

Work Order	4607.1
Setup-Code	221121-1298-2180-01



Test Report

ASTM E-2180

Standard Method for Determining the Activity of Incorporated Antimicrobial Agent(s) in Polymeric or Hydrophobic Material

Test Object:

Bacoban DL after dry abrasion versus Staphylococcus aureus DSM799 ATCC6538

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Report on Findings

Client: ROPILEX R. OPEL GmbH
Address: Bildstocker Straße 12-14
66538 Neunkirchen

Work order no.: 4607.1

Test object: Bacoban DL after dry abrasion versus *Staphylococcus aureus* DSM799 ATCC6538

Sample description: Bacoban DL coated leneta foil

Date of receipt of sample: 18 November 2022

Type of test: ASTM E-2180-18: Standard Method for Determining the Activity of Incorporated Antimicrobial Agent(s) in Polymeric or Hydrophobic Material

Test Germ: *Staphylococcus aureus* DSM799 ATCC6538

Test laboratory: QualityLabs BT GmbH

Address: Neumeyerstrasse 22
90411 Nuremberg, Germany

Setup-Code: 221121-1298-2180-01

Sample material: leneta foil

No. of pages in report: 6

Report on findings to the client: **Place and date of preparation:** Nuremberg, 25 November 2022
Recipient: ROPILEX R. OPEL GmbH

Approved:

Johanna Dittmann, Laboratory Manager
QualityLabs BT GmbH

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Declaration on Quality Assurance

This investigation was performed and supervised according to the standard operating procedure “SOP for ASTM E-2180-18” by QualityLabs BT GmbH. The laboratory and process are continually monitored by independent, external authorities, as well as by internal audits.

Archiving

A copy of the test report, a protocol of the measurement as well as the accompanying correspondence and business records are archived by QualityLabs BT GmbH.

The retention period is at least 10 years.

Test description

Anti-bacterial activity is determined in accordance with ASTM E-2180-18.

During the test, a thin film of agar-slurry containing the bacteria (2.5×10^6 / Inoculum) is applied directly to the test sample (3 cm x 3 cm). Immediately after inoculation, the bacteria from the reference sample are separated from the sample surfaces using ultrasound and vortex devices and the number of viable germs (CFU – colony-forming units) is determined (t_0 value). A further set of reference samples and samples given anti-microbial treatment is incubated with bacteria in a film of agar-slurry in a damp environment at 37°C. After a minimum of 24 hours, the bacteria are separated from the sample surfaces using ultrasound and vortex devices and the number of viable germs is determined (t_{24} value).

Assessment of antimicrobial activity

A germ reduction of $\geq 99.9\%$ of the antimicrobial sample in comparison to the respective reference is used as assessment criterion to pass the antimicrobial test.

Germ reduction [%]	Antibacterial activity
< 99.9%	No sufficient antimicrobial activity
$\geq 99.9\%$	Sufficient antimicrobial activity

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References to deviations, pre-incubations, special testing conditions

Abrasion of the samples was performed using BYK Gardner scrub mounted with an ISO-Holder (approx. 135 g) and a dry cotton cloth for 1.000 cycles and 2.000 cycles respectively at 25 cycles/minute.

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Test Results

No.	Sample Name	Sample Code	t ₀ (cell count / inoculum)			CV [%]	t ₂₄ (cell count / inoculum)			CV [%]	Reduction [%]
1	Leneta (reference)	12982111220007	1.1 x 10 ⁶	1.6 x 10 ⁶	1.2 x 10 ⁶	17.8	4.5 x 10 ⁶	4.7 x 10 ⁶	4.9 x 10 ⁶	3.6	Reference
2	Leneta coated with Bacoban DL	12982111220008					< 1.0 x 10 ¹	< 1.0 x 10 ¹	< 1.0 x 10 ¹	0.0	> 99.9
3	Leneta coated with Bacoban DL after 1000 cycles dry abrasion	12982111220009					< 1.0 x 10 ¹	< 1.0 x 10 ¹	< 1.0 x 10 ¹	0.0	> 99.9
4	Leneta coated with Bacoban DL after 2000 cycles dry abrasion	12982111220010					< 1.0 x 10 ¹	< 1.0 x 10 ¹	< 1.0 x 10 ¹	0.0	> 99.9

see "Interpretation of Results", page 6

Test strain	<i>Staphylococcus aureus</i> DSM799 ATCC6538
Initial cell count / inoculum	2.5 x 10⁶ / 400 µl
Initials of the editor	KH
Measurement ended on	25 November 2022

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Comments on test objects

NONE

Interpretation of the results based on the measurements

All the samples showed sufficient antibacterial activity against the test strain *Staphylococcus aureus* DSM799 ATCC6538 in comparison to the reference sample.

Editor: K. Hähre _____

Crosschecked: C. Görgey _____

References

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