Biofilm Resistant
Water-Base for PU & Silicone

Water-Based Hydrophilic Coating

Highly Lubricious, Non-Eluting, surface coating for the reduction of biofilm adhesion.

US FDA
MAF-1785

CE Approval has been secured by clients.
Coating process for polyurethane
- Wipe (sealed edge, knitted polyester wipe) catheter with heptane followed by IPA
- Air dry at R.T.
- Dip into top coat formula Aqua 65JL or Aqua 87JL (R.T. humidity 40 - 50%)
  - 30 sec. for clear PU
  - 1 min. for white PU (NEUTHANE 80AE with 20% BaSO₄)
- Air dry at Room Temperature for 15 min
- Cure at 60°C for 4 hours

Test for Lubricity of Water-Based Top Coat on polyurethane
- Coated tubes were tested for lubricity after soaking in PBS at 37°C for 72 hours.
- Place tubes in the test bed filled with water and a 350 gram weight was placed on the tubing
- Move the weight back and forth for 25 cycles and the force required to slide the weight was recorded and is proportional to the lubricity or Coefficient of Friction (COF).

<table>
<thead>
<tr>
<th></th>
<th>Aqua 65JL</th>
<th>Aqua 87JL</th>
<th>2276-169</th>
<th>3-TS-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg. of 1,2,3 cycles</td>
<td>95%</td>
<td>98%</td>
<td>33.00%</td>
<td>73%</td>
</tr>
<tr>
<td>25th cycles</td>
<td>87%</td>
<td>74%</td>
<td>N/D</td>
<td>49%</td>
</tr>
</tbody>
</table>

N/D: not determined
Test for Lubricity of Water-Based Top Coat on polyurethane

Polyurethane (Dow 2363-80AE)
no primer
after soaked in PBS @ 37°C for 72 Hours

Results of friction reduction:

<table>
<thead>
<tr>
<th></th>
<th>Aqua 65JL</th>
<th>Aqua 87JL</th>
<th>2276-169</th>
<th>3-TS-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg. of 1,2,3 cycles</td>
<td>97%</td>
<td>96%</td>
<td>33.00%</td>
<td>74%</td>
</tr>
<tr>
<td>25th cycles</td>
<td>85%</td>
<td>81%</td>
<td>NA</td>
<td>39%</td>
</tr>
</tbody>
</table>

Polyurethane (ICO RALLY, ProFLO, medical grade)
no primer
after soaked in PBS @ 37°C for 72 Hours

Results of friction reduction:

<table>
<thead>
<tr>
<th></th>
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<th>2276-169</th>
<th>3-TS-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg. of 1,2,3 cycles</td>
<td>98%</td>
<td>99%</td>
<td>33.00%</td>
<td>60%</td>
</tr>
<tr>
<td>25th cycles</td>
<td>84%</td>
<td>76%</td>
<td>NA</td>
<td>3%</td>
</tr>
</tbody>
</table>
Test for cytotoxicity of **Water-Based Top coat on Polyurethane with 20% BaSO$_4$**

(NEUTHANE 80AE RO20 with 20% BaSO$_4$)

Uncoated & coated Polyurethane tubes (no pre-wash) were extracted for 24 hours in cell culture medium (MEM) containing 5% FBS.

The extracts are then placed in duplicate 35mm wells with L929 cells at ~10% confluence.

The monolayers were incubated at 37$^\circ$C in the presence of 5% CO$_2$. Cells were examined by light microscopy at 72 hours for signs of toxicity.

<table>
<thead>
<tr>
<th>Grade</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>cytotoxic</td>
<td>none</td>
<td>slight</td>
<td>mild</td>
<td>moderate</td>
<td>severe</td>
</tr>
</tbody>
</table>

**Conclusion:** all three water-based top coats on pellethane are non-cytotoxic
Coating process for silicone:
- Wipe (sealed edge, knitted polyester wipe) catheter with heptane, air dry at R.T.
- Dip into primer solution Hydromer JL-35 (Heptane Base) for 2min
- Air dry for 15 - 30min
- Dip into formula Aqua 65JL or Aqua 87JL for 1min (R.T. humidity 40 - 50%)
- Air dry at R.T. for 15 min
- Cure at 60°C for 2 hours

Test for Lubricity of Water-Based Top Coat on silicone
- Coated tubes were tested for lubricity after soaking in PBS at 37°C for 72 hours.
  - Place tubes in the test bed filled with water and a 350 gram weight was placed on the tubing.
  - Move the weight back and forth for 25 cycles and the force required to slide the weight was recorded and is proportional to the lubricity or Coefficient of Friction (COF).

Results of friction reduction:

<table>
<thead>
<tr>
<th></th>
<th>Aqua 65JL</th>
<th>Aqua 87JL</th>
<th>2276-169</th>
<th>3-TS-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg. of 1,2,3 cycles</td>
<td>95%</td>
<td>99%</td>
<td>58%</td>
<td>82%</td>
</tr>
<tr>
<td>25th cycles</td>
<td>96%</td>
<td>89%</td>
<td>N/D</td>
<td>68%</td>
</tr>
</tbody>
</table>
Cytotoxicity Test of Water-Based Top coat on Silicone

Uncoated & coated silicone tubes (no pre-wash) were extracted for 24 hours in cell culture medium (MEM) containing 5% FBS. The extracts are then placed in duplicate 35mm wells with L929 cells at ~10% confluence. The monolayers were incubated at 37°C in the presence of 5% CO₂. Cells were examined by light microscopy at 72 hours for signs of toxicity.

Silicone: Dow Corning (medical grade; Lot# 0005372633)
Primer: JL-35

Grade: 0

Aqua 65JL, 200x

Aqua 87JL, 200x

uncoated, 200x

<table>
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<tr>
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<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>cytotoxic</td>
<td>none</td>
<td>slight</td>
<td>mild</td>
<td>moderate</td>
<td>severe</td>
</tr>
</tbody>
</table>

Conclusion: Both water-based top coats on silicone are non-cytotoxic
METHOD:

• Place tubing (5-6 cm length, coated and uncoated control) into a disposable culture tube (16 x 100 mm)

• Incubate in LB broth containing ~1 X 10^5 CFU/ml for 24 hours with moderate shaking @ 37°C (bacteria) or 72 hours @ 25°C for fungal strains

• Remove tubing and rinse with PBS

• Cut off both ends and place 3 cm section of tubing into 5 ml of LB broth (for bacteria) or Malt Extract Broth (MEB) (for yeast)

• Sonicate for 7 minutes followed by vortexing for 1 minute

For bacterial

• Mix 5-8 µl of this broth and 1.5 ml of LB then plate 1 ml of this mixture onto 3M petrifilm

• Count colonies after incubation at 32°C for 24-48 hours.

For yeast

• Mix 10 µl of this broth and 70 µl MEB, then spread onto MEB agar plate

• Count colonies after incubation at 25°C for 48-72 hours.

Test Method for Biofilm Resistivity

All tested tubings were washed and soaked in PBS at 37°C for 24 hours before antimicrobial activity test.
Test For Biofilm Resistivity Against E. coli (Gram negative)

Silicone: Dow Corning, medical grade (primer: JL-35)

Results of inhibition:
- Aqua 65JL: >95% inhibition
- Aqua 87JL: no inhibition
- 2276-169: no inhibition
- 3-TS-12: no inhibition

Polyurethane with 20% BaSO₄ (E.coli)

Results of inhibition:
- Aqua 65JL: 94% inhibition
- Aqua 87JL: 74% inhibition
- 2276-169: no inhibition
- 3-TS-12: no inhibition
Test For Biofilm Resistivity Activity Against S. aureus (Gram positive)

Silicone: Dow Corning, medical grade (primer: JL-35)

Results of inhibition:

Polyurethane with 20% BaSO₄ (S. aureus)

Results of inhibition:
Test For Biofilm Resistivity Against C. albicans (Yeast)

Silicone: Dow Corning, medical grade (primer: JL-35)

Results of inhibition:

- Aqua 65JL: >95% inhibition
- Aqua 87JL: 55% inhibition
- 3-TS-12: no inhibition

Polyurethane with 20% BaSO₄ (C. albicans)

Results of inhibition:

- Aqua 65JL: 87% inhibition
- Aqua 87JL: >95% inhibition
- 2276-169: 80% inhibition
- 3-TS-12: 58% inhibition
Please note that this report contains results from Hydromer’s in-house testing departments. It is the responsibility of our clients to seek FDA Approval for this coating system on their devices.

Hydromer is very interested in entering into cost sharing programs to assist in compiling additional product performance data.

Please contact us
For sample coatings and additional information

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Other HYDROMER® Products & Services:

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  - Biofilm Resistant
  - Anti-thrombogenic
  - Anti-cell adhesion/proliferation
  - Radio-opaque
- Contract manufacturing/coating
- Aquadapt® Medical Hydrogels
- Cosmetic Intermediaries
- Anti-fog / Anti-frost condensation control Coatings
- T-HEXX® Animal Health
- Sea-Slide® Marine Coating
- Coating formulation
- Process development
- Device design feedback
- Machine design & build
- Prototype production - GMP/ISO
- Contract manufacturing/coating
- Technology / process transfer

Analysis
Testing
Polymer Synthesis
Microbiology
Cell Biology
Blood Chemistry
Bio-Polymer Production
Web Coating/Film Coating
Tube Coating: External and Internal

A few of Hydromer’s brands:

Aquadapt® Medical Hydrogels
Sea-Slide® Marine Coating
T-HEXX® Animal Health

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