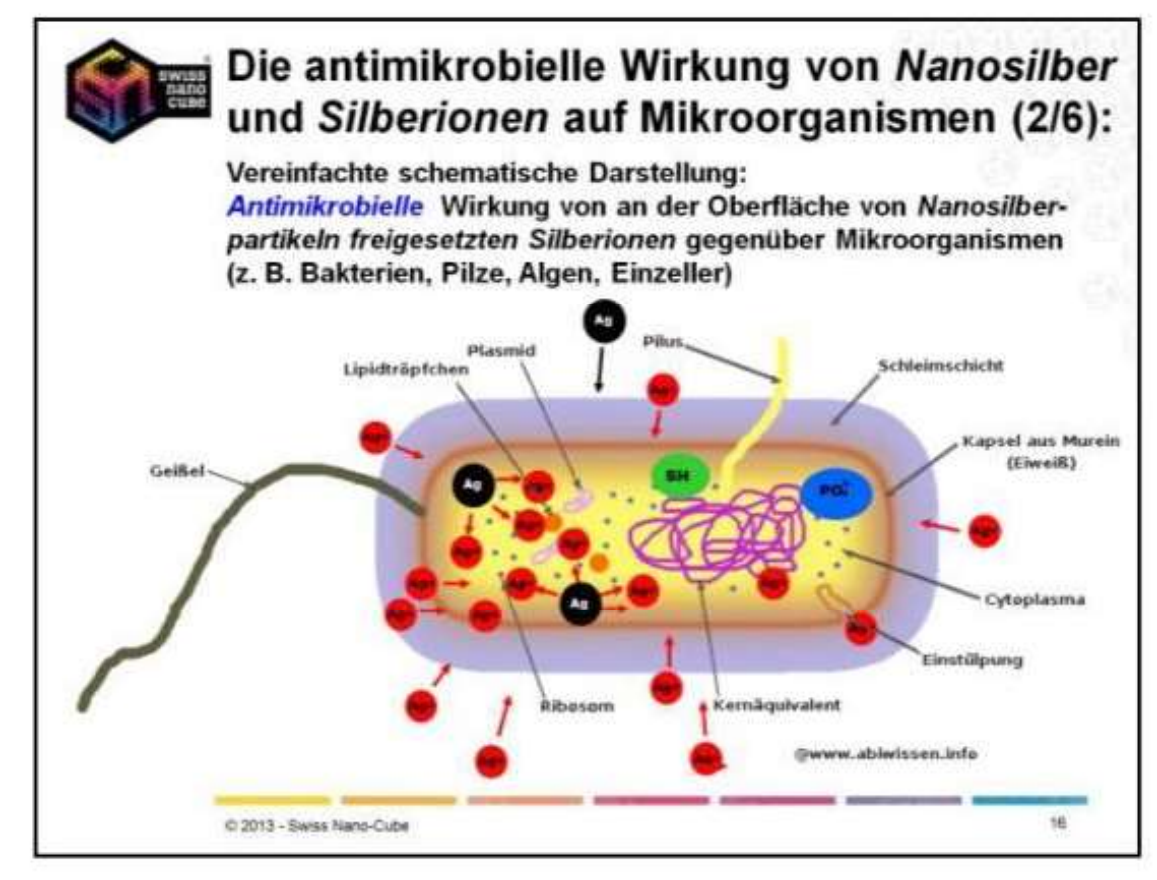

Abbildung: Die antimikrobielle Wirkung von Nanosilber und Silberionen auf Mikroorganismen

Nanosilber in Europa !

Nanosilber in Europa

- Der Wirkstoff Nanosilber ist nach Biozid-Verordnung (BPR) (EU) Nr. 528/2012 als sog. „Alter Wirkstoff" klassifiziert.
- Laut ECHA – List of compliant notifications vom 07.11.2016, ist Nanosilber als biozider Wirkstoff angemeldet und zugelassen worden.
- Die Vermarktung nanosilberhaltiger Biozidprodukte wird streng überwacht.
- Das Schweizer Institut Empa in Kooperation mit dem TVS, dem Textilverband Schweiz, weist Nanosilber in seinem Leitfaden für Textilunternehmen als „geeignetes Nanomaterial" aus.
- Zum Thema der möglicherweise schädlichen Wirkung von Nanosilber beziehen Forscher vom Hohenstein Institut für Textilinnovation e.V. (HIT) bzw. vom Institut für Textil- und Verfahrenstechnik (ITV) der Deutschen Institute für Textil- und Faserforschung Denkendorf (DIT, beide Baden-Württemberg), wie folgt Stellung:

Nanosilber in Europa

- Eine spezifische Resistenzbildung gegen Silber auf genetischer Ebene ist bislang nicht beobachtet worden.
- Trotz bestehender Abwehrmechanismen von Bakterien in Form geänderter Aufnahme- bzw. Ausscheidungsmechanismen für Metall-Ionen (Silber-Ionen) ist die Wahrscheinlichkeit der Resistenzbildung von Bakterien gegen Silber relativ gering.
- Ein direkter Vergleich mit Antibiotika-Resistenzen kann nicht gezogen werden.
- Zu einer eventuellen toxischen Wirkung von Nanosilber ist aus abgeschlossenen Forschungsvorhaben bereits bekannt, dass durch Abrieb freisetzbare Nanosilber-Partikel in der Regel keine signifikante Erhöhung der auch so allgegenwärtigen Nanopartikel-Hintergrundbelastung bewirken.
- Wie sich in diesem ITV-Forschungsprojekt ebenfalls zeigte, emittiert beispielsweise eine einzige brennende Kerze eine im Vergleich weitaus höhere Konzentration an Nanopartikeln.
- Auch die Wirkung silberhaltiger Textilien auf die menschliche Hautflora ist inzwischen geklärt. Das HIT hatte dazu im Rahmen einer vom Bundeswirtschaftsministerium unterstützten, Placebo-kontrollierten, vergleichenden intra-individuellen rechts/links Tragestudie bei 60 Probanden den Einfluss antibakterieller Fasersubstrate auf die Hautflora und das Mikroklima untersucht.
- Ergebnis: Die Messparameter zur Hautflora sowie zum Mikroklima der Haut zeigten sich von den funktionalisierten Chemiefasern unbeeinflusst, eine Beeinträchtigung der Hautflora war nicht zu verzeichnen. Trotz nachweisbarer – angestrebter – antibakterieller Aktivität erwiesen sich die Textilien als unbedenklich.
- Dennoch wird aus wissenschaftlicher Sicht eine strengere Forschung und Beobachtung von möglicherweise toxischen und umweltbelastenden Wirkungen von Nanosilber gefordert.
- Produkte mit Nanosilber müssen in der EU angemeldet werden.

Nanosilber-Mundschutz!

Nanosilber in Mundschutz-Produkten

- Für die antibakterielle Wirkung ist das Silberion und dessen Konzentration entscheidend.
- Es bedingt auf drei Arten die bakterizide Eigenschaft:
- zum Einen reagieren Silberionen mit schwefel- und phosphathaltigen Enzymen der Zellwand und führen dort zur Störung des trans-membrösen Stoffwechsels, zum Zweiten werden sie wie essentielle Calciumionen von den Zellen aufgenommen und binden essentielle schwefel- und phosphathaltige Makro-Moleküle. So können sie sich an die DNA binden und damit die Reproduktion verhindern. Zum Dritten verringern sie die Adhärenz der Mikroorganismen an Oberflächen.
- Ein Import-Stoff wurde in der Uniklinik Dresden getestet.
- Die Masken schützen vor Bakterien und Keimen durch eingewebte Silberfäden und schützen somit verstärkt deren Träger.
- Der Mundschutz ist wiederverwendbar, kann mehrmals gewaschen werden, wodurch er erheblich umweltfreundlichere Wirkungen erzielt.

Quellenverzeichnis:

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- Amtsblätter der Europäischen Union: CELEX_32012R0528_DE_TXT und CELEX_32019R0157_DE_TXT
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Hanvico-Mundschutz!

Hanvico - Mundschutz antimikrobiell

- Es folgen die Aussagen des Herstellers der Hanvico-Mundschutzmasken und des deutschen Auftraggebers zum Vergleich mit den vorher in namhaften Publikationen gefundenen Angaben.
- Im Anhang werden auch die uns vorgelegten Prüfberichte des Herstellers Hanvico gelistet.
- MAE empfiehlt dem Auftraggeber die Zulassung der Mundschutz-Produkte nach MDR Klasse II a durch akkreditierte deutsche Prüfinstitute.

Hanvico - Mundschutz antimikrobiell

- Die exklusiv für STH gefertigten, antibakteriellen Stoffe mit eingewebtem Nano-Silber, hergestellt in Vietnam, werden von Toray Chemical Inc. aus Japan und Korea geliefert.
- Toray Chemical ist der führende asiatische Hersteller für Fasern für die Textilindustrie, die in führenden Haushalten und den größten Unternehmen der Welt zum Einsatz kommen.
- Toray Chemical verfügt über überlegene Fähigkeiten, indem es den Fortschritt von Wissenschaft und modernster Technologie zusammen mit umfassenden Investitionen in Forschungs- und Entwicklungsmerkmale von Kunstfasern vereint.
- Die Polyesterstapel-Faser mit „Nanosilber-Contour-Cutting-Technologie" wird auf Nano-Fasergröße perforiert, um das Einbringen von Nanosilber-Partikeln in die Faserstruktur mit Hilfe von Silikon-Klebstoffen besonders haltbar zu gestalten, wodurch es sich nicht auswäscht, wie bei simpel beschichteten Nanosilber-Stoffen.
- Die Nanosilber-Faserproduktions- und Verarbeitungstechnologie, die wir exklusiv in Vietnam entwickelt haben und eine besonders umweltfreundliche Haltbarkeit und antimikrobielle Wirkung erzielt, wurde durch Prüfzertifizierungen von inter-nationalen Organisationen nachgewiesen: FDA (USA) Oeko_Tex100 Deutschland, Japanische Fiti, KSA Korea, Vietnam-Textile und Bekleidungs-Instituten.

Hanvico - Mundschutz antimikrobiell

- Außenschicht – Schutzschicht 1 vor Staub und Umwelteinflüssen - mit einer Dichte von 200 bis 400 Fasern / 1 Zoll im Quadrat, diese wird vor der Verarbeitung mit einem hochwertigen, farbschonendem Detergenten gereinigt.
- Die mittlere Schicht - die antibakterielle Nanosilber-Schicht - ist die funktionell wichtige Schicht, die laut Anhang eine antibakterielle Funktion von bis zu 93% erreicht, wobei mehr als 650 Bakterien-Stämme zerstört werden und so auch Gerüche verhindern. Die hochwertige Verarbeitungstechnologie ermöglicht bis zu 30 Wäschen der Maske bei 40-60 Grad Celsius, ohne die bakterizide Fähigkeit zu verlieren.
- Die TC-Strick-Schicht ist die Kontaktschicht mit der Gesichtshaut. Das Gewebe ist bakterizid behandelt, bevor es als Tuch geschnitten und eingearbeitet wird.

MEDICINA ALTERNATIVA EUROPE

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TEST REPORT

Test No: 104-14-02-20-1/TNX-2
Date of issue: February 19th, 2020

Client: HAN VIET COMPANY LIMITED
Address: Km14 National Highway 1A, Thanh Tri District, Hanoi
Date of Receipt:February 14th, 2020 Date(s) of performance: From Feb 14th to Feb 19th, 2020

Sample provided and identified by client
Sample Identification: Sample 1: 7Dx64mm ANTIBACTERIAL TPA PROCESSING Fibers.

Test Sample:

Sample

Test results: See the next page

The above results are Results are valid for tested samples provided by applicant only: 600 g
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Client, Sample identification and Manufacturer are introduced at client's requests.

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TEST REPORT

Test No: 104-14-02-20-1/TNX-2
Date of issue: February 19th, 2020

No.	Items		Units	Test Methods	Results
1	Average breaking strength		G/fibre	Reference to TCVN 4182: 2009	31.8
			CV (%)		2.6
	Average breaking tenacity		G/den		4.6
2	Cut length		mm	ISO 6989:1981 (Method A)	68.0
			CV (%)		9.4
3	Average crimp frequency of manufatured staple fibers		crimp/cm	ASTM D 3937-12(2018)	4.2
			CV (%)		19.9
4[1)]	Determining Antimicrobial Activity – The percent reduction of the organisms (%)	Escherichia coli ATCC 25922	0 hours (B), CFU/ml	AATCC 100-2012	1.7×10^5
			24 hour (A), CFU/ml		1.3×10^4
			% Reduction (R)		92.3
		Staphylococcus aureus ATCC 6538	0 hours (B), CFU/ml		1.7×10^5
			24 hour (A), CFU/ml		1.2×10^4
			% Reduction (R)		93.0

Remark:
1) Test specimens were incubated at 37°C for 24 h
CFU/ml: colony forming units per milliliter
R = 100 (B-A) / B where:
A: CFU per milliliter after the 1 hour contact time
B: CFU per milliliter at the "0" contact time

* * * End of report * * *

SIGNED FOR AND ON BEHALF OF VTRI

CÔNG TY CỔ PHẦN - VIỆN NGHIÊN CỨU DỆT MAY

GIÁM ĐỐC TRUNG TÂM THÍ NGHIỆM
ThS. Bùi Thị Thái Nam

VTRI - TTC - VILAS 089 - ISO/IEC 17025

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Client, Sample identification and Manufacturer are introduced at client's requests.

MEDICINA ALTERNATIVA EUROPE

QSA INTERNATIONAL

Certificate OF REGISTRATION

HAN VIET COMPANY LIMITED (HANVICO)
KM 14 HIGHWAY 1A. NGOC HOI COMMUNE, THANH TRI DISTRICT, HA NOI CITY, VIETNAM

has submitted declaration of Conformity (Dated: 20-02-2020) according to

Class-1, Medical Devices Directive 93/42 EEC Annexure VII

Organization has been assessed and found to be conforming with the requirements of the stated directive and standards submitted through Declaration of conformity

Hence manufacturer places the CE marking with his own responsibility as follows:

CE

For the Products of

NANO SILVER ANTIBACTERIAL MASK
By QSA International, UK

Registration Number : QSA-20012301
Initial Certification Date: 20 March 2020
Certification Expiry Date: 19 March 2023

Stratford Ray
Certification Manager

QSA INTERNATIONAL LIMITED
27, Old Gloucester Street, London, WC1N3AX, ENGLAND

CGA
Centre for Global Accreditation

Email: info@qsai.co.uk
Web:www.qsai.co.uk

Registered with Registrar of Companies for England and Wales through Registration Number 11936114
This certificate is a property of QSA International, UK. This certificate must not be altered in anyway and shall be returned upon the request by QSA International.

SGS

Test Report SL62006243167601TX Date:April 23,2020 Page 1 of 5
HAN VIET CO.,LTD
KM 14,1A HIGHWAY THANH TRI,HANOI VIETNAM

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)woven fabric (B)knitted fabric
Sample Color	:	(A)(dark green) 63" Cotton elastic Imitation linen cloth; (B)(off white) 63" Polyester cotton air layer
Sample Receiving Date	:	Mar 27, 2020
Testing Period	:	Apr 01, 2020 – Apr 23, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).
Test Performed	:	Selected test(s) as requested by applicant

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. HangZhou Branch

Jack Zhang (Account Executive)

The Open International University
- DIGITAL CAMPUS -

Ultraviolet Protection Factor (UPF)

(AATCC TM 183-2014; Test Conditions
1) Air temperature: 21±1oC
2) Relative humidity: 65±2% R.H.
3) Orientation of test specimen: Specimens were clamped on sample holder. Fabric face side is facing the incident UV light.
4) Test conducted in wavelength range 280-400 nm
5) Instrument: UV-VIS Spectrophotometer
6) No. of Scans: 6)

(A) As Received	Unit	Dry Evaluation	Wet Evaluation
Mean Ultraviolet Protection Factor (UPF)	No Unit	17	29
Standard Deviation	No Unit	1.3	1.7
Standard Error	No Unit	1.6	2.1
UPF Rating	No Unit	15	25
Protection Category	No Unit	Good	Very good
Percent Transmittance, T (UV-A)	%	6.72	4.44
Percent Transmittance, T (UV-B)	%	5.76	3.31
The Percent Blocking, UV-A	%	93.28	95.56
The Percent Blocking, UV-B	%	94.24	96.69

(B) As Received	Unit	Dry Evaluation	Wet Evaluation
Mean Ultraviolet Protection Factor (UPF)	No Unit	1285	889
Standard Deviation	No Unit	10.5	34.2
Standard Error	No Unit	13.1	42.4
UPF Rating	No Unit	50+	50+
Protection Category	No Unit	Excellent	Excellent
Percent Transmittance, T (UV-A)	%	0.67	1.39
Percent Transmittance, T (UV-B)	%	0.05	0.05
The Percent Blocking, UV-A	%	99.33	98.61
The Percent Blocking, UV-B	%	99.95	99.95

Remarks :
1. Refer to ASTM D6603, the UV protection category is determined by the UPF values,
UPF 40 or greater Excellent UV Protection
UPF in between 25 to 39 Very Good UV Protection
UFP in between 15 to 24 Good UV Protection
UPF less than 15 Unclassification

2. Ultraviolet Protection Factor (UPF) is the ratio of the average effective ultraviolet radiation (UV-R) irradiance transmitted and calculated through air to the average effective UV-R irradiance transmitted and calculated through fabric.

3. The limits of the spectral range of ultraviolet radiation are not well defined and may vary according to the user. Committee E-2.12 of the International Commission on Illumination (CIE) distinguishes in the spectral range between 400 and 100 nm :
UV-A : 315 - 400 nm
UV-B : 280 - 315 nm
UV-R : 280 - 400 nm

4. This method can also be used to determine the UPF of the fabrics in a stretched state. However, the techniques for stretching the specimens are not part of this method and are addressed in a separate test procedure. It must be noted that stretching the specimens could change the UPF properties.

5. The listed protection category is for reference only, the market claims for labeling UV-Protection product shall follow "Standard Guide For Labeling UV-Protection Textiles" as stated in ASTM D6603.

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Test Report SL62006243167601TX Date: April 23,2020 Page 4 of 5

Antimicrobial Activity Test^

Test Method : AATCC 100-2012 Antibacterial Finishes on Textile Material: Assessment of

(A)

Test organism	Klebsiella pneumoniae ATCC 4352
Concentration of bacteria(CFU/mL)	1.9x10^5
Sample -at "0H" contact time (CFU/sample)	1.6x10^5
Control sample- at "0H" contact time (CFU/sample)	1.9x10^5
Sample -at "24H" contact time (CFU/sample)	<100
Control sample- at "24H" contact time (CFU/sample)	1.3x10^8
Reduction(%)	>99.9%

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Test Report SL62006243167601TX Date: April 23,2020 Page 5 of 5

(B)

Test organism	Klebsiella pneumoniae ATCC 4352
Concentration of bacteria(CFU/mL)	1.9x10^5
Sample -at "0H" contact time (CFU/sample)	1.5x10^5
Control sample- at "0H" contact time (CFU/sample)	1.9x10^5
Sample -at "24H" contact time (CFU/sample)	<100
Control sample- at "24H" contact time (CFU/sample)	1.3x10^8
Reduction(%)	>99.9%

Notes :

Test sample was 4 swatches of 4.8 cm diameter circular ,1 mL inoculum per trial.
The sample had been sterilized in the autoclave before the testing.
The control sample was 100% cotton, provided by SGS laboratory.

^This test was carried out by SGS Shanghai Laboratory

End of Report

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chemg@baua.bund.de

Aktenzeichen / Our reference(s):
5.0-711 02/00/2017.0014

Dortmund, 24 October 2017

Administrative document
(Information on marketability of biocidal products in Germany)

Dear Sir or Madam,

According to § 12 b of the German Chemicals Act[1] the Federal Institute for Occupational Safety and Health (BAuA) is designated as the Competent Authority responsible for the authorisation of biocidal products.

You have notified "agpure" with the active substance Silver (CAS-No 7440-22-4) to BAuA as a biocidal product according to the German Biocide Reporting Order.

The notification number is N-73054.

The active substance Silver (CAS-No 7440-22-4) is included in Annex II of the Commission Delegated Regulation (EU) No 1062/2014[2] for the product types 2, 4 and 9.

1 Act on the Protection against Hazardous Substances (German Chemicals Act – ChemG) in the publication of 28 August 2013 published in the Federal Law Gazette volume 2013 part I no. 55 page 3498ff issued in Bonn on 6 September 2013 in the currently valid version

2 COMMISSION DELEGATED REGULATION (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council amended by Commission Delegated Regulation (EU) No 2017/698

Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.

Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.

Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.

Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.

Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.

Product-type 4: Food and feed area

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.

Products used to be incorporated into materials which may enter into contact with food.

Product-type 9: Fibre, leather, rubber and polymerised materials preservatives

Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration.

This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits.

Notified biocidal products exclusively based on active substances listed in Annex II of the Commission Delegated Regulation (EU) No 1062/2014 for the respective use may freely be sold in Germany according to the rules on biocidal products without authorisation at least until the approval of the active ingredients according to Regulation (EU) No 528/2012[3] is reached but no longer than until 31.December 2024[4], unless the use of the active ingredients is restricted or prohibited by other regulations.

Since 01 September 2015 one requirement for a biocidal product to be made available on the market in the EU during the transitional period is that the substance supplier or the product supplier is included in the list according to Article 95 of Regulation (EU) No 528/2012 for the product-type(s) to which the product belongs.

Yours sincerely,
on behalf of the Institute

Carsten Ruhm

3 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

4 The deadline 31 December 2024 is based on the Commission Delegated Regulation (EU) No 736/2013 of 17 May 2013 amending Regulation (EU) No 528/2012.

Produktdatenblatt

GEMELDETES BIOZID-PRODUKT

Handelsname:	**agpure**
Registriernummer:	N-73054
Meldedatum:	04.08.2017
Maximale Verkehrsfähigkeit (ChemBiozidMeldeV):	31.12.2024 Das Biozidprodukt kann für die Dauer des Genehmigungsverfahrens des Wirkstoffs bzw. des letzten zu genehmigenden Wirkstoffs ohne Zulassung auf dem Markt bereitgestellt werden.

WIRKSTOFFE

Wirkstoffname	Silber, als Nanomaterial
CAS-Nr.	7440-22-4
EC-Nr.	231-131-3
PT	4
Produktart	Lebens- und Futtermittelbereich
Wirkstoffname	Silber, als Nanomaterial
CAS-Nr.	7440-22-4
EC-Nr.	231-131-3
PT	2
Produktart	Desinfektionsmittel und Algenbekämpfungsmittel, die nicht für eine direkte Anwendung bei Menschen und Tieren bestimmt sind
Wirkstoffname	Silber, als Nanomaterial
CAS-Nr.	7440-22-4
EC-Nr.	231-131-3
PT	9
Produktart	Schutzmittel für Fasern, Leder, Gummi und polymerisierte Materialien

Anschrift:	93055 Regensburg, An der Irler Höhe 3 a
Land:	Deutschland

DATENBLATT DRUCKEN

TRANSLATION
BẢN DỊCH

MINISTRY OF HEALTH
NATIONAL INSTITUTE OF MEDICAL DEVICE AND CONSTRUCTION

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

CERTIFICATE OF TEST RESULT

No.: 026320/VTTB-DGCL

Requesting organization: Han Viet Company Limited

Product name: Nano Silver – 3D Facemask

Model: HVC

Manufacturer: Han Viet Company Limited

Address: Km 14, National Road 1A, Ngoc Hoi Commune, Thanh Tri District, Hanoi City

Origin: Vietnam

Tester: Tran Duc Anh

Method of testing: In accordance with the standards of TCCS 04/2020 of Han Viet Company Limited

Conclusion: The model meets all the standards of TCCS 04/2020.

Hanoi, April 03rd 2020

DIRECTOR

(Signed and sealed)

PhD. Le Thanh Hai

Address: 40 Phuong Mai – Dong Da – Hanoi * Tel: (024) 3 8523065

TEST REPORT

(In accordance with the standards of TCCS 04/2020)

Specifications

No.	Content	Requirement	Qualified	Underqualified
1	Structure and material	Non-woven fabric, flat type, with folding lines; with super-filter layer, nose clip and elastic band; no fault observed	X	
2	Size	In accordance with the standards of TCCS 04/2020	X	
3	Filtration efficiency	Filtration efficiency is no less than 94%	X	
4	Penetration	< 5%	X	
5	Resistance	< 24mmH_2O	X	
6	Airway resistance	Airway resistance is no more than 9mmH_2O	X	
7	Sight limitation	Sight limitation is no more than 6%	X	
8	Permissible limit of heavy metal content			
8.1	Arsenic content (As)	0.17 mg/kg	X	
8.2	Lead content (Pb)	1.00 mg/kg	X	
8.3	Mercury content (Hg)	0.12 mg/kg	X	
8.4	Antimony content (Sb)	0.10 mg/kg	X	
8.5	Cadmium content (Cd)	0.10 mg/kg	X	

** This test report is only valid with the samples provided by Han Viet Company Limited to National Institute of Medical Device and Construction on April 3rd 2020.*

SUPERVISOR
(Signed)
Ha Quang Thanh

Hanoi, April 3rd 2020
TESTER
(Signed)
Tran Duc Anh

Address: 40 Phuong Mai – Dong Da – Hanoi * Tel: (024) 3 8523065

HANVIET COMPANY LIMITED (HANVICO)

STANDARD

TCCS 04/2020

Edition 1

NANO SILVER - 3D mask

HANOI - 2020

Table of contents

Page

Preface.

TCCS 04/2020 is produced by Han Viet Company Company (HANVICO).

- TCVN 04/2020: Nano Silver - 3D facemask.

STANDARD

Nano Silver - 3D facemask

1. Scope of Application

This standard applies to Nano Silver – 3D facemask produced by Han Viet Co., Ltd. (HANVICO).

2. References

The following references are necessary to apply this standard. For the references with published year, the cited edition is applied. For the references without published, the latest edition is applied, including all amendments and supplements (if any).

TCVN 3154: 1979 Personal protective devices - Methods of determining market (sight).

TCVN 7312: 2003 Means of personal respiratory protection - Dust filter facemask.

3. Technical Requirements

3.1 General provisions

- The facemask shall not cause skin allergy for the wearer;

- The surface of the facemask must be clean, no excessive thread and no fault observed;

- The straps are sewn firmly at four corners of the mask;

- The edges fit the wearer's face.

3.2 Structure

3.2.1 Nano Silver - 3D Facemask includes the following parts:

- The fabric layers: from 2 to 4 layers of non-woven fabric, flat, folded lines;

- Microfiltration;

- Nose clip;

- Strap.

3.2.2 Design, size: No standard for design & size but design & size must cover the nose and mouth.

3.3 Requirements for materials

3.3.1 Fiber: nonwoven, waterproof, weighing 14 g/m^2 + $40g/m^2$, color: white or other colors.

3.3.2 Microfiltration, waterproof layer.

3.3.3 Nose clip: from plastic or metal, easy to adjust, to clip the mask properly over the bridge of the nose.

3.3.4. Strap: use elastic strap, for example, an elastic band, to wear and remove the mask easily.

3.4 Specifications of mask

Medical facemasks must meet the specifications set forth in Table 1.

Table 1 - The technical indicators of facemasks

Name of indicator	Levels	Note
1. Filtration efficiency	94%	Equivalent to FFP2
2. Penetration	<5%	Equivalent to FFP2
3. Water resistance	<24 $mmH_20\%$	Equivalent to FFP2

3.5 Permissible limit of heavy metal contents in nonwoven fabric: Permissible limit of heavy metal contents in nonwoven fabric are defined in the following table

Table 2 - Permissible limit of heavy metal contents in nonwoven fabric

Element	**Permissible limits, not more than mg/ kg of product**
Arsenic (As)	0.17
Lead (Pb)	1.0
Mercury (Hg)	0.12
Antimony (Sb)	0.1
Cadiri (Cd)	0.1

4. Test methods

4.1. Chemicals and reagents

Reagents used in analyzing are the certified pure chemicals and proper reagents.

4.1.1. Hydrochloric acid, 0.07 mol solution;

4.1.2. Hydrochloric acid, 2.0 mol solution;

4.1.3 Non-acid trichloroethane or other appropriate solution;

4.1.4. Proper chemicals of arsenic (As), lead (Pb), mercury (Hg), antimony (Sb) and cadmium (Cd).

4.1.5. Proceeding

- Mix 5 g of the prepared sample with 250 g of 0.07 mol solution of hydrochloric acid and shake for 1 min.

- Check the acidity of the mixture. If the pH is greater than 1.5, shake and add each drop of hydrochloric acid until pH 2.0 is less than or equal to 1.5. The standard is 250ml.

- The mixture is shaken continuously then let stand for 1 hour at 37°C +/- 2°C.

NOTE: Do not let the mixture exposed to the light.

- Cool the mixture and filter through blue filter paper. Get the filtrate to determine the heavy metal contents on Atomic Absorption Spectrometer.

5 Packaging and labeling

5.1 Packaging

Quantity and packing of the facemasks are adjusted for specific demands.

5.2 Labeling

The label should be pasted on the cardboard box with the following minimum information:

- Product's name,

- References,

- Name and address of the manufacturer,

- Manufacture date, expiry date,

- Inspection mark of QA Department,

- User manual.

HAN VIET COMPANY LIMITED

Add: 478 Minh Khai, Hai Ba Trung, Hanoi, Vietnam
Tel :(84-24) 2 215 6167 / 6 681 5577
Fax: (84-24) 3 862 2867
Email: lab_tri@viendetmay.org.vn
trungtamthinghiem@gmail.com
Website: www.viendetmay.org.vn

CÔNG TY CỔ PHẦN - VIỆN NGHIÊN CỨU DỆT MAY
VIETNAM TEXTILE RESEARCH INSTITUTE., JSC (VTRI)
TRUNG TÂM THÍ NGHIỆM DỆT MAY
TEXTILE TESTING CENTRE (TTC)

VILAS 089

TEST REPORT

Test No: 104-14-02-20-1/TNX-2
Date of issue: February 19th, 2020

Client: HAN VIET COMPANY LIMITED

Address: Km14 National Highway 1A, Thanh Tri District, Hanoi

Date of Receipt:February 14th, 2020 Date(s) of performance: From Feb 14th to Feb 19th, 2020

Sample provided and identified by client

Sample Identification: Sample 1: 7Dx64mm ANTIBACTERIAL TPA PROCESSING Fibers.

Test Sample:

Sample

Test results: See the next page

CÔNG TY CỔ PHẦN - VIỆN NGHIÊN CỨU DỆT MAY
VIETNAM TEXTILE RESEARCH INSTITUTE., JSC (VTRI)
TRUNG TÂM THÍ NGHIỆM DỆT MAY
TEXTILE TESTING CENTRE (TTC)
Add: 478 Minh Khai, Hai Ba Trung, Hanoi, Vietnam
Tel :(84-24) 2 215 6167 / 6 681 5577
Fax: (84-24) 3 862 2867
Email: lab_tri@viendetmay.org.vn
trungtamthinghiem@gmail.com
Website: www.viendetmay.org.vn

VILAS 089

TEST REPORT

Test No: 104-14-02-20-1/TNX-2
Date of issue: February 19th, 2020

No.	Items		Units	Test Methods	Results
1	Average breaking strength		G/fibre	Reference to TCVN 4182: 2009	31.8
			CV (%)		2.6
	Average breaking tenacity		G/den		4.6
2	Cut length		mm	ISO 6989:1981 (Method A)	68.0
			CV (%)		9.4
3	Average crimp frequency of manufatured staple fibers		crimp/cm	ASTM D 3937-12(2018)	4.2
			CV (%)		19.9
4[1)]	Determining Antimicrobial Activity – The percent reduction of the organisms (%)	Escherichia coli ATCC 25922	0 hours (B), CFU/ml	AATCC 100-2012	1.7×10^5
			24 hour (A), CFU/ml		1.3×10^4
			% Reduction (R)		**92.3**
		Staphylococcus aureus ATCC 6538	0 hours (B), CFU/ml		1.7×10^5
			24 hour (A), CFU/ml		1.2×10^4
			% Reduction (R)		**93.0**

Remark:

1) Test specimens were incubated at 37°C for 24 h
CFU/ml: colony forming units per milliliter
R = 100 (B-A) / B where:
A: CFU per milliliter after the 1 hour contact time
B: CFU per milliliter at the "0" contact time

* * * End of report * * *

SIGNED FOR AND ON BEHALF OF VTRI

CÔNG TY CỔ PHẦN - VIỆN NGHIÊN CỨU DỆT MAY
M.S.D.N: 0100102294 - C.T.C.P. - Q. HAI BÀ TRƯNG - TP. HÀ NỘI

GIÁM ĐỐC TRUNG TÂM THÍ NGHIỆM
ThS. Bùi Thị Thái Nam

CERTIFICATE OF APPROVAL

TORAY ADVANCED MATERIALS KOREA INC.

• HEAD OFFICE/GUMI 3 PLANT : 300, 3GONGDAN 2-RO, GUMI-SI, GYEONGSANGBUK-DO, KOREA
• SITE:Refer to the Appendix

Korean Standards Association hereby certifies that the Environmental Management System of the above organization has been assessed and found to meet the requirements of the standard and scope of certification detailed below:

CERTIFICATION No. EMS-0084

STANDARD KS I ISO 14001:2015/ISO 14001:2015

SCOPE OF CERTIFICATION
SITE:Refer to the Appendix

VALID FROM 24 November 2017

VALID UNTIL 23 November 2020

Original Certification Date : 24 November 1999

• This certificate is reissued due to the integration of the sites

Date of Issue : 01 April 2019

PRESIDENT OF KSA

KOREAN STANDARDS ASSOCIATION

305, Teheran-Ro, Gangnam-Gu, Seoul, Korea

KSA IAF KAB

KSA has been accredited in respect of ISO 14001 covered by the KAB Accreditation Certificate Number KAB-EC-111

HOHENSTEIN Textile Testing Institute GmbH & Co. KG
Schlosssteige 1, 74357 Bönnigheim, Germany

OEKO-TEX®
INSPIRING CONFIDENCE

CERTIFICATE

The company

Toray Advanced Materials Korea Inc.
35F, FKI Tower 24, Yeoui-Daero
Yeongdeungpo-gu
Seoul 150-881, KOREA, SOUTH

OEKO-TEX®
CONFIDENCE IN TEXTILES
STANDARD 100
16.HKR.87105 HOHENSTEIN HTTI
Tested for harmful substances
www.oeko-tex.com/standard100

is granted authorisation according to STANDARD 100 by OEKO-TEX® to use the STANDARD 100 by OEKO-TEX® mark, based on our test report **19.0.79663**.

for the following articles:

PET staple fibers branded 'ESLON' – regardless of cut length, undyed, dope dyed in sky blue or black, type: Solid (Regular), Low Melting (EZBON-L), Low Melting Black (EZBON-L), Hollow Conjugate (HC), Hollow Conjugate Siliconized (HCS), Micro (DOWNFILL), Short-Cut (Mini-ESLON), Dope Dyed Sky Blue, Dope Dyed Black, PE/PET Bi-Component, PE/PP Bi-Component, Mono PP, High Shrinkage (HS), Antimicrobial (Freshever/Silver), Post-Consumer Recycled (ECOWAY), Recycled Fiberfill (FF), Elastic Binder (E-PLEX), Sound Absorbing (SAF), ESFRON (Flame Retardant); partly finished with flame retardant and biological active products accepted by OEKO-TEX®.

The results of the inspection made according to STANDARD 100 by OEKO-TEX®, Appendix 6, **product class I** have shown that the above mentioned goods meet the human-ecological requirements of the STANDARD 100 by OEKO-TEX® presently established in Appendix 6 for baby articles.

The certified articles fulfil requirements of Annex XVII of REACH (incl. the use of azo colourants, nickel release, etc.), the American requirement regarding total content of lead in children's articles (CPSIA; with the exception of accessories made from glass) and of the Chinese standard GB 18401:2010 (labelling requirements were not verified).

The holder of the certificate, who has issued a conformity declaration according to ISO 17050-1, is under an obligation to use the STANDARD 100 by OEKO-TEX® mark only in conjunction with products that conform with the sample initially tested. The conformity is verified by audits.

The certificate 16.HKR.87105 is valid until 31.07.2020

Boennigheim, 30.07.2019

Dipl.-Ing. (FH) Ivonne Schramm
Head of Certification Body OEKO-TEX®

BẢN DỊCH
TRANSLATION

MINISTRY OF HEALTH
NATIONAL INSTITUTE OF MEDICAL DEVICE AND CONSTRUCTION

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

CERTIFICATE OF TEST RESULT

No.: 008920/VTTB-DGCL

Requesting organization: Han Viet Company Limited

Product name: Anti-droplet, anti-bacterial facemask

Model: Without nose clip

Manufacturer: Han Viet Company Limited

Address: Km 14, National Road 1A, Ngoc Hoi Commune, Thanh Tri District, Hanoi City

Origin: Vietnam

Testor: Tran Duc Anh

Method of testing: *Temporary technical instruction for anti-droplet, anti-bacterial cloth facemask* issued in Decision no. 870/QD-BYT dated March 12th 2020 by Minister of Ministry of Health.

Conclusion: The model meets all the technical criteria in accordance with Decision no. 870/QD-BYT.

Hanoi, March 19th 2020

DIRECTOR

(Signed and sealed)

PhD. Le Thanh Hai

Address: 40 Phuong Mai – Dong Da – Hanoi * Tel: (024) 62925544 – 3 8523065 – 3 8521248

TEST REPORT

Specifications

No.	Content	Requirement	Qualified	Underqualified
1	Structure and material	3 layers of cloth. The outer layer is airy with smooth surface. Water-resistant and anti-droplet. String with good elasticity.	X	
2	Anti-droplet efficiency	Filtration efficiency with oil droplet is no less than 90%	X	
3	Airway resistance (mmH_2O)	Airway resistance is no more than 9 mmH_2O	X	
4	Permissible limit of heavy metal content			
4.1	Arsenic content (As)	0.17 mg/kg	X	
4.2	Lead content (Pb)	1.00 mg/kg	X	
4.3	Mercury content (Hg)	0.12 mg/kg	X	
4.4	Antimony content (Sb)	0.10 mg/kg	X	
4.5	Cadmium content (Cd)	0.10 mg/kg	X	

** This test report is only valid with the samples provided by Han Viet Company Limited to National Institute of Medical Device and Construction on March 17th 2020.*

SUPERVISOR
(Signed)

Ha Quang Thanh

Hanoi, March 19th 2020
TESTOR
(Signed)

Tran Duc Anh

Address: 40 Phuong Mai – Dong Da – Hanoi * Tel: (024) 62925544 – 3 8523065 – 3 8521248

[제 41호 서식]

공증인 류혜민 사무소

전화:02)579-9900
팩스:02)579-9901

Registered No. 266 of 2020

NOTARIAL CERTIFICATE

THE NOTARY PUBLIC OFFICE OF HYE MIN RYU
Seowu Building 2F, 34-gil 6, Gangnam-daero, Seocho-gu, Seoul, Korea

210mm×297mm(보존용지(1종) 70g/㎡)

[별지 제43호 서식]

공증인 류혜민 사무소

전화:02)579-9900
팩스:02)579-9901

등부 2020 년 제 266 호

Registered No. 266 of 2020.

인 증

Notarial Certificate

위 **확 인 서** 에

CHOI DOO HYUN

attorney-in-fact of

기재된 **도레이첨단소재 주식회사**
대표이사 전해상 의

TORAY ADVANCED MATERIALS KOREA INC.
CEO
JEON HAE SANG

대리인 **최 두 현** 는

appeared before me and admitted the said principal's Subscription(s) to the attached

본 공증인의 면전에서 위 본인이 기명날인 한 것임을 자인하였다.

LETTER OF CONFIRMATION

2020 년 2 월 24 일
이 사무소에서 위 인증한다.

This is hereby attested on this 24TH day of FEB. 2020. at this office

THE NOTARY PUBLIC OFFICE OF HYE MIN RYU
Seoul Central District Prosecutors' Office
Seowu Building 2F, 34-gil 6, Gangnam-daero, Seocho-gu, Seoul, Korea

공증사무소 명칭 **공증인 류혜민 사무소**
소 속 서울중앙지방검찰청
소재지 표시 서울시 서초구 강남대로 34길 6, 서우빌딩 2층

류 혜 민

공증인 공증담당변호사

Ryu hye min

Attorney-at-Law
Ryu Hye-Min

This office has been authorized by the Minister of Justice, the Republic of Korea, to act as Notary Public since FEB, 1, 2019 under Law No. 208

210mm x 297(보존용지(1종)70g/㎡)

[제 41호 서식]

공증인 류혜민 사무소

전화:02)579-9900
팩스:02)579-9901

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Seowu Building 2F, 34-gil 6, Gangnam-daero, Seocho-gu, Seoul, Korea

210mm×297mm(보존용지(1종) 70g/㎡)

[별지 제43호 서식]

공증인 류혜민 사무소

전화:02)579-9900
팩스:02)579-9901

등부 2020 년 제 267 호

인 증

위 선 언 문 에

기재된 **도레이첨단소재 주식회사**
대표이사 전해상 의

대리인 **최 두 현** 는

본 공증인의 면전에서 위 본인이
기명날인 한 것임을 자인하였다.

2020 년 2 월 24 일
이 사무소에서 위 인증한다.

공증사무소 명칭 **공증인 류혜민 사무소**
소 속 서울중앙지방검찰청
소재지 표시 서울시 서초구 강남대로 34길 6, 서우빌딩 2층

류 혜 민

공증인 공증담당변호사

Registered No. 267 of 2020.

Notarial Certificate

CHOI DOO HYUN
attorney-in-fact of

TORAY ADVANCED MATERIALS KOREA INC.
CEO
JEON HAE SANG

appeared before me and admitted the said principal's Subscription(s) to the attached

DECLARATION

This is hereby attested on this 24TH day of FEB. 2020. at this office

THE NOTARY PUBLIC OFFICE OF HYE MIN RYU
Seoul Central District Prosecutors' Office
Seowu Building 2F, 34-gil 6,
Gangnam-daero, Seocho-gu, Seoul,
Korea

Ryu hye min

Attorney-at-Law
Ryu Hye-Min

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[제 41호 서식]

공증인 류혜민 사무소

전화:02)579-9900
팩스:02)579-9901

Registered No. 268 of 2020

NOTARIAL CERTIFICATE

THE NOTARY PUBLIC OFFICE OF HYE MIN RYU
Seowu Building 2F, 34-gil 6, Gangnam-daero, Seocho-gu, Seoul, Korea

210mm×297mm(보존용 [illegible]0g/m²)

[별지 제43호 서식]

공증인 류혜민 사무소

전화:02)579-9900
팩스:02)579-9901

등부 2020 년 제 268 호

인 증

위 **선 언 문** 에

기재된 **도레이첨단소재 주식회사**
대표이사 전해상 의

대리인 **최 두 현** 는

본 공증인의 면전에서 위 본인이
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2020 년 2 월 24 일
이 사무소에서 위 인증한다.

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소 속 서울중앙지방검찰청
소재지 표시 서울시 서초구 강남대로 34길 6, 서우빌딩 2층

류 혜 민

공증인 공증담당변호사

Registered No. 268 of 2020.

Notarial Certificate

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attorney-in-fact of

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CEO
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DECLARATION

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THE NOTARY PUBLIC OFFICE OF HYE MIN RYU
Seoul Central District Prosecutors' Office
Seowu Building 2F, 34-gil 6,
Gangnam-daero, Seocho-gu, Seoul,
Korea

Ryu hye min

Attorney-at-Law
Ryu Hye-Min

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210mm x 297(보존용지(1종)70g/㎡)

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Registered No. 269 of 2020

NOTARIAL CERTIFICATE

THE NOTARY PUBLIC OFFICE OF HYE MIN RYU
Seowu Building 2F, 34-gil 6, Gangnam-daero, Seocho-gu, Seoul, Korea

[별지 제43호 서식]

공증인 류혜민 사무소

전화:02)579-9900
팩스:02)579-9901

등부 2020 년 제 269 호

인 증

위 **선 언 문** 에

기재된 **도레이첨단소재 주식회사**
대표이사 전해상 의

대리인 **최 두 현** 는

본 공증인의 면전에서 위 본인이
기명날인 한 것임을 자인하였다.

2020 년 2 월 24 일
이 사무소에서 위 인증한다.

공증사무소 명칭 **공증인 류혜민 사무소**
소 속 서울중앙지방검찰청
소재지 표시 서울시 서초구 강남대로 34길 6, 서우빌딩 2층

류 혜 민

공증인 공증담당변호사

Registered No. 269 of 2020.

Notarial Certificate

CHOI DOO HYUN
attorney-in-fact of

TORAY ADVANCED MATERIALS KOREA INC.
CEO
JEON HAE SANG

appeared before me and admitted the said principal's Subscription(s) to the attached

DECLARATION

This is hereby attested on this 24TH day of FEB. 2020. at this office

THE NOTARY PUBLIC OFFICE OF HYE MIN RYU
Seoul Central District Prosecutors' Office
Seowu Building 2F, 34-gil 6, Gangnam-daero, Seocho-gu, Seoul, Korea

Ryu hye min

Attorney-at-Law

Ryu Hye-Min

This office has been authorized by the Minister of Justice, the Republic of Korea, to act as Notary Public since FEB, 1, 2019 under Law No. 208


RAS AG
materials & technologies

agpure® Nanosilber

Produkte und Anwendungen

2020

Das Unternehmen

RAS AG gegründet in 2016 als Zusammenschluss der Unternehmen

- rent a scientist GmbH
  wissenschaftliche **Dienstleistungen** seit 1995
- ras materials GmbH
  Herstellung und Vertrieb von **Nanomaterialien** seit 2010

rent a scientist®
ideen bewegen

ras
materials

Die **RAS AG** bietet ihren Kunden Entwicklungsdienstleistungen, Technologien und Materialien zur Schaffung technologisch basierter **Produktinnovationen** an.

Geschäftszahlen

2018 | 2019 INNOVATIV DURCH FORSCHUNG Ausgezeichnet durch den Stifterverband RAS5359REG

Mitarbeiter	21
Flächen	1.700 m²

- Chemisches Labor
- Technikum
- Silberspurenanalytik
- Mikrobiologie
  (Nachweis der antimikrobiellen Wirksamkeit)
- Kundenspezifische Entwicklungsumgebung
- Produktion Nanomaterialien
  (im Reinraum, QMH nach ISO 13485)


ZERTIFIKAT

RAS AG

EN ISO 13485 : 2016

RAS AG

Business Units

rent a scientist®

- Unsere F+E **Dienstleistung** bringt Innovationen in Unternehmen. Wir gestalten Märkte mit Kreativität und Knowhow.

RAS AG

ag**pure**®

- **Antimikrobielles** Additiv mit herausragenden Eigenschaften und maximaler Sicherheit für Mensch und Natur.

RAS AG

ECOS®

- „Silver Nanowire Technology“.
  Transparente, leitfähige Oberflächen für eine Vielzahl von Anwendungen.

RAS AG

RAS AG

Mitgliedschaften

u.a.

VDI-Gesellschaft Materials Engineering (GME) - Fachbereich 2 "Nanotechnik"

FA 202 Keimreduzierung im klinischen Umfeld durch Nanotechnologie

Div. ZIM-Netzwerke

Nanosilber, Antimik, CleanHand

NIA Nanotechnology Industries Association, Brüssel

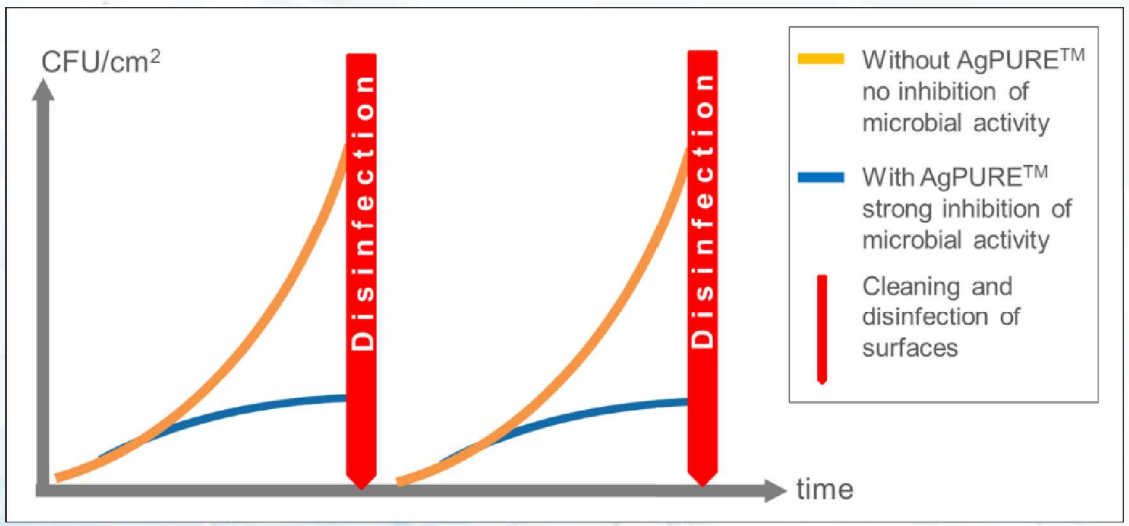
Projektbegleitende Ausschüsse diverser Forschungsprojekte

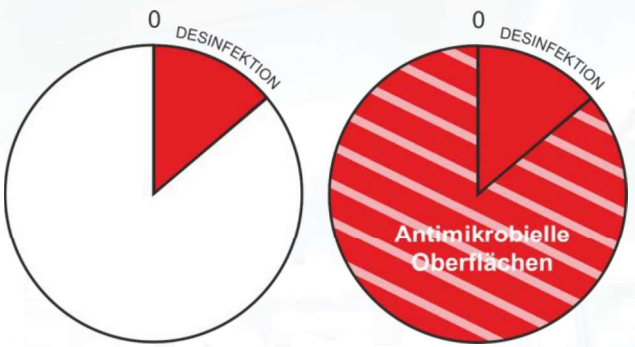
Warum brauchen wir mehr Hygiene?

http://www.martingrandjean.ch/connected-world-air-traffic-network/

Mehr Hygiene durch antimikrobielle Oberflächen

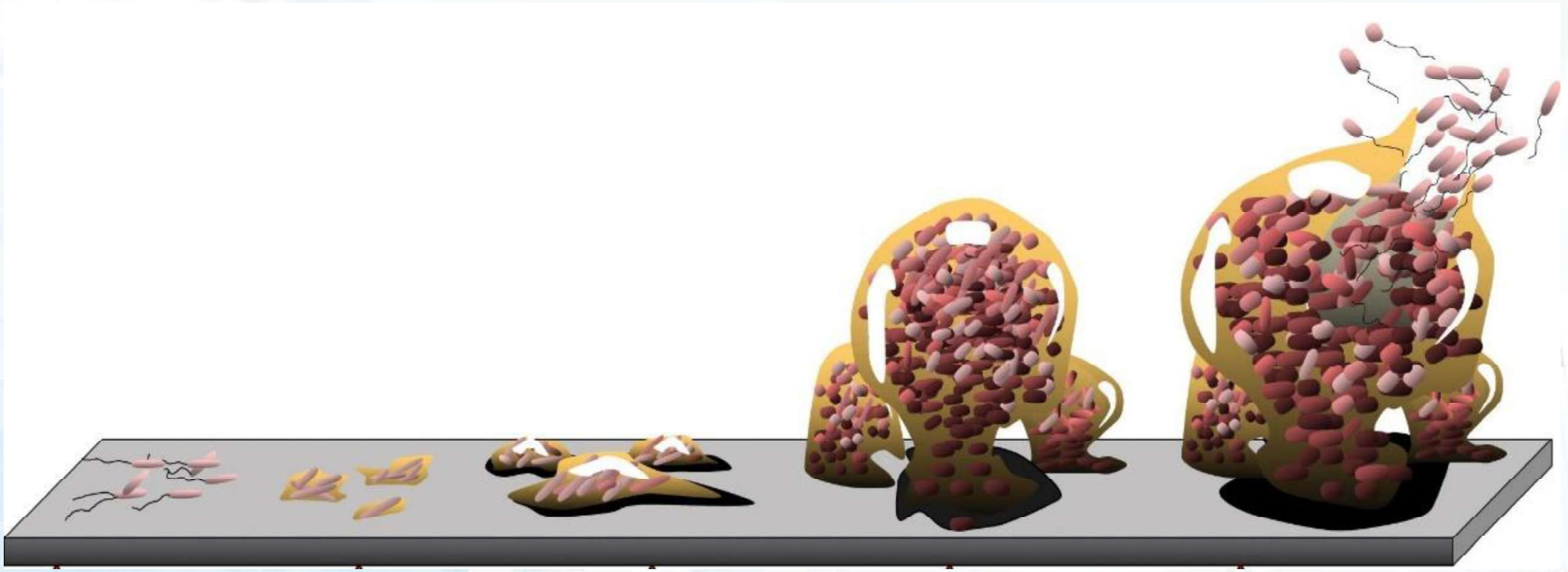
Zeitraumbezogene Wirksamkeit





- Prio 1: Sauber, Sauber, Sauber
- Nanosilber: Zusätzlicher Schutz neben Reinigung, Antibiotika und Desinfektionsmittel, aber keine Substitution

Problem - Biofilmbildung



D. Davis - From: D. Monroe, "Looking for Chinks in the Armor of Bacterial Biofilms", *PLoS Biology* **5** (11): e307). DOI 10.1371/journal.pbio.0050307.)

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Einführung Nanosilber

Historische Nutzung

- Die Nutzung von Nanosilber in der Medizin (sogar in ungebundener Form als Arzneimittel) ist historisch

Product	Use	Particle Size (nm)	Reference
Argyrol	Anti-Infective (early 1900s)	35 nm	DLS Study, NanoHorizons, 2009.
Collargol	Anti-Infective (early 1900s)	10-20 nm	Muller, 1926 (1). Bogdanchikova, 1992 (2).
Mesosilver	"Dietary Supplement"	2 nm	DLS Study, NanoHorizons, 2009.
Protargol	Anti-Infective (early 1900s)	2 nm	Bogdanchikova, 1992 (2).

SNWG "Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Oxide Pesticide Products", Presentation to Scientific Advisory Panel (November 4th, 2009).

https://www.pinterest.com/pin/287386019944709058/

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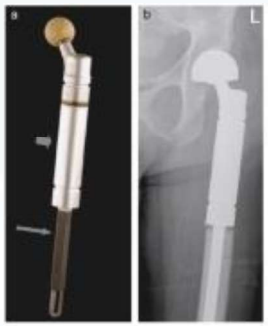
Einführung Nanosilber

Medizinische Nutzung

ACTICOAT, ein MARKENZEICHEN VON SMITH & NEPHEW



Hardes et al. (2007). Lack of toxicological side-effects in silver-coated megaprostheses in humans. Biomaterials, 28(18), 2869–75.

- Nanosilber entsteht auf jeder Silberoberfläche durch Reduktion von Silberionen zu metallischem Silber
  - Glover, R. D., Miller, J. M., & Hutchison, J. E. (2011). Generation of metal nanoparticles from silver and copper objects: nanoparticle dynamics on surfaces and potential sources of nanoparticles in the environment. ACS nano, 5(11), 8950–7. doi:10.1021/nn2031319
  - Mitrano, D., Rimmele, E., Wichser, A., & Erni, R. (2014). Presence of Nanoparticles in Wash Water from Conventional Silver and Nano-silver Textiles. ACS …, (7), 7208–7219.

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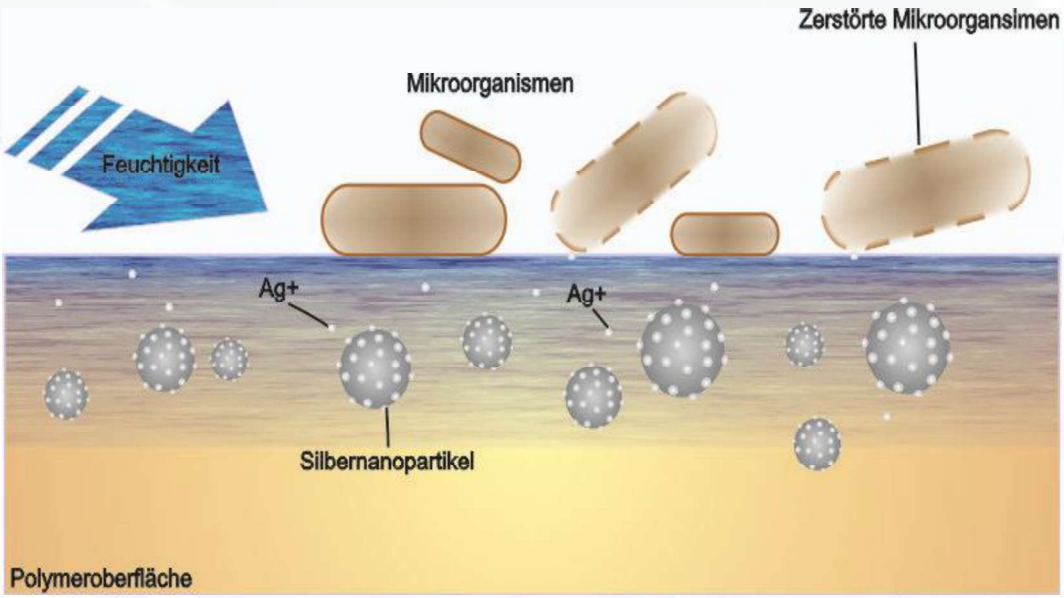
Wirkungsweise Nanosilber

Freisetzung Ag^+

- Biozid Freisetzung
  - Oberflächliche Korrosion von Ag^0 zu Ag^+
  - Diffusion des Ag^+ an die Materialoberfläche
  - Kontrollierte Freisetzung des bioziden Ag^+



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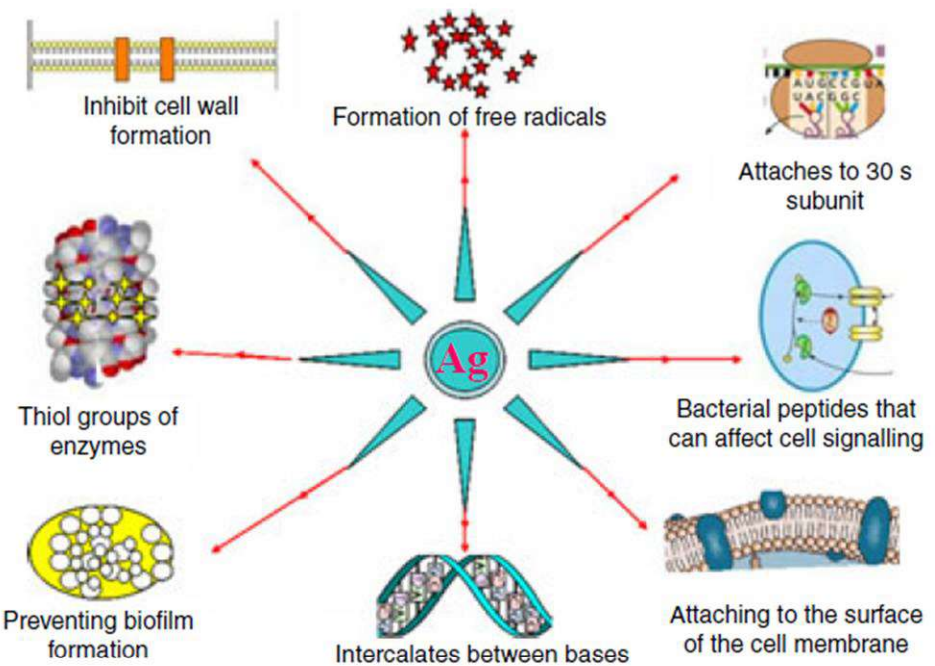
Wirkungsweise Nanosilber

Wirkung auf Mikroben

- Wirkung auf Mikroben u.a.:
  - Hemmung des Ionentransports durch die Membran
  - Irreversible Reaktion mit DNA/RNA



Rai, M. K., Deshmukh, S. D., Ingle, a. P., & Gade, a. K. (2012). Silver nanoparticles: The powerful nanoweapon against multidrug-resistant bacteria. Journal of Applied Microbiology, 112(5), 841–852. http://doi.org/10.1111/j.1365-2672.2012.05253.x

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Wirkung von Nanosilber gegen MR-Erreger

Stand der Wissenschaft

- Wirkung der Silberionen auf Erreger umfassend beschrieben
- Nanosilber-basiertes Metallcoating für Implantate mit hoher Wirksamkeit gegen MR-Keime
  - Gasquères, C., Schneider, G., Nusko, R., Maier, G., Dingeldein, E., & Eliezer, A. (2012). Innovative antibacterial coating by anodic spark deposition. Surface and Coatings Technology, 206(15), 3410–3414. http://doi.org/10.1016/j.surfcoat.2012.02.015
- Nanosilber-haltige Wundauflage zeigt Wirkung gegen Bakterien mit NDM-1 carbapenemase
  (Acinetobacter baumannii, Citrobacter freundii, Enterobacter spp., Escherichia coli and Klebsiella pneumoniae)
  - Hope, R., Mushtaq, S., Vaughan, K., Woodmansey, E., Roberts, C., & Livermore, D. (2012). The in-vitro antibacterial activity of nanocrystalline silver dressings against bacteria with NDM-1 carbapenemase. Ewma, (45), 35352.
- Interne und externe mikrobiologische Untersuchungen bestätigen die Wirksamkeit von agpure® Nanosilber in Oberflächen gegen multiresistente Erreger wie MRSA; 3,4 MRGN E.coli; ...

Wirkung von Nanosilber gegen MR-Keime

Stand der Wissenschaft

- Tabelle rechts

  Franci, G., Falanga, A., Galdiero, S., Palomba, L., Rai, M., Morelli, G., & Galdiero, M. (2015). Silver Nanoparticles as Potential Antibacterial Agents. Molecules, 20(5), 8856–8874. http://doi.org/10.3390/molecules20058856

- **Fazit:**

  Die hohe antimikrobielle Wirksamkeit von Nanosilber gegen MR-Erreger ist umfassend wissenschaftlich beschrieben.

Bacteria	Mechanism of Action	References
Acinetobacter baumannii	Alteration of cell wall and cytoplasm.	[26,27]
Escherichia coli	Alteration of membrane permeability and respiration	[26,28–44]
Enterococcus faecalis	Alteration of cell wall and cytoplasm.	[42,45,46]
Klebsiella pneumoniae	Alteration of membrane	[28,41,47]
Listeria monocytogenes	Morphological changes, separation of the cytoplasmic membrane from the cell wall, plasmolysis	[47]
Micrococcus luteus	Alteration of membrane	[28]
Nitrifying bacteria	inhibits respiratory activity	[31]
Pseudomonas aeruginosa	Irreversible damage on bacterial cells; Alteration of membrane permeability and respiration	[17,28,32,33,36,41–44,48–50]
Proteus mirabilis	Alteration of cell wall and cytoplasm.	[43,44]
Staphylococcus aureus	Irreversible damage on bacterial cells	[17,26,31,34,37,39–41,48,51,52]
Staphylococcus epidermidis	Inhibition of bacterial DNA replication, bacterial cytoplasm membranes damage, modification of intracellular ATP levels	[36,52]
Salmonella typhi	Inhibition of bacterial DNA replication, bacterial cytoplasm membranes damage, modification of intracellular ATP levels	[33,36,48,51]
Vibrio cholerae	Alteration of membrane permeability and respiration	[33]

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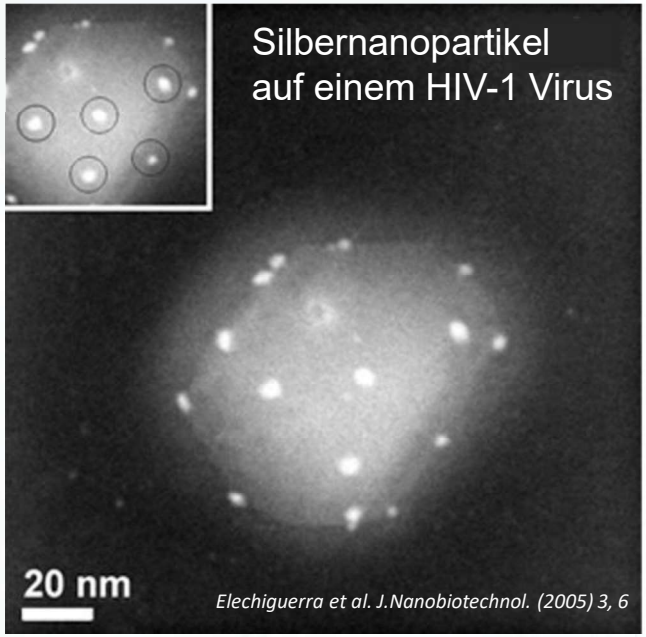
Antivirale Wirkung

- Silbernanopartikel zeigen eine antivirale Wirkung gegen:
  - Influenza (e.g. H5N1)
    Kheiri et al. (2009), DARU Vol 17, No. 2, 88
  - Hepatitis B
    Lu et al. Antivir Ther. (2008);13(2):253-62.
  - HIV (AIDS)
    Pedersen et al. Journal of Science of Healing Outcomes, (2008),1(1))
    Kheiri et al. DARU Vol 17, No. 2 (2009), 88
    Lu et al. Antivir Ther. (2008);13(2):253-62.
    Lara et al. Journal of Nanobiotechnology (2010), 8:1
    Sun et al. Chem Commun (Camb). (2005) Oct 28;(40):5059-61)
    Elechiguerra et al. J.Nanobiotechnol. (2005) 3, 6
  - HSV (Herpes)
    Fayaz et al. (2012). International journal of nanomedicine
  - Norovirus
    Castro-Mayorga et al (2017)



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agpure®

Nanosilber für antimikrobielle Anwendungen

Dimensionen

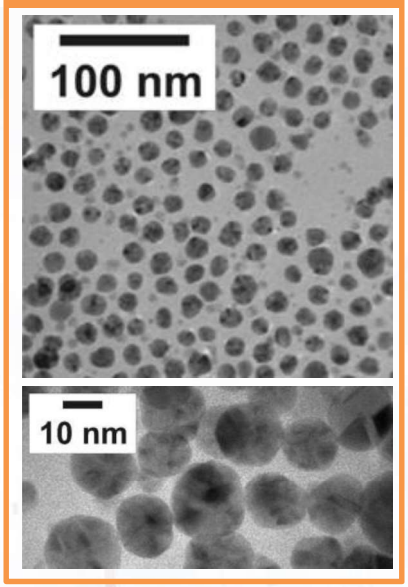
- Mittlerer Durchmesser 15 nm
- 99 % der Partikel < 20 nm

Formulierung

- Stabil in wässrigen und organischen Dispersionen
- Einarbeitung in Polymere und Harze

Dauerhaftigkeit

- Keine Freisetzung von Nanopartikeln (Ag^0) aus festen Matrices
- Kontinuierliche Abgabe geringster Mengen von Silberionen (Ag^+)



NM-series of representative manufactured nanomaterials. NM-300 Silver. Characterisation, stability, homogeneity. Klein, C.L.; et al.

RAS AG

agpure®

unsere Produkte

ag**pure**®W10
- 10,0 Gew.-% Nanosilber, stabilisiert, Lösungsmittel: **Wasser**

ag**pure**®W2
- 2,0 Gew.-% Nanosilber, Matrix: **Titandioxid**

ag**pure**®W3
- 3,0 Gew.-% Nanosilber, Matrix: **Polyetherphosphat**

ag**pure**®W50
- 45,0 Gew.-% Nanosilber, **stabilisiert**

ag**pure**®MB6500
- 0,65 Gew.-% Nanosilber Masterbatch, Standardmatrix**polymere**: PE Xpro und SANPURE®
- Nanosilber-**Sol-Gel Beschichtung**

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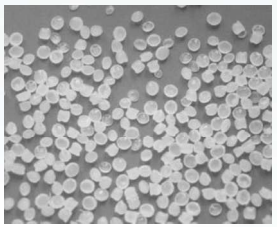
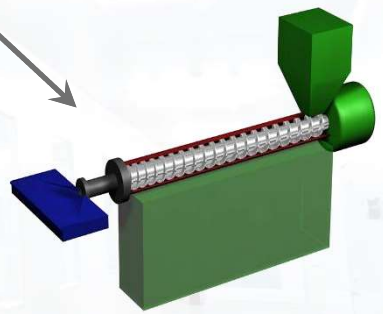
Der Weg zum Produkt

agpure® W50

agpure® Masterbatch

PET pellets





Faserherstellung

Nanosilberfaser

Antimikrobielles Tuch

RAS AG

agpure®

Produktbereiche

Keramik und Fliesen

Kale VitrA

SeraPool Porselen Sanayi ve Ticaret A.Ş. SERA POOL

Villeroy & Boch 1748

Textilien

evolon®

cleanbake

Lacke und Farben

CLOU®

BIONI

Rhenocoll Beschichtungen und Klebstoffe

Medizin

aap

RAUMEDIC Lifeline to Health

Reinste Nano Ventures

HEBA Perfektion im Ohr

Leica MICROSYSTEMS

MEDI-SIL Orthopädische Produkte

FREUDENBERG INNOVATING TOGETHER

Desinfektion

LAMILUX

FARBEN WERKE WUNSIEDEL

KERONA chemical solutions

MASTER TEC

SANPURE® ANTIMICROBIAL COATING

FRUTAROM SAVORY SOLUTIONS

Produktbeispiel Kunststoff 1

Entwicklung gefärbtes PA

- Ziel:
  Herstellung nanosilberhaltiges PA
- Konzentrationsreihe und
  Einfärbung rot, grün, blau
- Antimikrobielle Wirksamkeit hoch,
  auch bei eingefärbten Proben
- Prototyp für Türklinken und Griffe

RAS AG

Produktbeispiel Kunststoff 2

Vileda NanoTech micro von Freudenberg

- Vlies aus Endlos-Microfasern (70% PET, 30% PA) in die agpure® Nanosilberpartikel eingebettet sind
- Zertifiziert starke antibakterielle Wirkung auch nach über 200 Waschzyklen
- Produktvorteile:
  - Maschinelle Trocknung ist überflüssig, da die Tücher bis zu 72 Stunden lang feucht aufbewahrt werden können, ohne dass ein Bakterienwachstum einsetzt. Dies spart Zeit, Geld und verkürzt die Reinigungsvorbereitung beträchtlich.
  - Keine Geruchsemissionen von gebrauchten Tüchern
  - Geringe Silberabgabe durch Nanosilber-Partikel eingebettet in Endlos-Microfaser
- Reinigungstuch für alle Hygiene-Bereiche wie Krankenhäuser, Altenheime, Hotels, Restaurants, öffentlichen Bereiche

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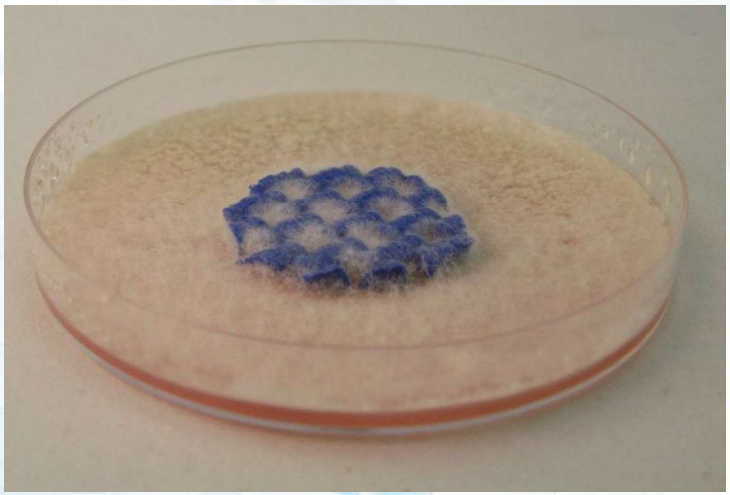
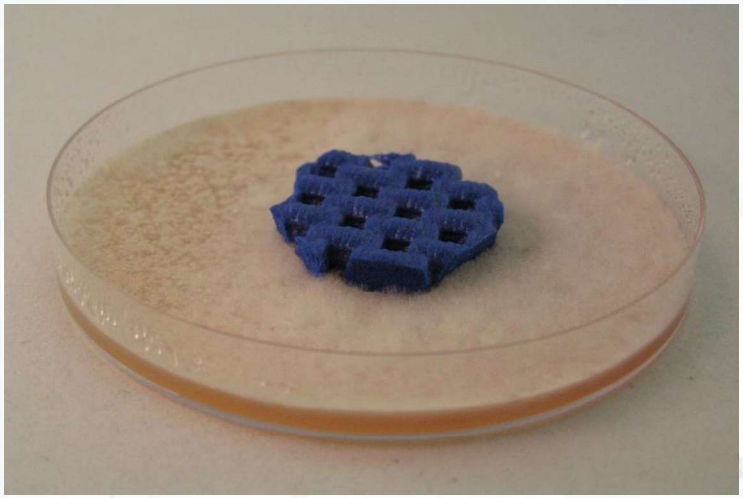
Produktbeispiel Kunststoff 3

Wunderlich Nano-San PVC-Plastisol-Matte



Ohne agpure®
(nach 30 Haushaltswäschen)
Ungehemmtes Pilzwachstum



Mit agpure®
(nach 30 Haushaltswäschen)
Pilzwachstum gehemmt

RAS AG

Produktbeispiel Keramik

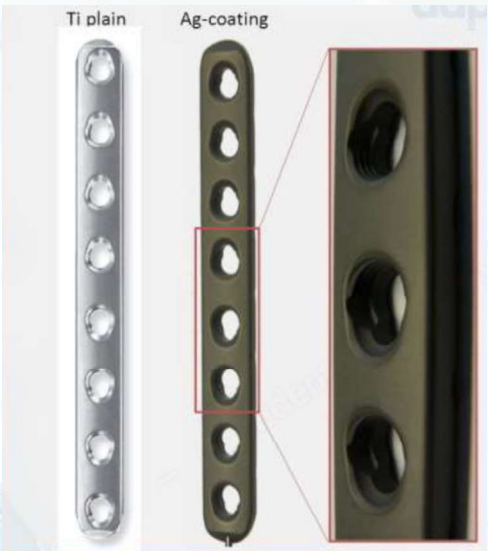
AntiBac von Villeroy & Boch

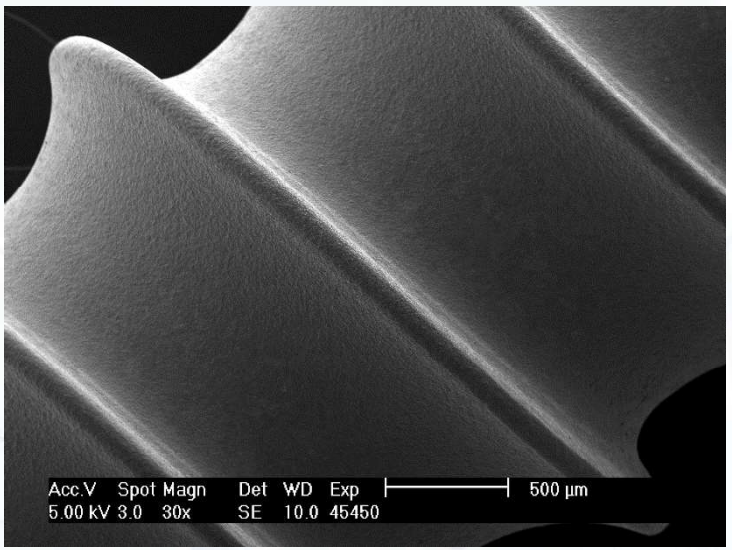
RAS AG

Beschichtung - Beispiel Medizinprodukt

Silver Coating Technology der aap Implantate AG, Berlin

- Entwicklungsstart 2008
- Plasma Electrolytic Oxidation
- Einbindung von agpure® Nanosilber in die aktive Schicht
- Hohe Biokompatibilität
- „Win the race for the surface!“
- CE in 2019





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Beschichtung – Beispiel Uvex sil-Wear

Einweg-Schutzbekleidung

- Chemikalienschutz Typ 3B
- Fluorcarbon-Beschichtung auf Vlies-Folienlaminat
- agpure® Nanosilber in der Beschichtung
- Zertifizierte Wirkung: > 3 log-Stufen Reduktion nach DIN EN ISO 20743:2007-10

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Beschichtung – Beispiel SANPURE®

Sol-Gel-Beschichtung mit agpure® Nanosilber

- Entwickelt von einem Joint Venture zwischen der RAS AG und der Gbneuhaus GmbH
- SANPURE® vereint die hervorragenden Eigenschaften der Sol-Gel-Beschichtungen mit den antimikrobiellen Eigenschaften von Silber-Nanopartikeln
- Substrate:
  - Kunststoff (Polycarbonat, ETFE- oder PC-Folien)
  - Glas (Borosilikatglas, Kalk-Natron-Glas, Quarzglas etc.)
  - Metalle und Legierungen (z. B. Stahl, Aluminium, Kupfer, Messing)
- Abriebbeständig, kratzfest, haftfest

SANPURE®
ANTIMICROBIAL COATING

RAS AG

Lackanwendung

Nanosilber-Produkte der Firma Alfred Clouth Lackfabrik GmbH & Co. KG

- CLOUCRYL Nano-Finish Antibak
  - Zweikomponenten-Polyurethan-Acrylharzlack
- CLOU Hartwachs-Öl antibakteriell

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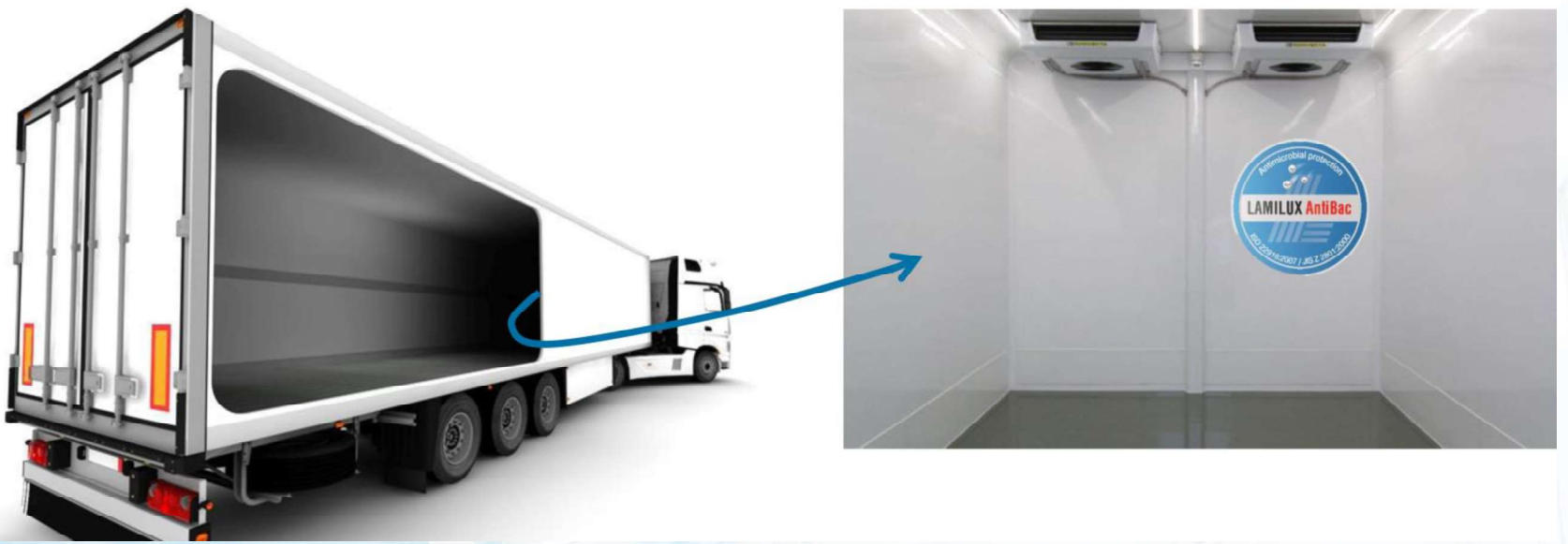
Referenzen aus dem Lebensmittelbereich

Lamilux AntiBac – GFK-Paneele



Warum Nano?

• Typische Werte • Antimikrobiell wirksame Dosis	**Silberdraht** 	**Silberbeschichtete Nylonfaser** 	**Nanosilber in PET-Faser** 
Silbergehalt	99,99 %	20,00 %	0,02 % „Nano – effect“
Ag^+ Elution [ng / g Material]	67	660	470
Benötigte Silbermenge			

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Weitere Vorteile von Nanosilber

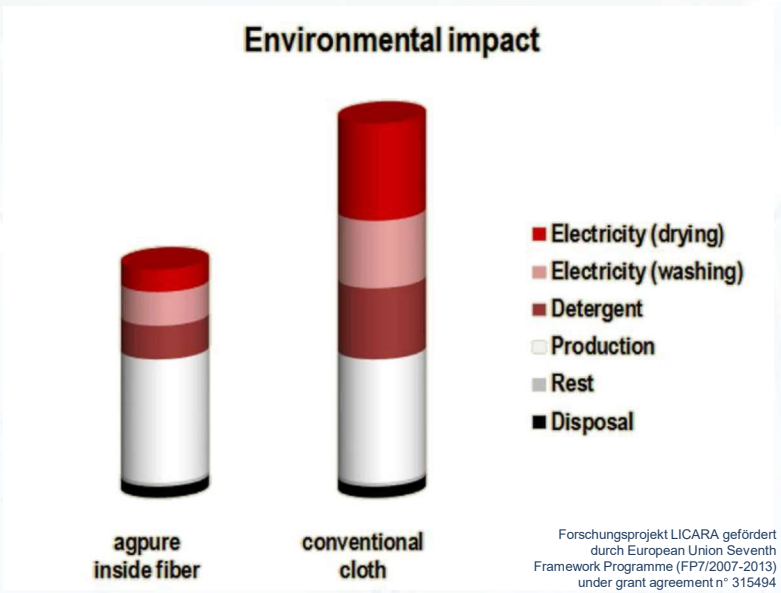
Ressourcenschonung am Beispiel **Microfasertuch** mit Nanosilber

- Weniger Waschzyklen
- Tuch kann feucht gelagert werden
- Kein Trocknen mehr nötig
- Bis zu 50% Energieeinsparung
- Ökobilanz ist 30% besser im Vergleich zu Tüchern ohne Nanosilber

  Ergebnisse aus dem Forschungsprojekt LICARA gefördert durch European Union Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 315494
- Waschbeständigkeit > 500 Industriewäschen
- Nano-Silber ersetzt Chlororganische Biozide
- Nanotechnologie: Gleiche Wirksamkeit

↔

deutlich weniger Materialeinsatz



Forschungsprojekt LICARA gefördert durch European Union Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 315494

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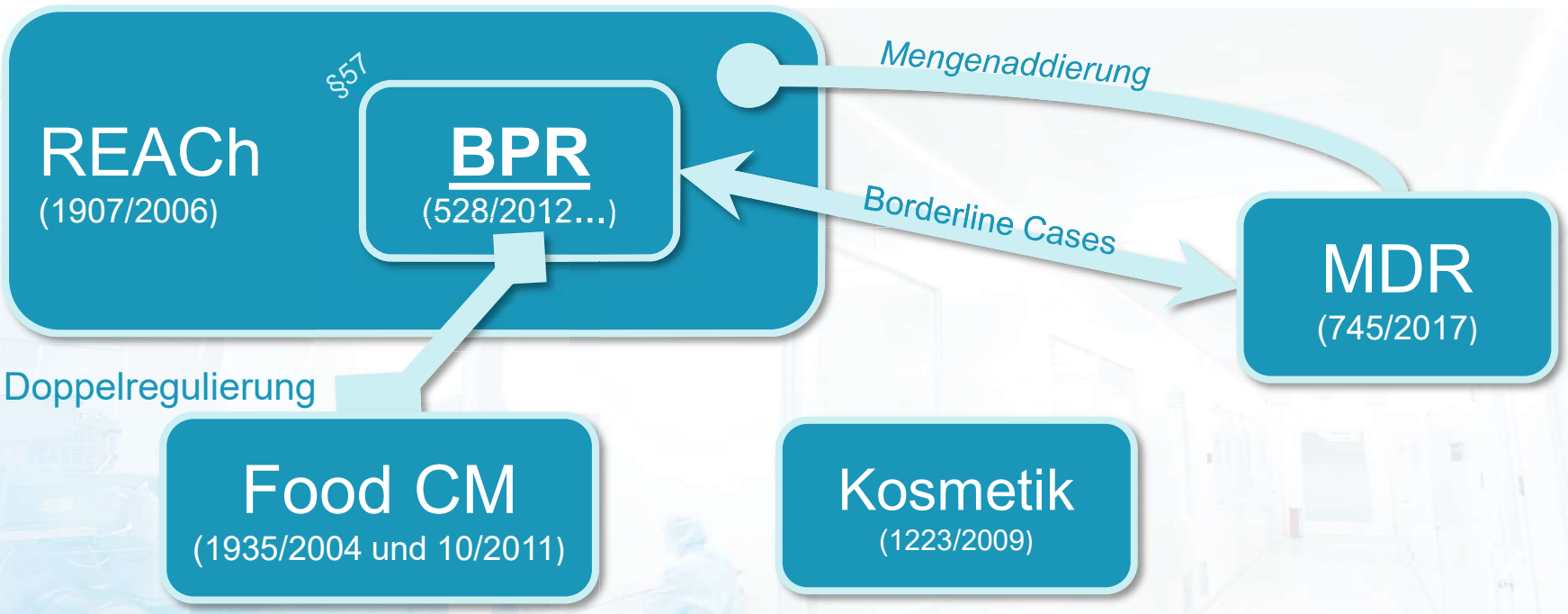
EU-Regularien und antimikrobielles Nanosilber



Regulatorischer Status

Kurzfassung

- Verkehrsfähig nach Biozid-Verordnung (BPR) (EU) Nr. 528/2012
- Eingetragen in DELEGIERTE VERORDNUNG (EU) 2017/698 DER KOMMISSION, Annex II unter CAS-Nr. 7440-22-4 - „Silber, als Nanomaterial“
  - Weil der Wirkstoff Nanosilber nun auf dieser Liste ist, darf laut ECHA Biozidprodukte oder behandelte Waren mit agpure-Nanosilber auf dem Markt bleiben, während das Wirkstoff-Dossier bewertet wird.
- Wirkstoff-Dossier zu dem Wirkstoff agpure-Nanosilber fristgerecht eingereicht seit 01. September 2015.
  - Bewertung voraussichtlich zu erwarten: 2021.
  - Biozid-Zulassung ist beantragt für die Produktarten (PA) 2, 4 und 9.
- agpure® darf unter bestimmten Vorgaben auch im Lebensmittelkontakt verwendet werden.

Regulatorischer Status

Einführung

- Antimikrobiell: Es gilt die EU-Biozidprodukte-Verordnung (BPR) (EU) Nr. 528/2012
- Übergangsvorschriften für Produkte mit Altwirkstoffen (= Nanosilber)
- Altwirkstoffe: Wirkstoffe die schon vor 2000 auf dem Markt waren und sich in der Bewertung im Review-Programm befinden (derzeit 2. Phase)
  - Altwirkstoff-Programm läuft bis 2024
  - Ablauf:
    - BAUA-Meldung: z.B.: N-73054 (für agpure®)
    - Wirkstoff-Zulassung
    - Veröffentlichung der Zulassung
    - Biozid-Produkt Zulassung → Keine Produktzulassung vor Wirkstoffzulassung
- Neuwirkstoffe: alle Wirkstoffe, die sich nicht im Altwirkstoffprogramm befinden
  - Vermarktung erst nach endgültiger Zulassung

Verkehrsfähigkeit

Gültig für agpure® Nanosilber

- Altwirkstoffverfahren
  - Silber (CAS 7440-22-4) ist notifiziert, agpure W ist gemeldet
  - Wirkstoffdossier für Silber wurde eingereicht
- Neuregelung von Nanomaterialien mit der BPR EU 528/2012
  - Zusätzliche Daten wurden notwendig (Einreichung eines zusätzlichen Wirkstoff-Dossiers für Nanosilber, phys-chem. Identität mit NM 300 K = agpure®)
- DELEGIERTE VERORDNUNG (EU) 2017/698 DER KOMMISSION, Annex II
  - Produktarten 2, 4 und 9
  - „Silber, als Nanomaterial“ CAS-Nr. 7440-22-4
    → Altwirkstoff
- ECHA: Biozidprodukte und behandelte Waren mit (agpure-) Nanosilber sind und bleiben weiterhin verkehrsfähig

Nummer des Eintrags	Bezeichnung des Stoffs	Berichterstat-tender Mitglied-staat	EG-Nummer	CAS-Nummer	1	2	3	4	5	6	7	8	9	10	11
401	Silber	SE	231-131-3	7440-22-4		x		x	x				x		x
1023	Silber, als Nanomaterial	SE	231-131-3	7440-22-4		x		x					x		

RAS AG

Regulatorischer Status agpure®

Lebensmittelkontakt

1. Voraussetzung: Verkehrsfähigkeit nach BPR PT 4 ☑
2. Die allgemeinen Bestimmungen der Verordnung (EG) Nr. 1935/2004 sind zu beachten:
   a) Die Verwendung von agpure® Nanosilber in Keramiken, Lacken, Anstrichen und (nicht-polymeren) Beschichtungen im Lebensmittelkontakt ist erlaubt
   b) Für Materialien und Gegenstände aus Kunststoff, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen gilt gemäß Artikel 9 Abs. 2 der Verordnung (EU) Nr. 10/2011 ist die Verwendung von Nanosilber noch nicht erlaubt.

   → Die RAS AG hat zum 27.07.2018 über das BVL einen Zulassungsantrag bei der EFSA für Nanosilber als Lebensmittelkontaktmaterial eingereicht.

Zeitschiene

Stand Februar 2019, ohne Gewähr

2012
- Inkrafttreten der BPR (EU) No. 528/2012 - zusätzliche Risikobewertung für Nanomaterialien gefordert → Nanosilber wurde zu einem „neuen Altwirkstoff“

2015
- Zulassungsantrag, Einreichung Wirkstoff-Dossier Nanosilber, PT 2, 4, und 9
  Bezahlung ECHA-Gebühr neues Dossier Art. 95

2017
- Veröffentlichung (EU) 2017/698 - Nanosilber ist eingetragen (Vorstufe zu Art. 95)
- Bezahlung ECHA-Gebühr für die Genehmigung des Wirkstoffes „Silber, als Nanomaterial“

2020
- Bewertung des Wirkstoffdossiers abgeschlossen,
  Bezahlung KEMI-Gebühr Dossierprüfung

2021+
- Aufnahme in Anhang I der BPR, Beginn Produktzulassungsverfahren

RAS AG

Risikobewertung - Referenzmaterial

OECD WPMN

- OECD Working Party on Manufactured Nanomaterials (OECD WPMN)
  - Exposure measurement
  - Hazard assessment
  - Risk assessment
  - Environmental impacts
- Sponsorship Program for the Testing of Manufactured Nanomaterials
  - Stage 1: Representative set of Manufactured Nanomaterials (13) and list of endpoints

The nanomaterials currently being evaluated are those with commercial relevance including:

Fullerenes (C60), SWCNTs, MWCNTs, Silver nanoparticles, Iron nanoparticles, TiO_2, AlO, CeO, ZnO, SiO_2, Dendrimers, Nanoclays and Gold nanoparticles

http://www.oecd.org/science/nanosafety/45910212.pdf

RAS AG

Risikobewertung - Referenzmaterial

Internationales Standardreferenzmaterial

- agpure® W10:
  Intern. Standard Referenz Material für Nanosilber
  (NM 300 K) bei OECD WPMN

- agpure® W10 ist das neu zertifizierte Referenzmaterial
  BAM-N001 bei der Bundesanstalt
  für Materialforschung
  - Als Größenstandard für die Partikelgrößenbestimmung
  - Für toxikologische Untersuchungen

RAS AG

Risikoforschung

Nanosilber – Daten Dossier

Flags	Name Type	Name	Country	Remarks
	other: 7440-22-4 (silver)	Silver Powder	Korea, Republic Of	Reference substance: silver / silver(1+) /7440-22-4, EC number: 231-131-3, EC name: silver, CAS number: 7440-22-4, IUPAC name: silver(1+)
	other: 7440-	Citrate-stabilized AgNPs		
		NanoComposix uncapped nano-scale silver, 10, 20, 30, 50 nm sizes		
		NM-300K silver < 20 nm		Klein C, Comero S, Stahlmecka B (2011): NM-Series of representative manufactured nanomaterials NM-300 silver characterization, stability, homogeneity. JRC Scientific and Technical Reports. DOI:10.2788/23079
		SARPU 200KW		
		Silver nanoparticle (Korea)	Korea, Republic Of	

ENV/JM/MONO(2015)16/PART1
Organisation for Economic Co-operation and Development. Working Party on Manufactured Nanomaterials (WPMN) DOSSIER ON SILVER NANOPARTICLES - PART 1 - Series on the Safety of Manufactured Nanomaterials No. 53. (2015)

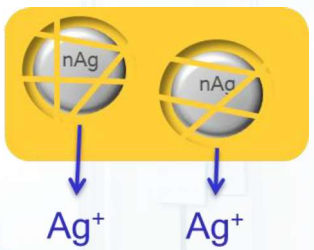
RAS AG

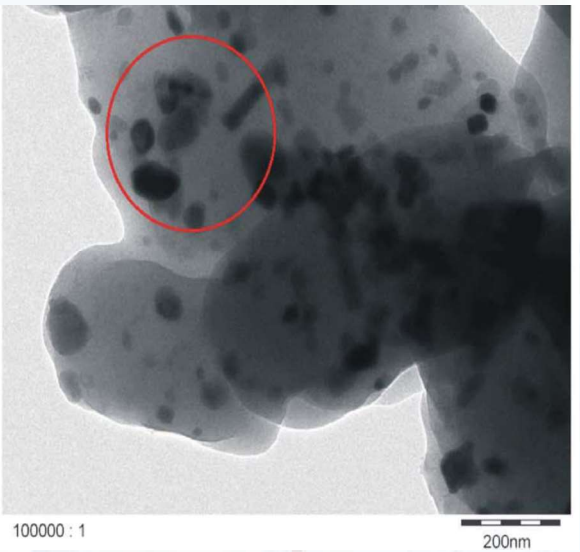
Ergebnisse Risikoforschung

Exposition

- Exposition am Arbeitsplatz, beim Verbraucher, in der Umwelt:
  - Wieviel Nano ist drin? ≠ Wieviel Nano kommt raus!
  - Nanosilberfreisetzung vs. Silberionenfreisetzung
- Silber Nanopartikel sind fest im Material eingebunden → es wird nur Ag^+ freigesetzt
- Aus Kunststoffschichten können keine Nanopartikel abgerieben werden

  M. Vorbau, L. Hillemann, P. Fiala, M. Stintz, A. Rommert, D. Eichstädt: Kleine Teilchen in der Luft? Farbe und Lack 116 (2010) 12, 25-29.
- Weitere Abriebversuche mit nanosilberhaltigen Mikrofasertextilien kommen zu demselben Ergebnis



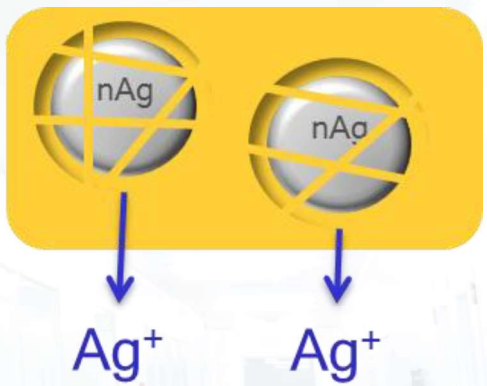


REACH-NanoHazEx: Rip-oN 3 + Stintz et al.

Nanosilber im Lebensmittelkontakt

Sicherheit für den Verbraucher - Migration

- Die Einbindung von Nanosilber in Lebensmittelkontaktmaterialien ist Stand der Technik
- Die Freisetzung von Silber in das Lebensmittel wird durch Migrationstests (PIM EU Nr. 10/2011) untersucht
- Bott (2017) zeigt in seiner Dissertation, dass (agpure®-) **Nanosilber fest** in den Kunststoff eingebunden ist und die Migration von Nanopartikeln gleich „null“ ist
- Lediglich antimikrobiell **aktive Silberionen** diffundieren aus dem Lebensmittelkontaktmaterial
- Exposition nAg = 0 → Risiko = Risiko (Ag^+)

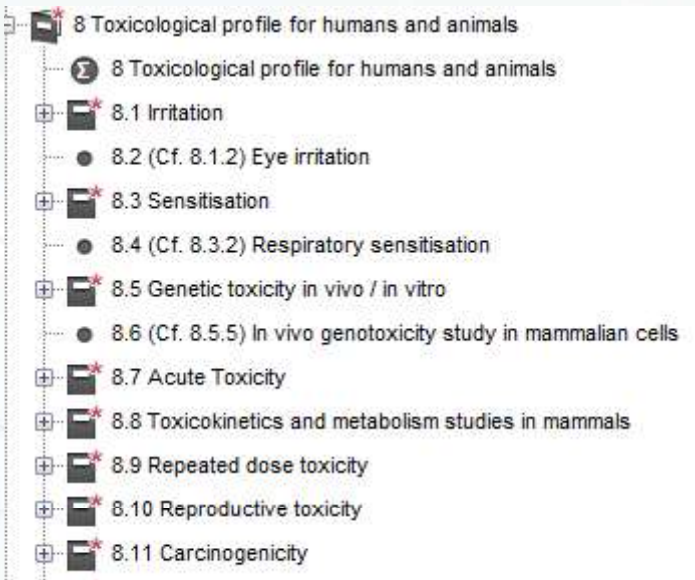


(Quelle: Bott, J. W. (2017). *Untersuchungen zum Migrationspotential von Nanomaterialien aus Kunststoff-Lebensmittelverpackungen*. Technische Universität München.)

Ergebnisse Risikoforschung und BPR-Wirkstoffdossier

Biokompatibilität und Umweltverträglichkeit

- Für die relevanten Personengruppen wurde eine Sicherheitsbewertung durchgeführt:
  - Akzeptables Risiko für Nanosilber
- Umwelt
  - Für sämtliche Umweltkompartimenten und auf allen relevanten Expositionspfaden wurde das Umweltrisiko berechnet
  - Ist der Risikoquotient (RQ) kleiner 1, werden keine unerwünschten Nebenwirkungen erwartet
  - Ergebnis für Nanosilber:
    - RQ < 1 (d.h., PEC < PNEC)



Ergebnisse Risikoforschung

Zusammenfassung

- Durch seine besondere Herstellung, Formulierung
- und bei bestimmungsgemäßem Gebrauch

kann agpure -Nanosilber
risikolos für die Umwelt und den Verbraucher
verwendet werden.

- Die Daten werden für die erfolgreiche Zulassung als Biozidprodukt verwendet.

Vielen Dank

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RAS AG

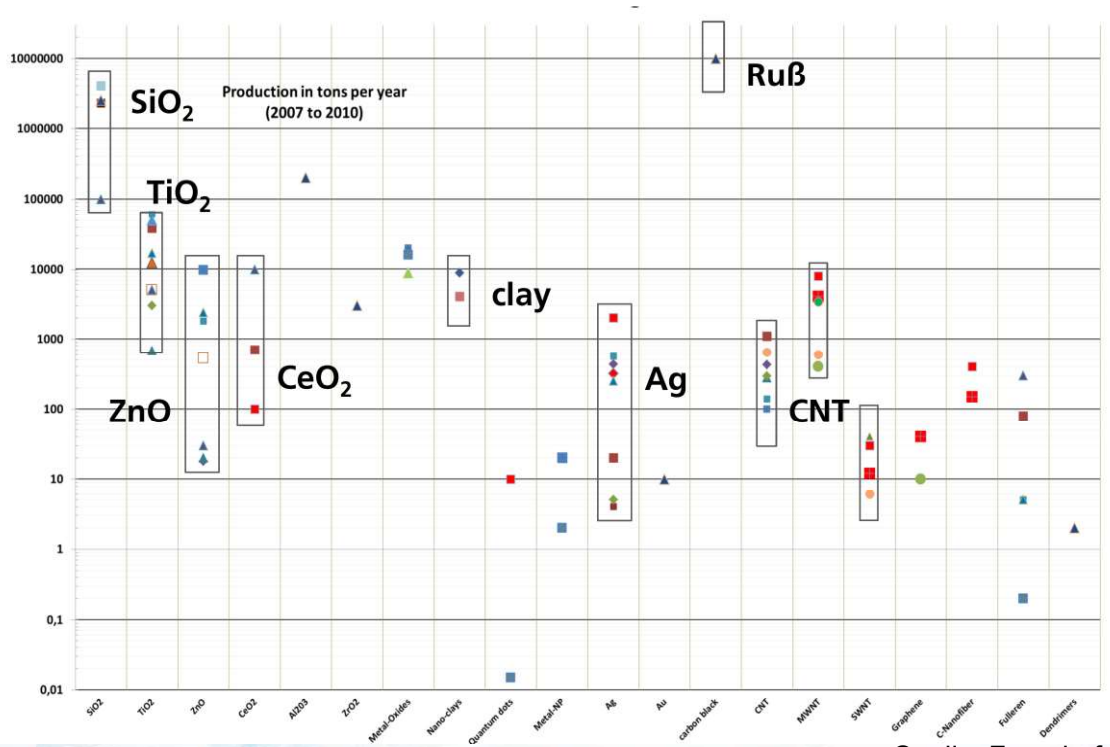
Anhang

Produktarten

- PT 2: Desinfektionsmittel und Algenbekämpfungsmittel, die nicht für eine direkte Anwendung bei Menschen und Tieren bestimmt sind.
  - Produkte zur Desinfektion von Oberflächen, Stoffen, Einrichtungen und Möbeln, die nicht für eine direkte Berührung mit Lebens- oder Futtermitteln verwendet werden. […]
  - Produkte als Zusatz in Textilien, Geweben, Masken, Farben und anderen Gegenständen oder Stoffen, um behandelte Waren mit Desinfektionseigenschaften herzustellen.
- PT 4: Lebens- und Futtermittelbereich
  - Produkte zur Desinfektion von Einrichtungen, Behältern, Besteck und Geschirr, Oberflächen und Leitungen, die im Zusammenhang mit der Herstellung, Beförderung, Lagerung oder dem Verzehr von Lebens- oder Futtermitteln (einschließlich Trinkwasser) für Menschen und Tiere Verwendung finden.
  - Produkte zur Aufnahme in Materialien, die mit Lebensmitteln in Berührung kommen können.
- PT 9: Schutzmittel für Fasern, Leder, Gummi und polymerisierte Materialien
  - Produkte zum Schutz von faserigen oder polymerisierten Materialien wie Leder, Gummi, Papier und Textilerzeugnissen gegen mikrobielle Schädigung.
  - Diese Produktart umfasst Biozid-Produkte, die der Ansiedlung von Mikroorganismen auf der Oberfläche von Materialien entgegenwirken und somit die Entwicklung von Gerüchen hemmen oder ausschließen und/oder Vorteile anderer Art mit sich bringen.

Einsatz von Nanomaterialien

2007 – 2010 (to / y)



Quelle: Fraunhofer ICT

Vermeintliche Silber Resistenz

- Synergistischer Effekt von Nanosilberpartikeln und Antibiotika
  - Mischung verschiedener Antibiotika (Imipenem, Gentamicin, Ciprofloxacin und Vancomycin) mit 100 µg/g Nanosilber und Vergleich der antibakteriellen Aktivität
  - → Sensitivität der getesteten Organismen gegenüber den Antibiotika wurde um 20-35 % erhöht

    Naqvi, S. Z. H., Kiran, U., Ali, M. I., Jamal, A., Hameed, A., Ahmed, S., & Ali, N. (2013). Combined efficacy of biologically synthesized silver nanoparticles and different antibiotics against multidrug-resistant bacteria. *International Journal of Nanomedicine*, *8*, 3187–3195. http://doi.org/10.2147/IJN.S49284
- Wissenschaftliche Daten führen zu folgender Schlussfolgerung
  - Molekularbiologische Methoden lassen ein Silberresistenz-Gen vermuten
  - Genotype ≠ Phenotype
  - Studie der Forschungsinstitute Hohenstein (mit *S. aureus*):
    - "Gewöhnung an steigende Silberkonzentrationen über 2000 Generationen, um eine Resistenz hervorzurufen.
    - Nach einer Generation auf Silber-freiem Medium verhält er sich wie jeder andere Stamm und wächst nicht auf Silber
    - Es fand also keine Resistenzbildung statt.
  - Es wurde bis jetzt keine Resistenz von Bakterien auf subinhibitorische Silberkonzentrationen bewiesen.
  - Bakterien sind solchen Konzentrationen seit Milliarden Jahren in verschiedensten Habitaten ausgesetzt ohne dass sich eine Resistenz gebildet hätte (Silber ist ubiquitär vorhanden. *Daunderer et al 2006*)
  - Es gibt keine direkte Evidenz, dass Silberresistenz-Gene eine Kreuzresistenz gegenüber Antibiotika verursachen kann.
  - Eine Resistenz speziell gegen Nanosilber kann es nicht geben.

Definition Risiko

Nach Krug und Wick. Angew. Chem. 2011, 123, 2 – 23

- Hier stellt sich die Frage nach einem Risiko (R), das sich einerseits aus der Exposition gegenüber den neuen Materialien ergibt (E), andererseits besteht aber nur dann ein Risiko, wenn die Nanomaterialien auch eine biologische Wirkung haben (H; für engl. „hazard“). Das Ganze ist aber gleichzeitig eine Funktion der Wahrscheinlichkeit (P; für engl. „probability“), da ein Risiko nur dann besteht, wenn eine gewisse Wahrscheinlichkeit für die Ausprägung eines biologischen Effektes gegeben ist.

$$R = f_p \{E,H\}$$

- An einem einfachen Beispiel sei diese Funktion erläutert. TiO_2 ist mit einer Primärpartikelgröße von 25 nm in kosmetischen Sonnenschutzcremes enthalten, um möglichst hohe UV-Schutzfaktoren zu erreichen. Eine Exposition ist immer dann gegeben, wenn man sich damit eincremt, E ist also relativ hoch. Ein Risiko besteht aber nur dann, wenn TiO_2 auch eine biologische Wirkung hat und an den Wirkort gelangt. Mittlerweile haben mehr als 40 Studien zeigen können (z.B. das europäische Projekt NanoDerm), dass TiO_2 nicht durch die Haut in den Körper gelangt und generell biologische Wirkungen eher gering ausfallen.

HAN VIET CO.,LTD
KM 14,1A HIGHWAY THANH TRI,HANOI VIETNAM

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)woven fabric (B)knitted fabric
Sample Color	:	(A)(dark green) 63" Cotton elastic Imitation linen cloth; (B)(off white) 63" Polyester cotton air layer
Sample Receiving Date	:	Mar 27, 2020
Testing Period	:	Apr 01, 2020 – Apr 23, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).
Test Performed	:	Selected test(s) as requested by applicant

Signed for and on behalf of
SGS-CSTC Standards Technical
Services Co., Ltd. HangZhou Branch

Jack Zhang

Jack Zhang (Account Executive)

3-6/F, No.4 Building, Huaye Hi-Tech Zone, No.1180, Bin'an Road, Binjiang District, Hangzhou, Zhejiang, China 310052 t (86-571)86791199 www.sgsgroup.com.cn
中国·浙江·杭州·滨江区滨安路1180号华业高科技产业园4号楼3-6层 邮编: 310052 t (86-571)86791199 sgs.china@sgs.com

Test Result

Ultraviolet Protection Factor (UPF)

(AATCC TM 183-2014; Test Conditions
1) Air temperature: 21±1oC
2) Relative humidity: 65±2% R.H.
3) Orientation of test specimen: Specimens were clamped on sample holder. Fabric face side is facing the incident UV light.
4) Test conducted in wavelength range 280-400 nm
5) Instrument: UV-VIS Spectrophotometer
6) No. of Scans: 6)

(A)	Unit	Dry Evaluation	Wet Evaluation
As Received			
Mean Ultraviolet Protection Factor (UPF)	No Unit	17	29
Standard Deviation	No Unit	1.3	1.7
Standard Error	No Unit	1.6	2.1
UPF Rating	No Unit	15	25
Protection Category	No Unit	Good	Very good
Percent Transmittance, T (UV-A)	%	6.72	4.44
Percent Transmittance, T (UV-B)	%	5.76	3.31
The Percent Blocking, UV-A	%	93.28	95.56
The Percent Blocking, UV-B	%	94.24	96.69

(B)	Unit	Dry Evaluation	Wet Evaluation
As Received			
Mean Ultraviolet Protection Factor (UPF)	No Unit	1285	889
Standard Deviation	No Unit	10.5	34.2
Standard Error	No Unit	13.1	42.4
UPF Rating	No Unit	50+	50+
Protection Category	No Unit	Excellent	Excellent
Percent Transmittance, T (UV-A)	%	0.67	1.39
Percent Transmittance, T (UV-B)	%	0.05	0.05
The Percent Blocking, UV-A	%	99.33	98.61
The Percent Blocking, UV-B	%	99.95	99.95

Remarks :

1. Refer to ASTM D6603, the UV protection category is determined by the UPF values,
UPF 40 or greater Excellent UV Protection
UPF in between 25 to 39 Very Good UV Protection
UFP in between 15 to 24 Good UV Protection
UPF less than 15 Unclassification

2. Ultraviolet Protection Factor (UPF) is the ratio of the average effective ultraviolet radiation (UV-R) irradiance transmitted and calculated through air to the average effective UV-R irradiance transmitted and calculated through fabric.

3. The limits of the spectral range of ultraviolet radiation are not well defined and may vary according to the user. Committee E-2.12 of the International Commission on Illumination (CIE) distinguishes in the spectral range between 400 and 100 nm :
UV-A : 315 - 400 nm
UV-B : 280 - 315 nm
UV-R : 280 - 400 nm

4. This method can also be used to determine the UPF of the fabrics in a stretched state. However, the techniques for stretching the specimens are not part of this method and are addressed in a separate test procedure. It must be noted that stretching the specimens could change the UPF properties.

5. The listed protection category is for reference only, the market claims for labeling UV-Protection product shall follow "Standard Guide For Labeling UV-Protection Textiles" as stated in ASTM D6603.

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Antimicrobial Activity Test^

Test Method : AATCC 100-2012 Antibacterial Finishes on Textile Material: Assessment of

(A)

Test organism	Klebsiella pneumoniae ATCC 4352
Concentration of bacteria(CFU/mL)	1.9x10^5
Sample -at "0H" contact time (CFU/sample)	1.6x10^5
Control sample- at "0H" contact time (CFU/sample)	1.9x10^5
Sample -at "24H" contact time (CFU/sample)	<100
Control sample- at "24H" contact time (CFU/sample)	1.3x10^8
Reduction(%)	>99.9%

(B)

Test organism	Klebsiella pneumoniae ATCC 4352
Concentration of bacteria(CFU/mL)	1.9x10^5
Sample -at "0H" contact time (CFU/sample)	1.5x10^5
Control sample- at "0H" contact time (CFU/sample)	1.9x10^5
Sample -at "24H" contact time (CFU/sample)	<100
Control sample- at "24H" contact time (CFU/sample)	1.3x10^8
Reduction(%)	>99.9%

Notes :

Test sample was 4 swatches of 4.8 cm diameter circular ,1 mL inoculum per trial.
The sample had been sterilized in the autoclave before the testing.
The control sample was 100% cotton, provided by SGS laboratory.

^This test was carried out by SGS Shanghai Laboratory

End of Report

SGS-CSTC Standards Technical Services Co.,Ltd. Hangzhou Branch
检验检测专用章 Inspection & Testing Services
HZSL 2654797
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SGS

Report No.: SCb2006243167TX

SOFTLINE LABORA

Sample Card

SGS-CSTC Standards Technical Services Co., Ltd.

Prepared By: _____

(41758) 498, Waryong-ro, Seo-gu, Daegu, Korea
Tel : 053-551-2150 Fax : 053-551-2148

TEST REPORT

APPLICANT : TORAY ADVANCED MATERIALS KOREA INC.

REPORT NO. : T270-20-00748
SAMPLE RECEIVED DATE : 2020-02-12
TEST STARTED DATE : 2020-02-12
REPORT ISSUED DATE : 2020-02-25
PAGE : 1 OF 4

DESCRIPTION : ONE(1) PIECE OF SUBMITTED CUTTING SAID TO BE FIBER.

==========

ITEM : FRESHEVER_FF

==========

TEST CONDUCTED : AS REQUESTED BY THE APPLICANT, FOR DETAILS PLEASE SEE ATTACHED PAGES.

==========

PREPARED AND CHECKED BY
FOR FITI

YOUNG MIN, JEON
QUALITY MANAGER

AUTHORIZED BY
FOR FITI

JE-GOO JUN
PRESIDENT

※ Report Verification No.: N5CQ-4JTJ-BVYB ※
(You can see the authenticity of your test report through the above "Report Verification No." at FITI homepage.)

(41758) 498, Waryong-ro, Seo-gu, Daegu, Korea
Tel : 053-551-2150 Fax : 053-551-2148

01. ANTIBACTERIAL ACTIVITY OF TEXTILES (KS K 0693 : 2016) : CFU/mL, BACTERIOSTATIC REDUCTION RATE %

		BLANK	#1
BACTERIA-1	AT BEGINNING	2.2×10^4	2.2×10^4
	AFTER 18 h	1.2×10^7	5.6×10^2
	BACTERIOSTATIC REDUCTION RATE	-	99.9
BACTERIA-2	AT BEGINNING	1.8×10^4	1.8×10^4
	AFTER 18 h	3.8×10^7	< 10
	BACTERIOSTATIC REDUCTION RATE	-	99.9

NOTE) STANDARD FABRIC : COTTON
NONIONIC SURFACTANT AGENTS : TWEEN 80, 0.05 %
TEST BACTERIA : BACTERIA-1 - *Staphylococcus aureus* ATCC 6538
BACTERIA-2 - *Klebsiella pneumoniae ATCC* 4352.
< = LESS THAN
SEE ATTACHED PHOTOS.

** End of The Report **

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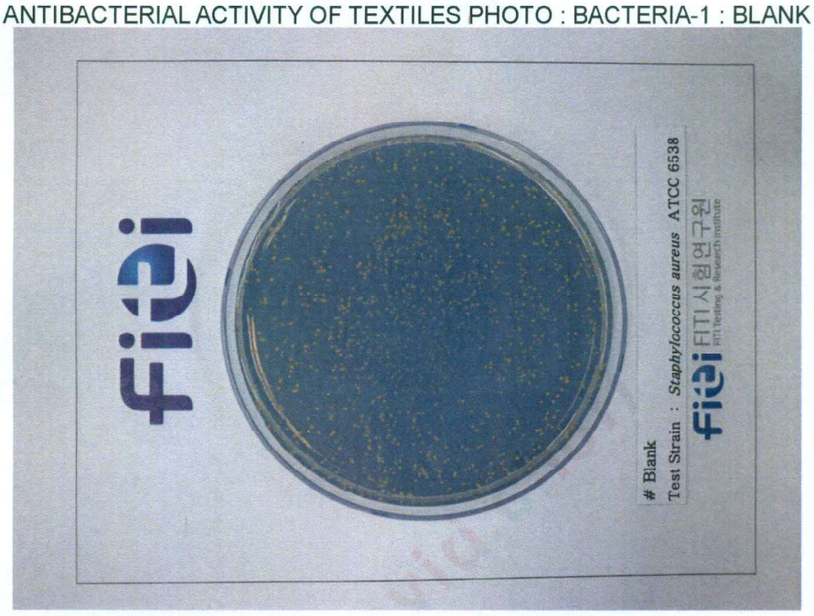
Tel : 053-551-2150 Fax : 053-551-2148

- ANTIBACTERIAL ACTIVITY OF TEXTILES PHOTO : BACTERIA-1 : BLANK -



- ANTIBACTERIAL ACTIVITY OF TEXTILES PHOTO : BACTERIA-1 : #1 -

(41758) 498, Waryong-ro, Seo-gu, Daegu, Korea
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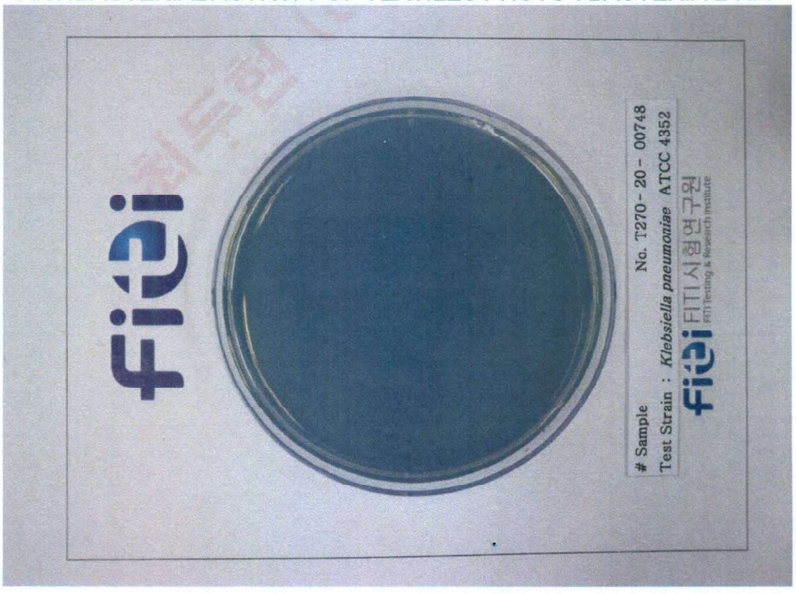
- ANTIBACTERIAL ACTIVITY OF TEXTILES PHOTO : BACTERIA-2 : BLANK -

- ANTIBACTERIAL ACTIVITY OF TEXTILES PHOTO : BACTERIA-2 : #1 -



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Tel : 053-551-2150 Fax : 053-551-2148

TEST REPORT

APPLICANT : TORAY ADVANCED MATERIALS KOREA INC.

REPORT NO.	: T270-20-00747
SAMPLE RECEIVED DATE	: 2020-02-12
TEST STARTED DATE	: 2020-02-12
REPORT ISSUED DATE	: 2020-02-25
PAGE	: 1 OF 4

DESCRIPTION : ONE(1) PIECE OF SUBMITTED CUTTING SAID TO BE FIBER.

==========

ITEM : FRESHEVER_C/J

==========

TEST CONDUCTED : AS REQUESTED BY THE APPLICANT, FOR DETAILS PLEASE SEE ATTACHED PAGES.

==========

PREPARED AND CHECKED BY
FOR FITI

YOUNG MIN, JEON
QUALITY MANAGER

AUTHORIZED BY
FOR FITI

JE-GOO JUN
PRESIDENT

※ Report Verification No.: 6R2D-JX21-1GNH ※
(You can see the authenticity of your test report through the above "Report Verification No." at FITI homepage.)

(41758) 498, Waryong-ro, Seo-gu, Daegu, Korea
Tel : 053-551-2150 Fax : 053-551-2148

01. ANTIBACTERIAL ACTIVITY OF TEXTILES (KS K 0693 : 2016) : CFU/mL, BACTERIOSTATIC REDUCTION RATE %

		BLANK	#1
BACTERIA-1	AT BEGINNING	2.2×10^4	2.2×10^4
	AFTER 18 h	9.8×10^6	4.1×10^4
	BACTERIOSTATIC REDUCTION RATE	-	99.6
BACTERIA-2	AT BEGINNING	1.8×10^4	1.8×10^4
	AFTER 18 h	3.8×10^7	6.4×10^3
	BACTERIOSTATIC REDUCTION RATE	-	99.9

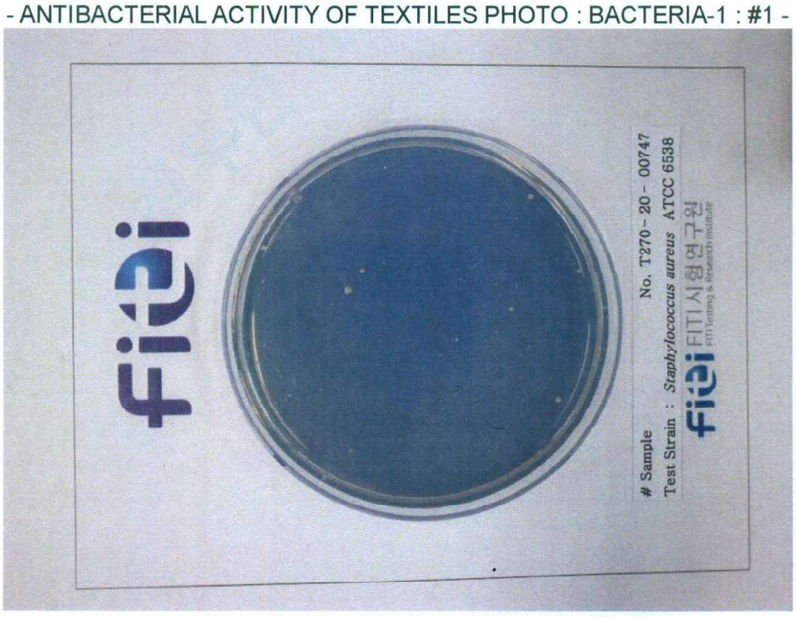
NOTE) STANDARD FABRIC : COTTON
NONIONIC SURFACTANT AGENTS : TWEEN 80, 0.05 %
TEST BACTERIA : BACTERIA-1 - *Staphylococcus aureus* ATCC 6538
BACTERIA-2 - *Klebsiella pneumoniae ATCC* 4352.
SEE ATTACHED PHOTOS.

** End of The Report **

(41758) 498, Waryong-ro, Seo-gu, Daegu, Korea
Tel : 053-551-2150 Fax : 053-551-2148

- ANTIBACTERIAL ACTIVITY OF TEXTILES PHOTO : BACTERIA-1 : BLANK -

- ANTIBACTERIAL ACTIVITY OF TEXTILES PHOTO : BACTERIA-1 : #1 -



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Tel : 053-551-2150 Fax : 053-551-2148

TEST REPORT

APPLICANT : TORAY ADVANCED MATERIALS KOREA INC.

REPORT NO. : T270-20-00748
SAMPLE RECEIVED DATE : 2020-02-12
TEST STARTED DATE : 2020-02-12
REPORT ISSUED DATE : 2020-02-25
PAGE : 1 OF 4

DESCRIPTION : ONE(1) PIECE OF SUBMITTED CUTTING SAID TO BE FIBER.

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ITEM : FRESHEVER_FF

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TEST CONDUCTED : AS REQUESTED BY THE APPLICANT, FOR DETAILS PLEASE SEE ATTACHED PAGES.

==========

PREPARED AND CHECKED BY
FOR FITI

YOUNG MIN, JEON
QUALITY MANAGER

AUTHORIZED BY
FOR FITI

JE-GOO JUN
PRESIDENT

※ Report Verification No.: N5CQ-4JTJ-BVYB ※
(You can see the authenticity of your test report through the above "Report Verification No." at FITI homepage.)

(41758) 498, Waryong-ro, Seo-gu, Daegu, Korea
Tel : 053-551-2150 Fax : 053-551-2148

01. ANTIBACTERIAL ACTIVITY OF TEXTILES (KS K 0693 : 2016) : CFU/mL, BACTERIOSTATIC REDUCTION RATE %

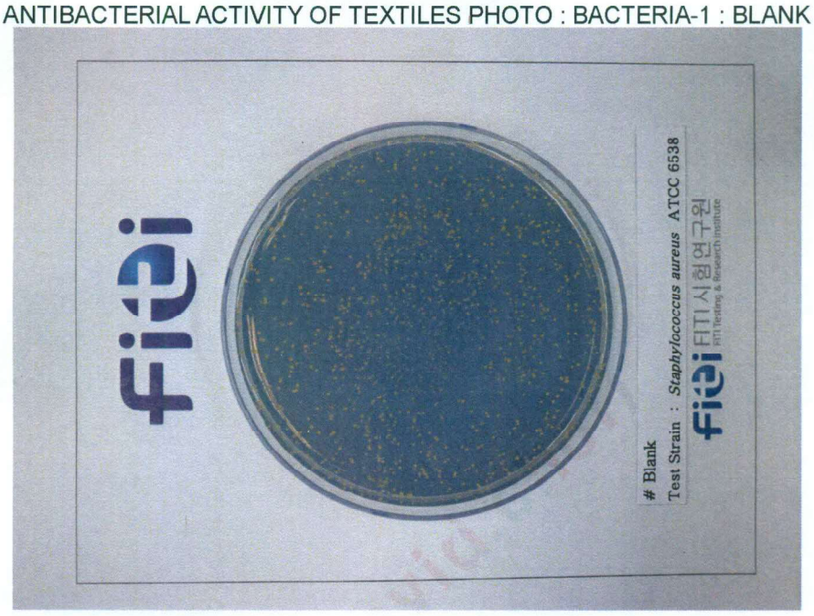
		BLANK	#1
BACTERIA-1	AT BEGINNING	2.2×10^4	2.2×10^4
	AFTER 18 h	1.2×10^7	5.6×10^2
	BACTERIOSTATIC REDUCTION RATE	-	99.9
BACTERIA-2	AT BEGINNING	1.8×10^4	1.8×10^4
	AFTER 18 h	3.8×10^7	< 10
	BACTERIOSTATIC REDUCTION RATE	-	99.9

NOTE) STANDARD FABRIC : COTTON
NONIONIC SURFACTANT AGENTS : TWEEN 80, 0.05 %
TEST BACTERIA : BACTERIA-1 - *Staphylococcus aureus* ATCC 6538
BACTERIA-2 - *Klebsiella pneumoniae ATCC* 4352.
< = LESS THAN
SEE ATTACHED PHOTOS.

** End of The Report **

(41758) 498, Waryong-ro, Seo-gu, Daegu, Korea
Tel : 053-551-2150 Fax : 053-551-2148

- ANTIBACTERIAL ACTIVITY OF TEXTILES PHOTO : BACTERIA-1 : BLANK -



- ANTIBACTERIAL ACTIVITY OF TEXTILES PHOTO : BACTERIA-1 : #1 -

Technical Information

Revision 5.0

August 2017

agpure®

Antimicrobial
Additive

1 Description

1.1. Introduction

agpure® is designed for the antimicrobial functionalization of surfaces and bulk materials. Due to the high activity of nanoparticles only low levels of silver are necessary for the best antimicrobial performance. Consequently, the release of silver ions can be fixed at an accurate level ensuring the best antimicrobial efficacy and thus also avoiding cytotoxicity.

Potential applications of agpure® products range from paints, varnishes and coatings over thermoplastic, duroplastic and elastomeric polymers to textile fibers. agpure® is also utilized as an antimicrobial additive for many chemical formulations like detergents, cleaners, cosmetics and especially certain resins based on organic substances.

Low levels of agpure® nanosilver provide long-term preservation against microbial attack. Treated material is protected against staining, embrittlement and the growth of microorganisms. Adverse odors and the spread of diseases, even nosocomial infections caused by MRSA or 3,4 MRGN are avoided.

This Technical Information is intended to give our customers technical background information on our agpure® materials and to help them select the right agpure® grade for their specific application. Additional information for use and application of agpure® can be requested at our laboratory. Material Safety Data Sheets and Technical Product Data Sheets can be downloaded from our website or obtained from our office.

Name	Ag-Conc.	Water content	Aggregate state	Density (kg/dm^3)	color	Area	Application e.g.
agpure® W10	10,0 ± 0,50 %	75 %	liquid	1,1	Orange	Aqueous solutions	Coatings, ceramics
agpure® W50	45,0 ± 1,50 %	< 5 %	liquid	2,7	Brown	Monomer resins (coating, bulk)	Medical devices, polymers, ceramics
agpure® W3	3,0 ± 0,1 %	< 0,5 %	liquid	1,1	Brown	Solvent based formulations and coatings	Sol/gel coatings, resins, varnish
agpure® I	3,0 ± 0,1 %	< 0,5 %	liquid	1,1	Gray	Solvent based colour sensitive applications	Resins, varnish
agpure® W20	4,0 ± 0,2 %	80 %	liquid	1,1	Brown	Aqueous dispersion, colour sensitive applications	Polymers, resins
agpure® W2	2,0 ± 0,1 %	< 1 %	solid	0,8	Gray	Powder additive, colour sensitive applications	Paints, resins
agpure® PBT6500	0,65 ± 0,05 %		solid	0,8 – 1,2	Brown	PET/PBT (All other polymer types on request)	Yarns, thermoplastic objects
SANPURE® K130	200 ppm		liquid		Yellow	Invisible coating on metal, glass, ceramic, polymers	Door handles, touch applications

Table 1: agpure® grades and properties

1.2. Chemical character

agpure® W10 is a nanosilver colloidal dispersion with a nominal silver content of 10 w/w%. agpure® W10 dispersion is dark orange; it is an aqueous dispersion of nanosilver with stabilizing agents, consisting of < 10 % emulsifying agent.

agpure® contains silver particles of about 15 nm size with a narrow size distribution of 99 % of the particle number concentration exhibiting a diameter of below 20 nm. A second, much smaller abundance of particles was identified by TEM to have narrow diameter distribution of around 5 nm. The silver content and particle number was shown to be stable up to 12 months.

agpure® W50 is based on W10. They differ in the absolute content of the ingredients (Table 1). As absolute concentrate of our technology it is the basis for applications with special demands and for the most of our special agpure® grades.

agpure® W3 is based on W50. The addition of special dispersants makes the formulation of solvent based products easier. Especially varnishes and sol/gel coatings are easier to formulate for our customers.

agpure® I is a liquid additive for color sensitive applications. It is designed for organic varnishes and duroplastic resins.

agpure® W20 contains silver nanoparticles adsorbed on larger silicon dioxide particles. This stable aggregate shows reduced colour effects compared to W10 or W50 additives.

agpure® W2 contains silver nanoparticles adsorbed on larger titanium dioxide particles. This powder shows drastically reduced colour effects compared to W10 or W50 additives.

agpure® PBT6500 is composed of the crude PBT polymer and agpure® W50.

SANPURE® K130 is a siloxane based sol containing agpure® silver nanoparticles for sol/gel coatings. It allows the invisible and costly equipment of hard surfaces with antimicrobial properties.

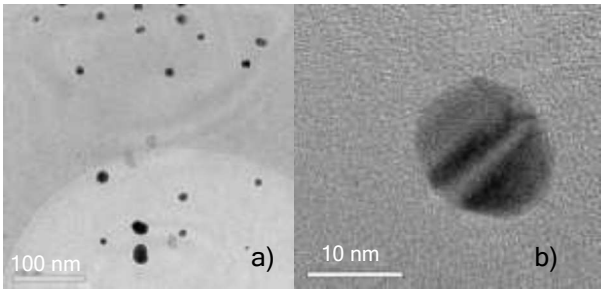


Figure 1: a) and b) Electron microscope images of agpure® silver nanoparticles.

2 Key advantages

- Anti-allergic, non toxic, non sensitizing
- Natural biocide
- Easy to use – application appropriate grades
- Homogenous particle distribution
- Liquid grades are free of any fillers – very small structures / layers are accessible
- Processable at high temperatures (> 300°C)
- Stable in UV-light
- Resistant to cleaning or washing
- Silver depot
- Long lasting / permanent antimicrobial effect
- Excellent leach-resistance
- High efficiacy – low additive concentration

3 Application areas

3.1. Varnishes & coatings

For the manufacture of antimicrobial varnishes, two possibilities can be chosen. agpure® can be mixed with the pigment paste and subsequently incorporated into the varnish, or simply combined with the readymade varnish. The stability of the obtained dispersion should be controlled. Coagulation or precipitations should not occur within days subsequent to the mixing process.

For aqueous based or highly polar varnishes our W10, W50 and W2 grades are recommended. Organic solvent based, nonpolar varnishes or sols for sol/gel coating should be formulated with W3, I or W2 grades.

It is strongly recommended that the dosage of agpure® is adapted to the required antimicrobial efficacy of the specific varnish formulation. Standard dosages may be obtained through our laboratory.

Slight discoloration may occur, whereas the transparency of the resulting varnish should not be affected. We recommend controlling of the curing process and storage conditions.

With SANPURE® K130 a readymade sol/gel coating for invisible antimicrobial functionalization is available. Curing is best at temperatures of about 130 °C.

3.2. Paints

State of the art organic biocides for fungicidal paints are sensitizing and cause allergic reactions. Even more their biocidal effect is due to their volatility and degradability non permanent.

Non sensitizing, permanent active fungicidal mineral fillers containing paints are best formulated with agpure® W2 grades.

3.3. Textiles & Fibers

agpure® products are widely used for textiles and fibers. It can be applied in various ways ranging from coating, finishing and fiber compounds. agpure® products can be distinguished by their excellent stability at high temperatures (<300°C). Consequently there are no restrictions in the choice of polymer material.

For fiber spinning processes, agpure® masterbatches are recommended. Our standard product is agpure® PBT6500 that is based on Polybutylene terephthalate. Furthermore available standard polymers that lend themselves for processing are: Polyolefins (PP, PE), Polyester (PET), Polyamide (PA) among others. The particle size distribution of nanosilver persists in the fibers resulting in the best efficiency and highest washability without loss of the antimicrobial effect.

Tests at the Hohenstein Institute during the "Feldstudie Antimikrobielle Textilien" - AiF Project-No.: 17832 N showed that

- the antimicrobial activity of agpure® blended PES fiber against K. pneumoniae and S. aureus according to DIN EN ISO 20743 is still significant after 100 washing cycles and
- the antimicrobial activity of agpure® blended PA spunbond fiber against K. pneumoniae and S. aureus according to DIN EN ISO 20743 is still significant after even 200 washing cycles.

agpure® is designed for use in dyes and as a component for finishing. Possible textile substrates include natural as well as synthetic fibers. agpure® grades can be formulated both with aqueous or solvent based dispersions. Microbiological evaluations to determine ideal nanosilver levels are recommended. In some cases color shifts are possible. Preliminary tests concerning UV stability and washability should be performed.

4 Product Use Recommendations

4.1. Miscibility

agpure® dispersions are miscible with water at any ratio. Precipitation or agglomeration will not occur with pure water. Such dispersions show excellent stability.

In case of addition of other solvents, salts or solids, agglomeration might occur. Preliminary tests are recommended to assess compatibilities with other components.

agpure® has a negative zeta potential.

Please ask for the suitable agpure grade.

4.2. Dispersing agpure®

Please carry out the following instructions to handle agpure® properly:

- Don't use saturated or highly concentrated saline solutions.
- Dispersions will not stable at pH-values below 4.
- Mix vigorously; the use of dispersing instruments (e.g. ULTRA-TURRAX®) is recommended if the dispersion is not satisfying.

A small amount of clumping and/or settling during shipping and storage might occur at our liquid agpure grades. Shaking by hand is usually enough to redisperse particles within the dispersion.

4.3. Use levels

Please find below a helpful table, how to dose agpure® into your product at typical concentrations correctly. Table 2 gives you the dosage in g/kg whereas Table 3 gives you the dosage in % w/w.

agpure grade Final silver conc.	W10	W50	W3 / I	W20	W2	PBT 6500
100 ppm	1,0	0,22	3,3	2,50	2,50	15,4
250 ppm	2,5	0,55	8,3	6,25	6,25	38,5
500 ppm	5,0	1,11	16,7	12,5	12,5	76,9
1.000 ppm	10,0	2,22	33,3	25,0	25,0	154

Table 2: Dosage of agpure®-product to achieve final nanosilver concentration in the product. **(in g/kg)**

agpure grade	W10	W50	W3 / I	W20	W2	PBT 6500
Final silver conc.						
100 ppm	0,10	0,02	0,33	0,25	0,25	1,54
250 ppm	0,25	0,06	0,83	0,63	0,63	3,85
500 ppm	0,50	0,11	1,67	1,25	1,25	7,69
1.000 ppm	1,00	0,22	3,33	2,50	2,50	15,4

Table 3: Amount of agpure®-product, that has to be dosed, to achieve final nanosilver concentration in the product. **(in % w/w)**

5 Antimicrobial Efficacy

5.1. Mode of action

agpure® provides antimicrobial activity to all properly equipped products. agpure® exhibits strong activity against all gram-positive and gram-negative Bacteria, even antibiotic-resistant strains, yeast and fungi. (Viruses can be inactivated by unbound nanosilver particles.)

Due to the different modes of action (reduction of germ adherence, disturbance of the germs' K^+-metabolism and irreversible reaction with S-containing amino acids) and due to the marginal Ag^+-release, agpure® containing products do not induce or propagate bacterial resistance.

Products properly equipped with antimicrobial agpure® are non-toxic to humans and animals and safe to the environment. Due to the slow release of silver-ions (oxidation of metallic silver followed by elution of Ag^+-ions) the antimicrobial effect of products supplemented with agpure® is very persistent.

The high surface/volume-ratio of agpure® silver nanoparticles provides the high efficiacy of agpure® treatments/finishing. Low levels of silver are enough for lifetime protection against microbial attack.

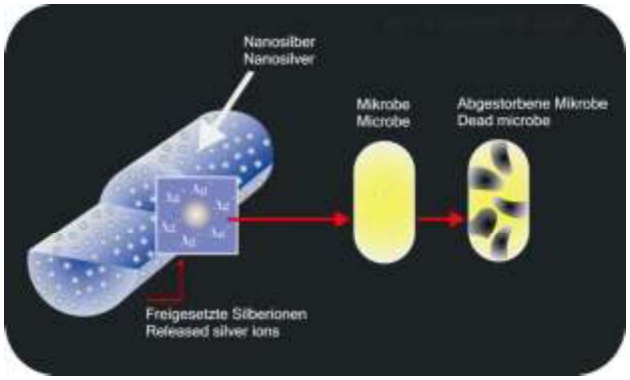


Figure 2: Mode of antimicrobial action

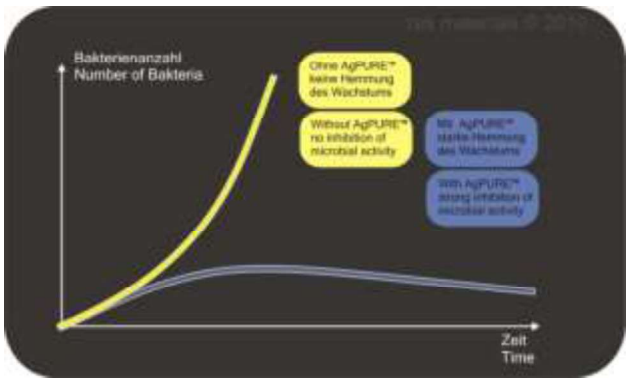


Figure 3: Inhibition of microbial growth

5.2. Efficacy testing

agpure® is a long-term shield against microbial growth. It is not a sterilizing agent and does not have long range effects. Test procedures for the verification of the antimicrobial effect based on strong release / long range action of a biocide (e.g. zone of inhibition test) will not respond to agpure® products.

Therefore several research institutes agreed to use verified international test methods to determine antimicrobial action of agpure® nanosilver products:

Rigid surfaces: JIS Z 2801:2000 or ISO 22196:2007

Textiles: JIS L 1902:2002 or DIN EN ISO 20743:2007

A grading scheme (Table 4) was introduced to judge the antimicrobial activity of products tested according to the test methods mentioned above.

Antimic. Act. / Test results	Slight	Significant	Strong
Reduction (R-) Value (log-steps)	≥ 0,5 to < 1	≥ 1 to < 3	≥ 3
%-Reduction of viable cells	≥ 67 % to < 90 %	≥ 90 % to < 99,9 %	≥ 99,9 %

Table 4: Grading scheme. Because of the instability of bacterial growth, the biological variance (lab standard ± 0.5 log steps) has to be considered in this grading scheme, especially at slight efficacy).

A lot of test results with agpure® treated products were obtained in the last years in our laboratories or by external independent Institutes (Table 5):

Application	R-Value	Strain
PET-Microfiber Cloth	3	*S. aureus*
	3	*K. pneumonia*
	> 4	*E. coli*
	2	*C. albicans*
PP staple fiber	2	*E. coli*
Soft PVC	3	*E. coli*
PA tubes	> 3	*P. aeruginosa*
Silicone	> 3	*S. aureus*
Laquer	3	*E. coli*
Silvercoating for Med.	> 4	*S. epidermidis*
Disposable coverall	> 5	*L. pneumophila*

Table 5: Typical microbiological test results, test methods: Rigid surfaces: JIS Z 2801:2000 or ISO 22196:2007; for Textiles: JIS L 1902:2002 or DIN EN ISO 20743:2007

The SN 195921 is a test method to test the antifungal activity.

Figure 4: SN 195921 test: Left: Blank PVC-sample after 2 weeks Right: Fungicidal activity of PVC-sample after 2 weeks with agpure®

The antimicrobial activity can be certified:

Figure 5: Certificates on the antimicrobial efficacy of products treated with agpure® nanosilver

The detection and certification of the antimicrobial activity of products containing agpure® must be executed with approved microbiological test routines.
In order to support our clients in the design of antimicrobial products, we provide our chemical and biological know-how. We recommend to carefully test all factors that may influence the release of bioactive silver.

RAS AG is providing extensive testing facilities to assist the costumer in developing an antimicrobial product, containing the optimal dosage of agpure® nanosilver.

5.3. Recommended dosage

Depending on the dosage of agpure® nanosilver (100 – 2000 ppm nanosilver) in the product, one can achieve a bacterial reduction of 90% up to 99,999% (Reduction value: 1 – 5 log steps)

Antimic. Act. / Application	Slight	Significant	Strong
Textile via coat	50	100	250
Textile via MB	100	200	400
Coatings	250	500	1000
Med. Device	400	800	1500

Table 6: Final nanosilver concentration to achieve activity in certain applications. Typical values of antimicrobial activity according to JIS Z 2801:2000, ISO 22196:2007, JIS L 1902:2002 or DIN EN ISO 20743:2007-10

6 Handling Precautions

When handling agpure® products, due attention should be paid to the information and details in the material safety data sheets and the technical information in the technical product data sheets. Furthermore, all precautions necessary for handling chemicals must receive careful attention.

Avoid contact with skin, eyes and clothing. When using do not eat, drink or smoke.

Please use chemical resistant disposable gloves and eye protection.

Wash off affected skin with plenty of water. Remove contaminated clothing and wash off affected cloth with plenty of water.

7 Risk assessment

7.1. Nanotechnology risks and benefits - R&D projects

agpure® was selected as the official nanosilver reference- and testing materials (NM-300 K silver) for the "OECD - sponsorship program"

There were many international and national research projects on the safety of nanomaterials which are using agpure® nanosilver.

- UMSICHT
  - Ecological fate of nanosilver
- SILBERNANOPARTIKEL
  - Risk potential of nanosilver in medical devices
- OECD-WPMN Silver
  - Chemical Database (Tox, etc.)
  - Data set for FDA, EPA, EFSA…
  - NANEX, ENPRA, …
- LICARA nano

Overall result of these independent research projects is that there is no harm for humans, animals or the environment resulting from agpure® in carefully equipped products.

For details on nanosilver research ask our experts. They will provide detailed information and scientific literature to interested customers, research institutes and the public.

7.2. Exposure

Exposure of silver nano particles during the production process was not detectable. (REACH-NanoHazEx: Rip-oN 3)

No abrasion of nano particles is detectable from polymer materials. (Vorbau et al. 2010)

7.3. Safe to human tissue

agpure® containing microfiber cloth: No irritations on the skin of the test persons even those having atopic eczema (Test report Dermatronnier, DT-NR: 16/01/06)

agpure® nanosilver causes no sensitization to the laboratory animals (according to Local Lymph Node Assay – LLNA, Test report BSL Bioservice, Project No.: 070516)

8 Storage and Disposal

8.1. Recommended Storage

agpure® W grades can be stored in original containers for 12 months at a temperature range of 10-30°C. Contents of unsealed containers should be used as soon as practicable. Subsequent to any removal of material, the containers should be closed tightly. Keep product protected against frost.

If it is not possible to store the product in the original containers, please take notice of the following advice:

- Use opaque containers
- HDPE recommended
- Other polymers are not proven for long term storage.
- Glassware has limited qualification only suitable for high concentrates.

Once opened, we recommend, that agpure® W50 is completely emptied, to assure product quality.

agpure® PBT6500 can be stored in original package for 6 month at a temperature range of 10-30 °C. Open packages should be used up soon.

It has to be ensured that no external particles are brought into the master batch through opening or taking out master batch of the bag. External particles can reduce considerably the usability of master batch even up to production out time or production loss especially on the field of microfibers.

The water content of the master batch has to be determined by the user. If necessary the master batch has to be dried before use. With which degree of moisture the master batch will still be usable is incumbent upon the user.

SANPURE® K130 sol for sol/gel coatings are highly sensitive for improper storage conditions and processing conditions. Please take care that

SANPURE K130 is stored below 23 °C and processed at a relative humidity below 50 %.

8.2. Disposal

Avoid contamination of water, food or feed by storage or disposal.

Plastic drums which cannot be reconditioned and recycled should be punctured or crushed, and disposed at landfill or by other procedures approved by state or local authorities.

9 Available Packaging

agpure® W10, W3:

1 kg in HDPE Bottles, Narrow Mouth, UN Approved (3H1/X1.9/250) with Thread. Screw closure PP, black, with tamper evident ring and teflon cup seal.

5 kg in HDPE jerry cans, UN Approved (3H1/X/250). with Thread. Screw closure PE, black, with tamper evident ring and cup seal.

agpure® W50:

0,50kg and 1,00 kg in HDPE Bottles, Narrow Mouth, UN Approved (3H1/X1.9/250) with Thread. Screw closure PP, black, with tamper evident ring and teflon cup seal.

Once opened, we recommend, that agpure® W50 is completely emptied, to assure product quality.

agpure® W20, W2:

1l, 6l or 20l HDPE cans with screw cap and elastomeric sealing, UN Approved (1H2/X20/S).

agpure® PBT6500:

25 kg in fibre-reinforced PE-bag.

10 Regulatory

agpure® is a proven auxiliary for biological active finish of textiles according to Oeko-Tex® Standard 100: (https://www.oeko-tex.com/de/manufacturers/certified_products/active_chemical_products/products_with_biological_activity/products_with_biological_activity.html)

Certification in accordance with DIN EN ISO 13485:2010, regulation under progress.

agpure® is notified according to Regulation (EU) No. 528/2012 (Biocides) under N-73054:

- Disinfectants for private usage and the public sector as well as other biocide products (PT 2)
- Disinfectants for the food and animal feed sector (PT 4)
- Fibre, leather, rubber and polymerised materials preservatives (PT 9)

11 Note

RAS AG provides the information contained herein in good faith and makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgement in determining its appropriateness for a particular purpose. RAS AG makes no representations or warranties either express or implied, by fact or law, regarding the suitability of the material for any purpose, the merchantability of the product for a special application or the accuracy of the information contained within this document. Accordingly, RAS AG will not be responsible for damages resulting from use of or reliance upon this information. Nothing contained herein shall be construed to imply the nonexistence of any relevant patents or to constitute the permission, inducement or recommendation to practice any invention covered by any patent, without the authority from the owner of the patent.

Scientific literature cited in this data sheet can be provided on request.

12 Contact data

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HRB 15542

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