1-Step Coating
for SILICONE,
HDPE, PU, PVC

Hydromer®

One-Step Coating Solvent-Based For *Difficult Materials*

Formula 2314-172

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

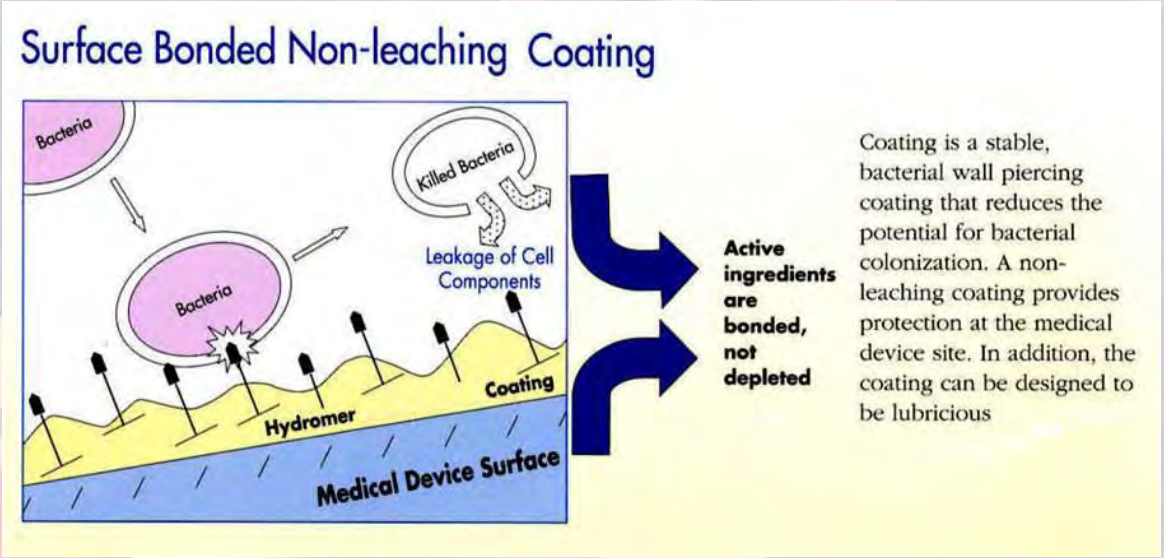
US FDA MAF-1786

New 2011

11/01/2013

How it works: “A one-two punch”

- Based on proprietary and patent pending polyvinyl-pyrrolidone-polyurethane interpolymers with non-leaching Tertiary Amine functional groups.
- Highly effective by employing two different strategies: minimizing the ability of bacteria to adhere to the coated surface and destroying the few colony forming units that do adhere.
- Upon exposure to body fluids Hydromer 2314-172 Kills surface contacting bacteria rapidly via the electrostatic interaction between the coatings cationic electrostatic force and the anionic bacterial outer membrane. This results in damaging the bacterium's outer membrane leading to its permeability and demise.
- Since this is not a drug the Hydromer 2314-172 reduces the likelihood of Bacterial mutation, adaptation or resistance.



Test for Lubricity on silicone , Dow Corning, RX-50 Medical Grade

2314-172 Before PBS

Hydromer Inc.
35 Industrial Parkway
Somerville, NJ. 08876 USA
&
Biosearch Medical Products, Inc.
(a subsidiary of Hydromer, Inc.)
Tel: 908-722-5000

COF Values

UNCOATED
0.826

HYDROMER Coated
HYDROMER (AVG. 1st,2nd,3rd cycles)
0.051

HYDROMER Coated
HYDROMER (25th cycle)
0.054

Friction Reduction Factor:
Uncoated / Avg. of 1,2,3 cycles

16.287

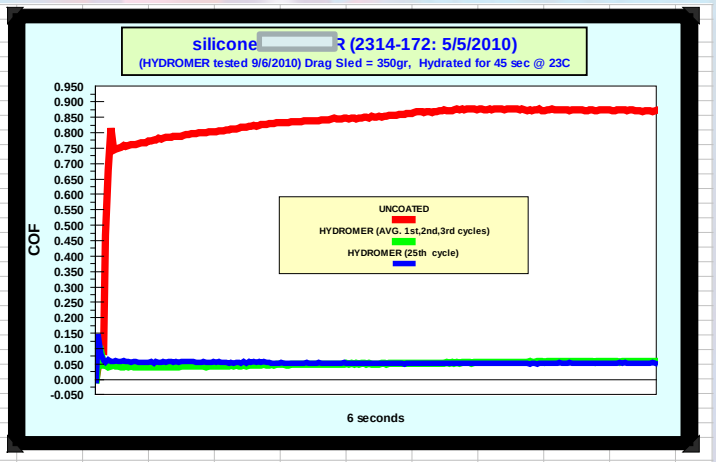
Primer: no
Top coating: 2316-66

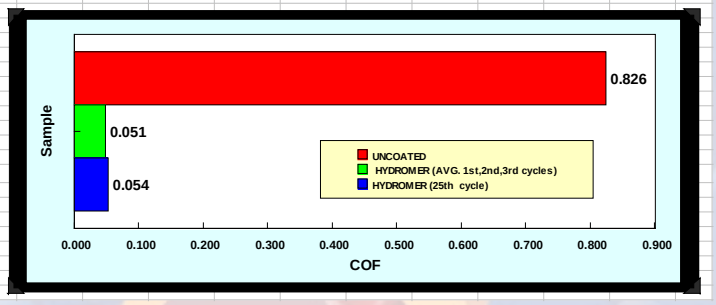
Friction test: ASTM D1894

COF= (Pull Force/ Sled Wgt)

Sled Wgt.= 350 gm = 0.77 lb

Test method is per Biosearch:
STM-92023, Rev. F





Tested for lubricity after soaking in PBS at 37°C for 72 hours.

2314-172 After PBS

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COF Values

UNCOATED
0.826

HYDROMER Coated
HYDROMER (AVG. 1st,2nd,3rd cycles)
0.025

HYDROMER Coated
HYDROMER (25th cycle)
0.042

Friction Reduction Factor:
Uncoated / Avg. of 1,2,3 cycles

33.497

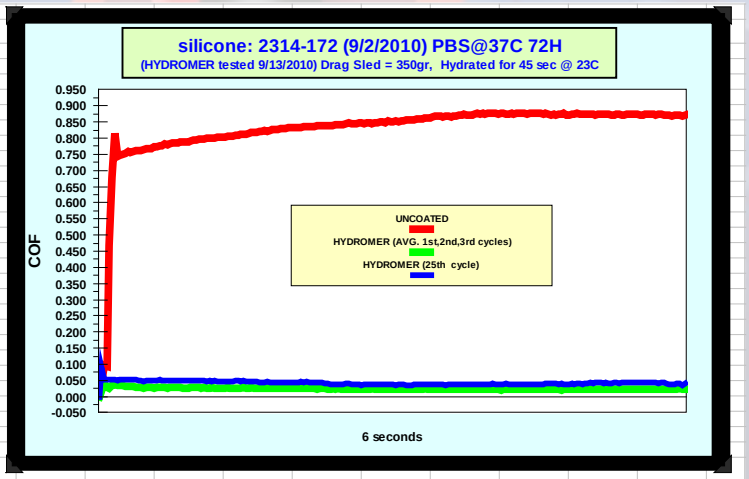
Primer: no
Top coating: 2316-63

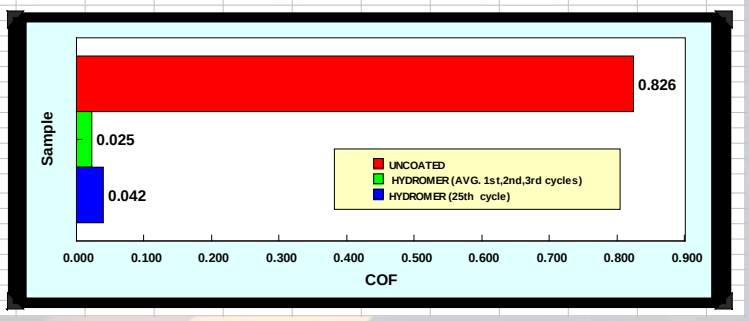
Friction test: ASTM D1894

COF= (Pull Force/ Sled Wgt)

Sled Wgt.= 350 gm = 0.77 lb

Test method is per Biosearch:
STM-92023, Rev. F





A break-through in the coating of High Density Polyethylene HDPE!

- ❖ No chemical pre-treatment
- ❖ No Corona or Plasma pre-treatment
- ❖ One-step coating process!
- ❖ oven cure@ 160F for 2 hours

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COF Values

UNCOATED
0.415

HYDROMER Coated
HYDROMER (AVG. 1st,2nd,3rd cycles)
0.052

HYDROMER Coated
HYDROMER (25th cycle)
0.064

Friction Reduction Factor:
Uncoated / Avg. of 1,2,3 cycles

8.037

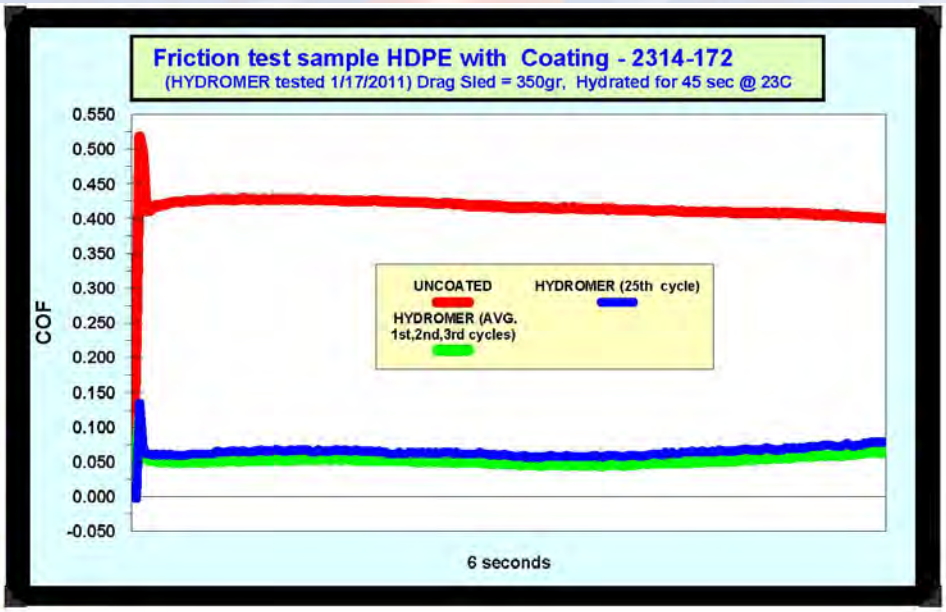
Primer: N/A
Top coating: 2314-172
Cure: 160F @ 2 hours

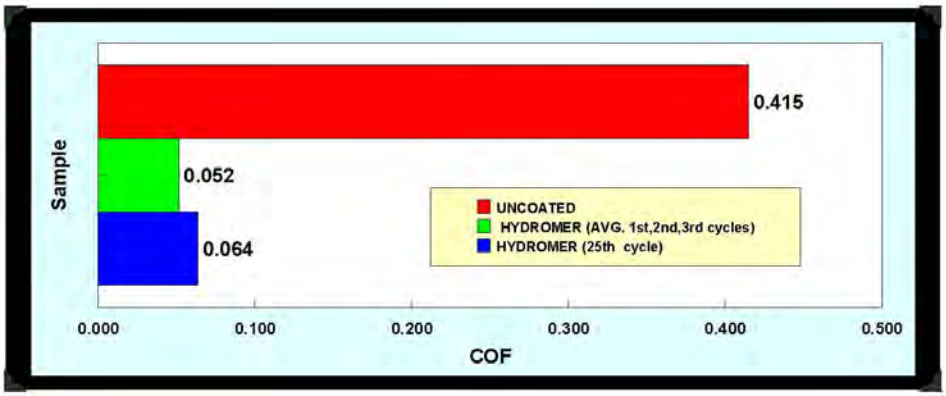
Friction test: ASTM D1894

COF= (Pull Force/ Sled Wgt)

Sled Wgt.= 350 gm = 0.77 lb

Test method is per Biosearch:
STM-92023, Rev. F





Test for cytotoxicity of Hydromer 2314-172 as applied to Dow Corning, RX-50 Medical Grade SIlicone

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^{o}C in the presence of 5% CO_2. Cells were examined by light microscopy at 72 hours for signs of toxicity.

uncoated, 200x

Grade: 0

2314-172, 200x

Grade: 0

Grade	0	1	2	3	4
cytotoxic	none	slight	mild	moderate	severe

Conclusion: Hydromer 2314-172 is non-cytotoxic

Test Method for Biofilm Activity

All tested tubings were washed and soaked in PBS at 37°C for 24 hours before Biofilm activity test.

METHOD:

- **Place tubing (5-6cm length, coated and uncoated control) into a disposable culture tube (16 x 100mm)**
- **Incubate in LB broth containing ~1 X 10^5 CFU/ml for 24 hours with moderate shaking @ 37^0C (bacteria) or 72 hours @ 25^0C 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**

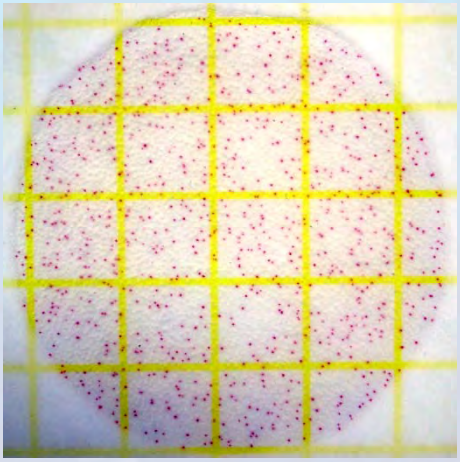
For bacterial

- **Mix 5-8µl of this broth and 1.5ml of LB then plate 1ml of this mixture onto 3M petrifilm**
- **Count colonies after incubation at 32^0C for 24-48 hours.**

For yeast

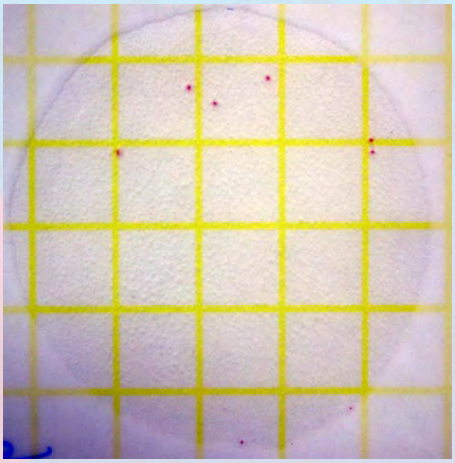
- **Mix 10ul of this broth and 70µl MEB, then spread onto MEB agar plate**
- **Count colonies after incubation at 25^0C for 48-72 hours.**

Test For Biofilm Resistivity Against E. coli (Gram negative)

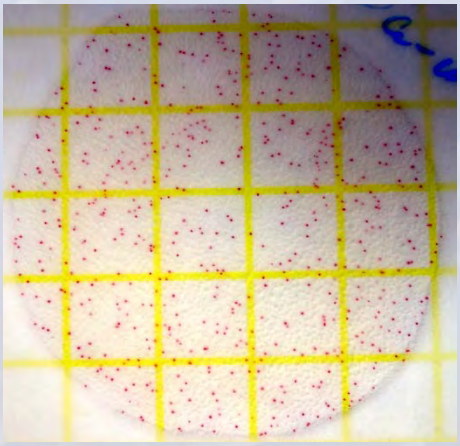


uncoated: 830 colonies

2314-172: 7 colonies:
< 95% inhibition

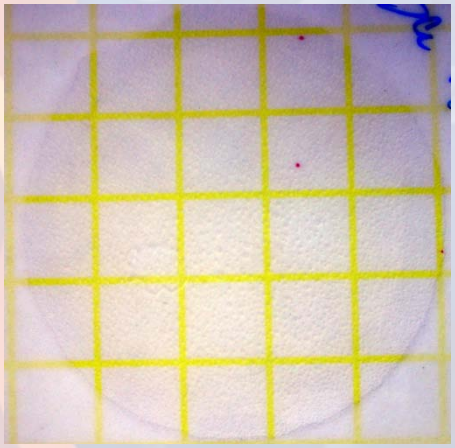


Test For Biofilm Resistivity Against S. aureus (Gram positive)



uncoated: 520 colonies

2314-172: 2 colonies:
< 95% inhibition



Test For Biofilm Resistivity Against C. albicans (Yeast)

uncoated: 295 colonies

2314-172: 69 colonies:
< 76% 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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