



## **White Paper #26: Compatibility of Materials Subject to Chlorine Dioxide Gas Sterilization**

Chlorine dioxide gas is an oxidating agent. Oxidizers remove hydrogen atoms through the addition of oxygen. While this process may result in no material changes, a difference in material weight could be detrimental to the final product. To determine the compatibility of materials with Chlorine dioxide gas sterilization, two studies were completed. One was at Microchem Laboratory in Round Rock, Texas, and the other at ClorDiSys Solutions in Branchburg, New Jersey.

Microchem Laboratory conducted material testing under Study Identification Number NG10301-A1. Compatibility for both studies is assessed by calculating the change in weight of a material before and after exposure to the test substance. Aesthetic changes are also recorded as these often denote a chemical reaction of the test substance with the material. A total of thirty-three materials were examined in Microchem Laboratory's testing, and fifty-six were examined in ClorDiSys' tests. These selected materials are commonly utilized in the design of equipment and devices. A minimal change in weight coupled with minimal aesthetic change indicates favorable material compatibility.

### **Microchem Laboratory Study**

#### **Materials:**

- |  |                                     |
|--|-------------------------------------|
| 1. Polycarbonate                                   | 16. Brass                           |
| 2. ABS   | 17. Viton                           |
| 3. High Density Polyethylene (HDPE)                | 18. EPDM                            |
| 4. Stainless Steel (316)                           | 19. Teflon                          |
| 5. Stainless Steel (304)                           | 20. USB Drive                       |
| 6. Polyurethane                                    | 21. Epoxy Paint                     |
| 7. Acrylic   | 22. Vinyl Floor Tile (Lowe's)       |
| 8. Anodized Aluminum                               | 23. Tyvek                           |
| 9. Copper  | 24. Stranded Wire (Lowe's)          |
| 10. Siloxane Gel (3 types: yellow, pink, and blue) | 25. Low Density Polyethylene (LDPE) |
| 11. Galvanized Steel                               | 26. Silicone Gasket                 |
| 12. Powder Coated Painted Steel                    | 27. Silicone Caulk                  |
| 13. PET  | 28. Titanium Sheet                  |
| 14. Polypropylene                                  | 29. Santoprene                      |
| 15. PVC  | 30. Delrin                          |
|  | 31. Fiberglass Insulation           |

#### **Procedure Summary**

- The test surfaces were received and cut into smaller pieces, if applicable. If the materials were tested in replicates, the replicates were marked to distinguish them from each other.
- All replicates of each material were weighed, and aesthetic observations were recorded prior to exposure to the test substance to establish a baseline. Photographs of each surface were taken pre- and post-exposure.



- The test surfaces were sent to ClorDiSys Solutions for treatment. Surfaces were treated with a chlorine dioxide generating device.
- Test surfaces were sent back to Microchem after treatment. Surfaces were weighed and general aesthetic observations were made.
- The final weights of the materials were recorded and the percent weight changes were calculated.

#### Criteria for Scientific Defensibility of a Materials Compatibility Study

For Microchem Laboratory to consider a Materials Compatibility study to be scientifically defensible, the following criteria must be met:

- All replicates must be treated identically such that they all are exposed to the same amount and potency of Test Substance and for equal lengths of time.
- All Test Materials will be treated equally with the Test Substance such that they all are exposed to an appropriate amount of the Test Substance and for an equal length of time.
- Weights are recorded before and after exposure to the Test Substance in which the weight change is assessed according to the replicate's own initial weight.

#### Testing Parameters

- Replicates: 3
- Treatment Duration: A total of 5 chlorine dioxide gas decontamination cycles were performed. The testing parameters were as follows: 65% relative humidity, 1.0 mg/L, 720 ppm-hrs. The total chlorine dioxide dosage for all runs was 3,600 ppm-hrs
- Number of Test Surface Types: 33
- Test Substance Active Ingredient: Chlorine Dioxide Gas

#### Study Modifications

- The test surfaces were treated off-site by ClorDiSys.
- The test substance was delivered in gas form.

#### Notable Aesthetic Observations

- No test surfaces had notable aesthetic changes.

#### Controls

- One replicate of each surface type was not treated but was weighed before and after the test replicates were treated as a control for each surface type.

#### Calculations

- Percent Weight Change:

$$= [ (\text{Final Weight} - \text{Initial Weight}) / \text{Initial Weight} ] \times 100$$

- Average Percent Change:

$$= (\text{R1 Percent Weight Change} + \text{R2 Percent Weight Change} + \text{R3 Percent Weight Change}) / 3$$

## Results

All materials tested were found to have favorable material compatibility, as there were minimal weight change and aesthetic changes after treatment with Chlorine dioxide gas.

*Table 1: Weight changes for each test and control surface*

Test Surface	Replicate	Initial Weight (g)	Final Weight (g)	Weight Change (g)	Percent Weight Change	Average Percent Weight Change (g)
Fiberglass Insulation	Control	1.2959	1.2920	-0.0039	0.30%	0.11%
	1	1.5467	1.5494	0.0027	0.17%	
	2	1.7256	1.7243	-0.0013	0.08%	
	3	1.7477	1.7493	0.0016	0.09%	
Delrin	Control	8.2641	8.2545	-0.0096	0.12%	0.09%
	1	8.4685	8.4585	-0.0100	0.12%	
	2	8.2811	8.2752	-0.0059	0.07%	
	3	7.6736	7.6668	-0.0068	0.09%	
Santoprene	Control	5.6540	5.6549	0.0009	0.02%	0.15%
	1	5.3859	5.3915	0.0056	0.10%	
	2	5.5418	5.5518	0.0100	0.18%	
	3	5.4000	5.4095	0.0095	0.18%	
ABS	Control	4.1744	4.1690	-0.0054	0.13%	0.51%
	1	4.2453	4.2242	-0.0211	0.50%	
	2	4.5201	4.4835	-0.0366	0.81%	
	3	4.2912	4.2811	-0.0101	0.24%	
Acrylic	Control	4.8300	4.7986	-0.0314	0.65%	0.23%
	1	4.7906	4.7793	-0.0113	0.24%	
	2	4.7752	4.7691	-0.0061	0.13%	
	3	4.7738	4.7576	-0.0162	0.34%	
Anodized Aluminum	Control	22.7285	22.7300	0.0015	0.01%	0.02%
	1	22.7215	22.7244	0.0029	0.01%	
	2	22.9275	22.9307	0.0032	0.01%	
	3	22.8561	22.8608	0.0047	0.02%	
Brass	Control	53.7748	53.7747	-0.0001	0.00%	0.00%
	1	53.2257	53.2266	0.0009	0.00%	
	2	53.1217	53.1235	0.0018	0.00%	
	3	53.8601	53.8622	0.0021	0.00%	
Copper	Control	19.2149	19.2175	0.0026	0.01%	0.01%
	1	18.7894	18.7919	0.0025	0.01%	
	2	19.6785	19.6790	0.0005	0.00%	
	3	20.1946	20.1953	0.0007	0.00%	
EPDM	Control	2.2949	2.2945	-0.0004	0.02%	0.08%
	1	2.2717	2.2701	-0.0016	0.07%	
	2	2.2406	2.2388	-0.0018	0.08%	
	3	2.2324	2.2304	-0.0020	0.09%	
Epoxy Paint	Control	6.4542	6.3278	-0.1264	1.96%	1.38%
	1	6.3137	6.2272	-0.0865	1.37%	
	2	6.1213	6.0365	-0.0848	1.39%	
	3	5.9233	5.8404	-0.0829	1.40%	

Table 1: (continued)

Test Surface	Replicate	Initial Weight (g)	Final Weight (g)	Weight Change (g)	Percent Weight Change	Average Percent Weight Change (g)
Galvanized Steel	Control	215.74	215.8	0.0600	0.03%	0.03%
	1	214.35	212.3	-2.0500	0.96%	0.33%
	2	212.57	212.6	0.0300	0.01%	
	3	212.31	212.3	-0.0100	0.00%	
HDPE	Control	1.9101	1.9117	0.0016	0.08%	0.08%
	1	1.9380	1.9385	0.0005	0.03%	0.05%
	2	1.8863	1.8878	0.0015	0.08%	
	3	1.8692	1.8703	0.0011	0.06%	
LDPE	Control	3.5570	3.5593	0.0023	0.06%	0.06%
	1	3.5300	3.5317	0.0017	0.05%	0.05%
	2	3.5248	3.5270	0.0022	0.06%	
	3	3.5143	3.5154	0.0011	0.03%	
PET	Control	22.2485	22.2483	-0.0002	0.00%	0.00%
	1	22.6781	22.6786	0.0005	0.00%	0.01%
	2	22.0298	22.0321	0.0023	0.01%	
	3	23.5323	23.5283	-0.0040	0.02%	
Polycarbonate	Control	5.1637	5.1480	-0.0157	0.30%	0.30%
	1	5.3566	5.3497	-0.0069	0.13%	0.17%
	2	5.0894	5.0719	-0.0175	0.34%	
	3	5.1602	5.1629	0.0027	0.05%	
Polypropylene	Control	3.7810	3.7799	-0.0011	0.03%	0.03%
	1	3.7864	3.7718	-0.0146	0.39%	0.55%
	2	3.7780	3.7565	-0.0215	0.57%	
	3	3.7813	3.7548	-0.0265	0.70%	
Polyurethane	Control	5.2027	5.1866	-0.0161	0.31%	0.31%
	1	4.9495	4.9402	-0.0093	0.19%	0.22%
	2	5.1017	5.0887	-0.0130	0.25%	
	3	4.9810	4.9705	-0.0105	0.21%	
Powder Coated Steel	Control	36.7531	36.7531	0.0000	0.00%	0.00%
	1	36.2765	36.2777	0.0012	0.00%	0.00%
	2	35.9855	35.9856	0.0001	0.00%	
	3	35.5638	35.5639	0.0001	0.00%	
PVC	Control	6.3637	6.3610	-0.0027	0.04%	0.04%
	1	6.1759	6.1756	-0.0003	0.00%	0.04%
	2	6.2568	6.2597	0.0029	0.05%	
	3	6.0780	6.0813	0.0033	0.05%	
Silicone Caulk	Control	26.8321	26.5497	-0.2824	1.05%	1.05%
	1	19.7549	19.6242	-0.1307	0.66%	0.95%
	2	18.3550	18.1339	-0.2211	1.20%	
	3	17.4887	17.3149	-0.1738	0.99%	
Silicone Gasket	Control	1.0162	1.0158	-0.0004	0.04%	0.04%
	1	1.0386	1.0530	0.0144	1.39%	1.41%
	2	0.9450	0.9577	0.0127	1.34%	
	3	0.9329	0.9470	0.0141	1.51%	

Table 1: (continued)

Test Surface	Replicate	Initial Weight (g)	Final Weight (g)	Weight Change (g)	Percent Weight Change	Average Percent Weight Change (g)
Teflon	Control	4.7340	4.7399	0.0059	0.12%	0.12%
	1	4.6591	4.6615	0.0024	0.05%	0.10%
	2	4.8414	4.8478	0.0064	0.13%	
	3	4.6109	4.6160	0.0051	0.11%	
Titanium	Control	4.5139	4.5142	0.0003	0.01%	0.01%
	1	4.6303	4.6325	0.0022	0.05%	0.05%
	2	4.8508	4.8529	0.0021	0.04%	
	3	4.5547	4.5570	0.0023	0.05%	
Tyvek	Control	0.1123	0.1210	0.0087	7.75%	7.75%
	1	0.1152	0.1164	0.0012	1.04%	1.00%
	2	0.1075	0.1092	0.0017	1.58%	
	3	0.1103	0.1107	0.0004	0.36%	
USB Drive	Control	7.3054	7.3016	-0.0038	0.05%	0.05%
	1	7.4381	7.4350	-0.0031	0.04%	0.05%
	2	7.3996	7.3962	-0.0034	0.05%	
	3	7.3454	7.3419	-0.0035	0.05%	
Vinyl Floor Tile	Control	14.1658	14.1639	-0.0019	0.01%	0.01%
	1	13.0822	13.0844	0.0022	0.02%	0.01%
	2	13.3392	13.3377	-0.0015	0.01%	
	3	13.5593	13.5571	-0.0022	0.02%	
Viton	Control	7.4110	7.4117	0.0007	0.01%	0.01%
	1	7.3824	7.3822	-0.0002	0.00%	0.01%
	2	7.3704	7.3717	0.0013	0.02%	
	3	7.3952	7.3967	0.0015	0.02%	
Stranded Wire	Control	15.8802	15.8851	0.0049	0.03%	0.03%
	1	15.9459	15.9581	0.0122	0.08%	0.08%
	2	15.6743	15.6895	0.0152	0.10%	
	3	16.2589	16.2677	0.0088	0.05%	
304 Stainless Steel	Control	14.7670	14.7730	0.0060	0.04%	0.04%
	1	14.8031	14.8055	0.0024	0.02%	0.01%
	2	14.6175	14.6190	0.0015	0.01%	
	3	14.3372	14.3385	0.0013	0.01%	
316 Stainless Steel	Control	13.9777	13.9792	0.0015	0.01%	0.01%
	1	14.3545	14.3553	0.0008	0.01%	0.01%
	2	13.9820	13.9833	0.0013	0.01%	
	3	14.3029	14.3041	0.0012	0.01%	

Test Surface	Replicate	Initial Weight (g)	Final Weight (g)	Weight Change (g)	Percent Weight Change	Average Percent Weight Change (g)
Siloxane Gel – Pink	Control	44	43.8603	-0.1397	0.32%	0.21%
	1	57	56.9671	-0.0329	0.06%	
	2	53	53.1566	0.1566	0.30%	
	3	44	44.1183	0.1183	0.27%	
Siloxane Gel – Blue	Control	55	54.7796	-0.2204	0.40%	0.17%
	1	50	49.9642	-0.0358	0.07%	
	2	55	54.8423	-0.1577	0.29%	
	3	58	57.9121	-0.0879	0.15%	
Siloxane Gel – Yellow	Control	54	55.1241	1.1241	2.08%	1.01%
	1	51	51.7631	0.7631	1.50%	
	2	51	50.4950	-0.5050	0.99%	
	3	56	55.6887	-0.3113	0.56%	

### Summary:

When observing the material weight variations between the controls and the sterilized items, ClorDiSys determined that no sample had a substantial weight difference after sterilization that would immediately signify incompatibility. If a drastic loss of weight was seen, then one could infer that significant oxidation or corrosion occurred. If a significant increase in weight was seen, then one could conclude that a high absorption of humidity or gas occurred, or some other chemical change.

Although material studies of the effects of chlorine dioxide gas on material coupons indicate favorable results, the final determination of material compatibility must be made by a device manufacturer and must consider the device in its final form. This is due to unique polymer blends that components may be made of, as well as the final assembly of all components together potentially influencing the device's function and overall compatibility to the sterilization cycle.

## **ClorDiSys Solutions Study**

### Materials:

- |                                |                               |
|--------------------------------|-------------------------------|
| 1. 18-8 Stainless Steel        | 13. Copper                    |
| 2. 316 Stainless Steel         | 14. EPDM                      |
| 3. Aluminum                    | 15. Epichlorohydrin           |
| 4. Aluminum Oxide              | 16. ETFE                      |
| 5. Black-Oxide Steel           | 17. FEP                       |
| 6. Brass                       | 18. Fiberglass                |
| 7. Bronze                      | 19. Galvanized Malleable Iron |
| 8. Buna-N Rubber               | 20. Galvanized Steel          |
| 9. Butyl                       | 21. Gold                      |
| 10. Cellulose                  | 22. Hypalon                   |
| 11. Cellulose Acetate Butyrate | 23. Latex                     |
| 12. Cellulose Ester            | 24. Liquid Crystal Polymer    |

- |                                 |                       |
|---------------------------------|-----------------------|
| 25. Magnesium                   | 41. Polyimides        |
| 26. Natural Gum Rubber          | 42. Polyketones       |
| 27. Neoprene                    | 43. Polyurethane      |
| 28. Nickel                      | 44. PVA               |
| 29. Nickel-Copper               | 45. PVF               |
| 30. Nitinol                     | 46. Santoprene        |
| 31. Nylon 6/6                   | 47. SBR Black         |
| 32. Oil Resistant Vinyl (Black) | 48. Silica            |
| 33. PFA                         | 49. Silicone          |
| 34. PGA Polyglycolides          | 50. Silver            |
| 35. Phenolic                    | 51. Sorbothane        |
| 36. PLGA                        | 52. Titanium          |
| 37. Polyacetals                 | 53. Vinyl             |
| 38. Polyacrylates               | 54. Viton             |
| 39. Polylactides                | 55. Zinc-Plated Steel |
| 40. Polyester                   | 56. Zirconium Oxide   |

#### Procedure Summary:

- Two material coupons were selected of each material. One is the control for comparison, and the other underwent two chlorine dioxide gas sterilization cycles in the Steridox-100.
- Weights, comparisons, and photos were taken before Cycle 1 as a control, and after Cycle 2 to observe the effects of chlorine dioxide gas sterilization on the materials.
- Cycle 1: 3,350 PPM, 3.0 mg/L, 30 min condition, 75% RH, 5.0 kPa initial vacuum level
- Cycle 2: 3,350 PPM, 3.0 mg/L, 30 min condition, 75% RH, 5.0 kPa initial vacuum level

#### Testing Parameters:

- Materials for the runs were placed inside the Steridox-100 Chamber (SVP-05A-2021). The Steridox-100 was used to raise the RH and generate the chlorine dioxide gas. The cycles were performed using 75% RH at 3.0 mg/L until a dosage of 3,350 PPM hours was achieved. During exposure the RH was monitored and recorded using a Vaisala RH probe. Two cycles were performed for a total of 6,700PPM hour dosage on the materials.

#### Results:

Chlorine dioxide gas at a dosage of 6,700ppm-hours had no effect on the 18-8 Stainless Steel, 316 Stainless Steel, Aluminum, Aluminum Oxide, Black-Oxide Steel, Brass, Buna-N Rubber, Cellulose Ester, Copper, EPDM, Epichlorohydrin, ETFE, FEP, Gold, Hypalon, Liquid Crystal Polymer, Magnesium, Neoprene, Nickel, Nitinol, Nylon 6/6, Oil Resistant Vinyl (Black), PFA, PGA Polyglycolides, Phenolic, PLGA, Polyacetals, Polylactides, Polyester, Polyimides, Polyketones, Polyurethane, PVA, Santoprene, SBR Black, Silica, Silicone, Vinyl, Viton, Zinc-Plated Steel, and Zirconium Oxide.

Treatment caused color changes to the Butyl, Cellulose, Cellulose Acetate Butyrate, Fiberglass, Latex, Natural Gum Rubber, Polyacrylates, and PVF samples.

In addition to color changes, the following also showed signs of physical changes such as oxidation and pitting: Bronze, Galvanized Malleable Iron, Galvanized Steel, Nickel-Copper,





Silver, and Titanium. However, varying grades and applications of the materials may result in different product outcomes.

Sorbothane was the most adversely affected by chlorine dioxide gas. It caused the surface to degrade, becoming gel-like and tacky.

*Table 2: Material Compatibility Results of ClorDiSys Study*

Material	Weight Before (g)	Weight After (g)	Percent Change	Physical Change
Santoprene	1.401	1.425	1.71	None
Silicone	1.550	1.565	0.97	None
Natural Gum Rubber	1.350	1.364	1.04	Color Darkened
Buna-N Rubber	1.913	1.922	0.47	None
SBR Black	1.969	1.987	0.91	None
Oil Resistant Vinyl (Black)	1.660	1.663	0.18	None
Sorbothane	4.320	4.325	0.12	Melty/Sticky
Epichlorohydrin	1.945	1.955	0.51	None
Viton	3.051	3.063	0.39	None
Butyl	1.398	1.399	0.07	Color Darkened
EPDM	1.434	1.448	0.98	None
Hypalon	1.385	1.388	0.22	None
Neoprene	1.747	1.750	0.17	None
Latex	1.694	1.695	0.06	Slight Color Difference
Polyurethane	1.683	1.685	0.12	None
Nylon 6/6	0.062	0.064	3.23	None
Fiberglass	0.135	0.137	1.48	Yellowing
Phenolic	0.312	0.313	0.32	None
Polyester	0.005	0.009	80.00	None
Vinyl	0.041	0.043	4.88	None
Titanium	2.536	2.537	0.04	Slightly Lighter
Galvanized Malleable Iron	8.360	8.365	0.06	Duller and Smoother

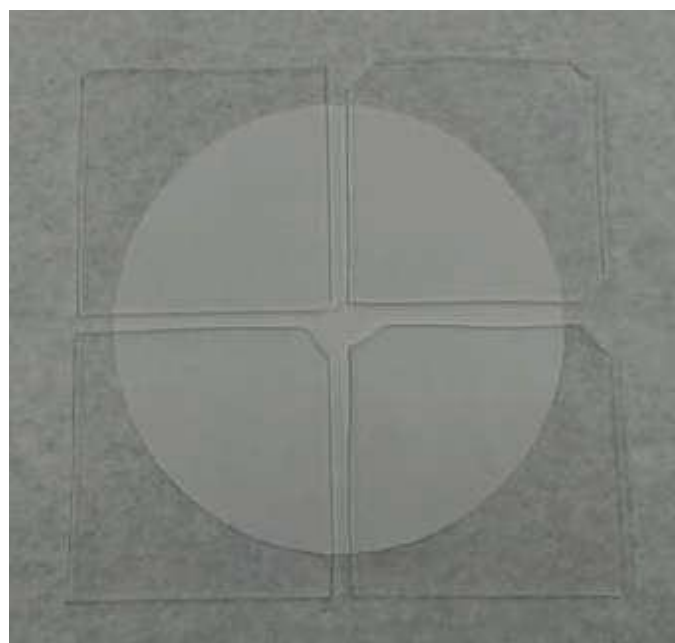
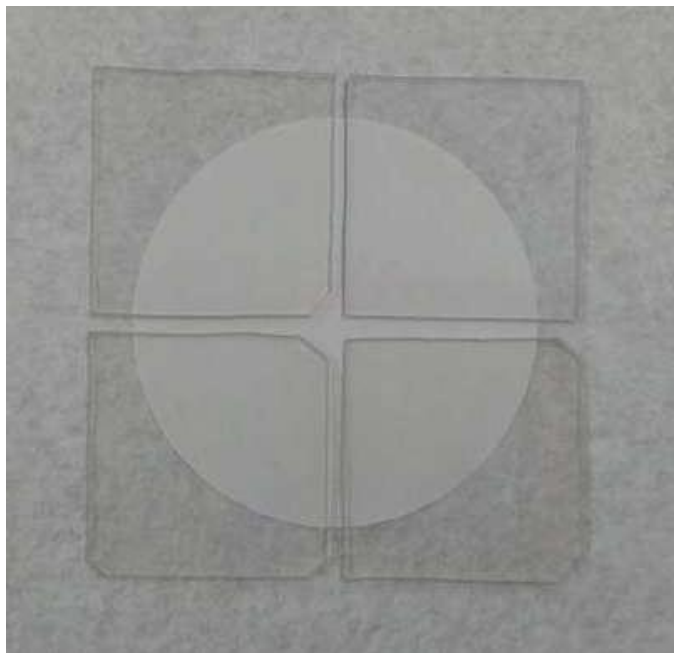


Material	Weight Before (g)	Weight After (g)	Percent Change	Physical Change
Brass	0.859	0.859	0.00	None
Aluminum	0.679	0.679	0.00	None
Bronze	1.839	1.841	0.11	One side is dull/corroded
Copper	2.209	2.209	0.00	None
316SS	0.812	0.813	0.12	None
Galvanized Steel	2.728	2.731	0.11	Duller and Smoother
Zinc-Plated Steel	1.109	1.110	0.09	None
Nickel-Copper	2.243	2.243	0.00	Less shiny and less smooth
Nickel	0.465	0.436	-6.24	None
18-8 SS	3.325	3.323	-0.06	None
Black-Oxide Steel	3.465	3.465	0.00	None
PVA	0.941	0.942	0.11	None
FEP	0.383	0.386	0.78	None
PolyKetones	1.102	1.104	0.18	None
Nitinol	0.122	0.124	1.64	None
Zirconium Oxide	0.814	0.814	0.00	None
Cellulose Ester	0.067	0.068	1.49	None
PFA	0.923	0.918	-0.54	None
Polyacetals	5.698	5.697	-0.02	None
PGA Polyglycolides	0.677	0.689	1.77	Paper holder is darker
Silver	3.783	3.781	-0.05	Discoloration/Corrosion
Aluminum Oxide	5.237	5.237	0.00	None
Cellulose Acetate Butyrate	0.851	0.851	0.00	Cloudy
PFV	N/A	N/A	N/A	N/A
Polyacrylates	4.648	4.856	4.48	Slightly Darker/Redish
Gold	2.803	2.804	0.04	None

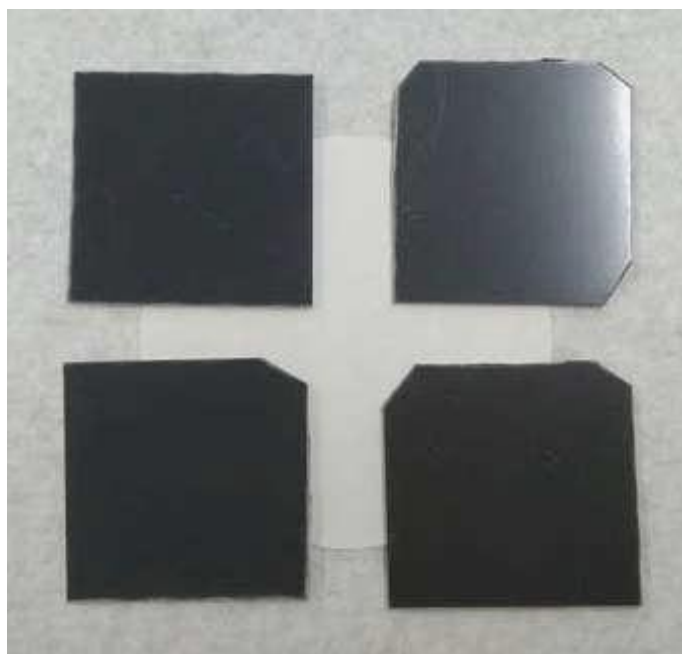


Material	Weight Before (g)	Weight After (g)	Percent Change	Physical Change
PVF	0.620	0.615	-0.81	Slight Yellowish Tint
Polylactides	0.126	0.125	-0.79	None
Cellulose	1.067	1.101	3.19	Color has faded/ gotten lighter
ETFE	1.149	1.146	-0.26	None
Polyimides	1.261	1.258	-0.24	No Control
Magnesium	5.401	5.398	-0.06	No Control
Silica	1.514	1.589	4.95	None
PLGA	2.366	2.369	0.13	No Control
Liquid Crystal Polymer	0.168	0.157	-6.55	Color Change Happens Faster than control

## Appendix 1: Microchem Study Photos



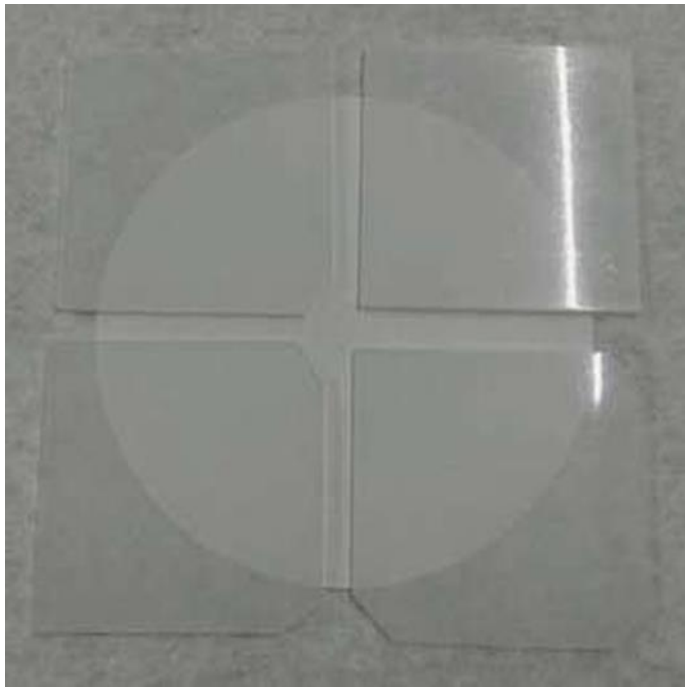
*1: Polycarbonate control and test replicates after treatment    2: Acrylic control and test replicates after treatment*



*3: PVC control and test replicates after treatment*



*4: ABS Control and test replicates after treatment*



*5: LDPE control and test replicates after treatment*



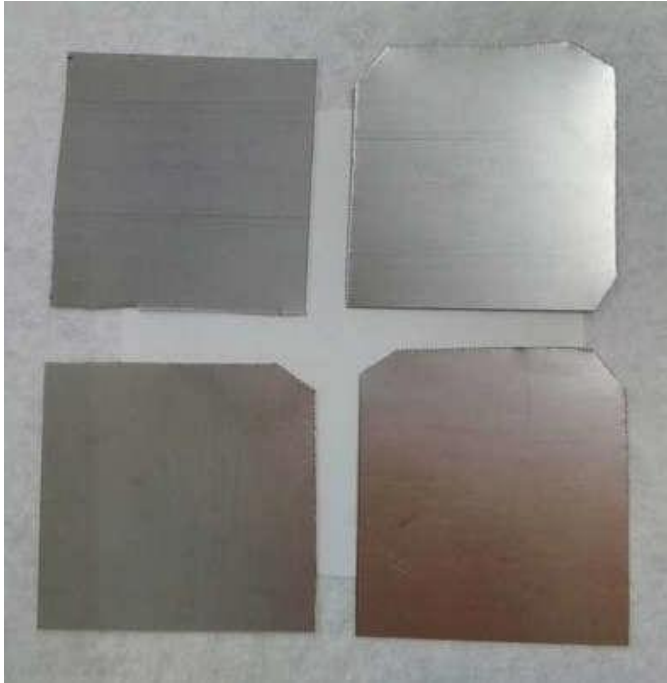
*6: HDPE control and test replicates after treatment*



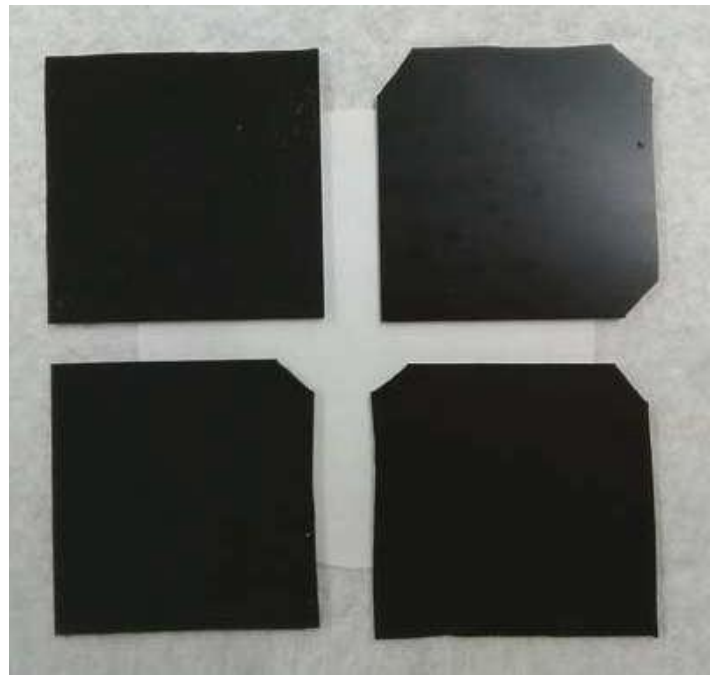
*7: Polypropylene control and test replicates after treatment*



*8: EPDM control and test replicates after treatment*



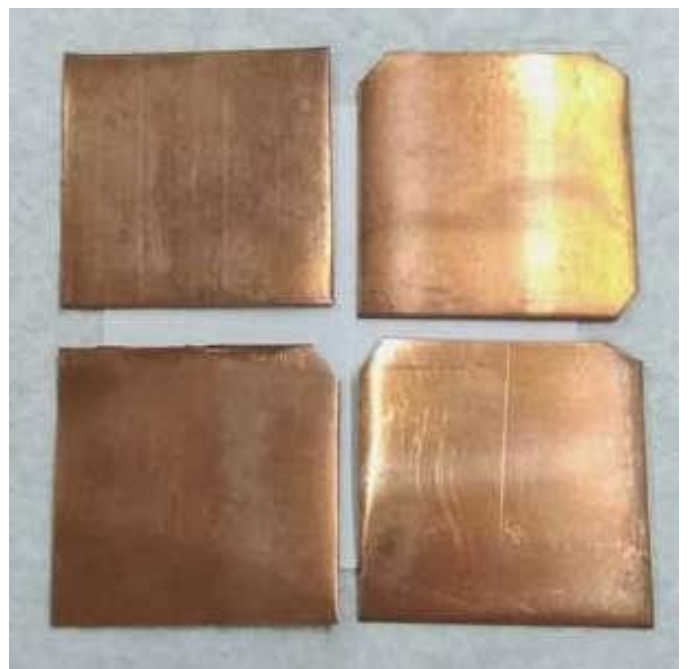
*9: Titanium control and test replicates after treatment*



*10: Polyurethane control and test replicates after treatment*



*11: 304 Stainless Steel control and test replicates after treatment*



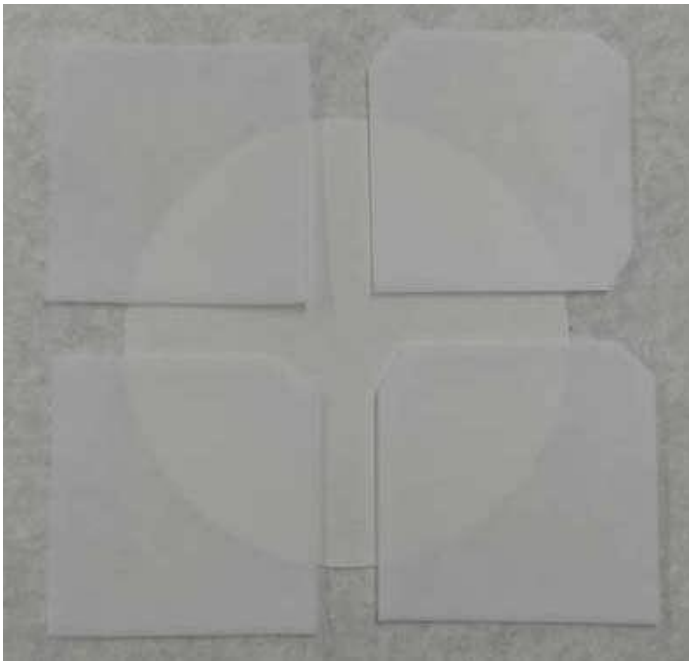
*12: Copper control and test replicates after treatment*



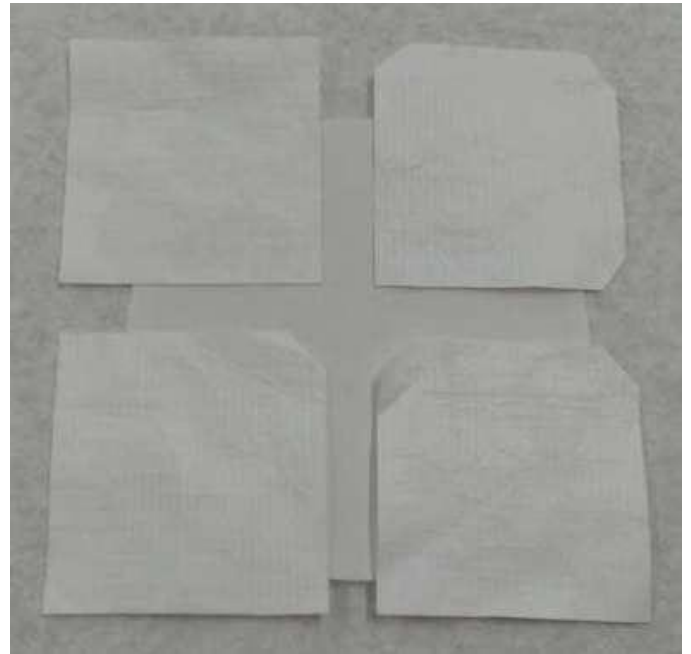
*13: PET control and test replicates after treatment*



*14: 316 Stainless Steel control and test replicates after treatment*



*15: Teflon control and test replicates after treatment*



*16: Tyvek control and test replicates after treatment*





*17: Silicone Gasket control and test replicates after treatment*



*18: Viton control and test replicates after treatment*



*19: Galvanized steel control and test replicates after treatment*

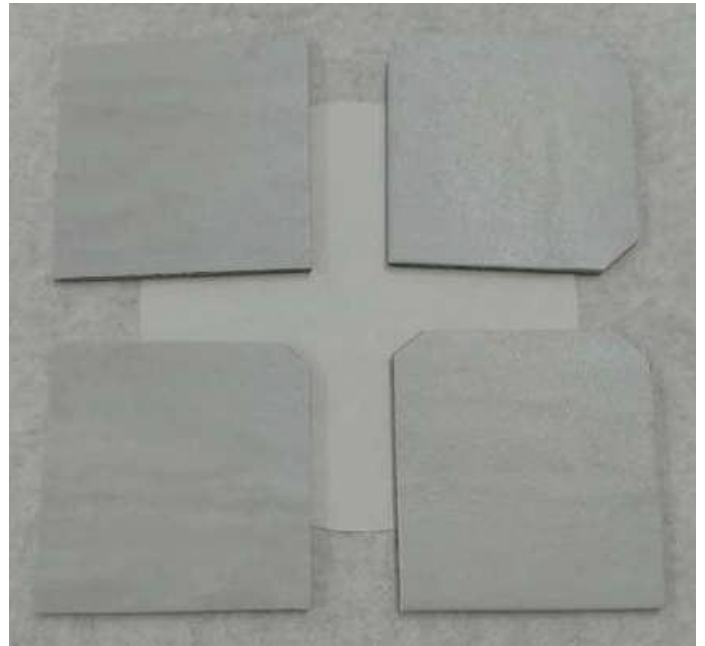


*20: Brass control and test replicates after treatment*





*21: Epoxy Paint control and test replicates after treatment*



*22: Vinyl Floor Tile control and test replicates after treatment*



*23: Silicone Caulk control and test replicates after treatment*



*24: Powder coated painted steel control and test replicates after treatment*



25: Stranded Wire control and test replicates after treatment



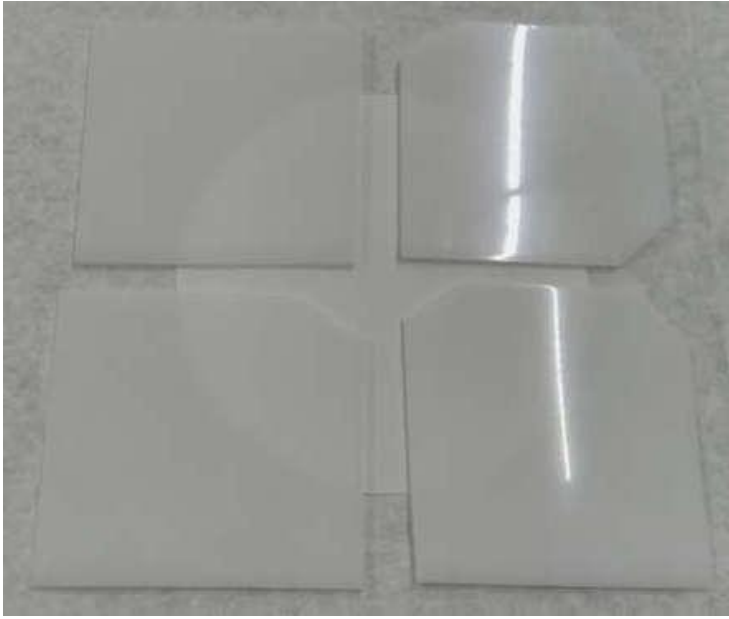
26: USB Drive control and test replicates after treatment



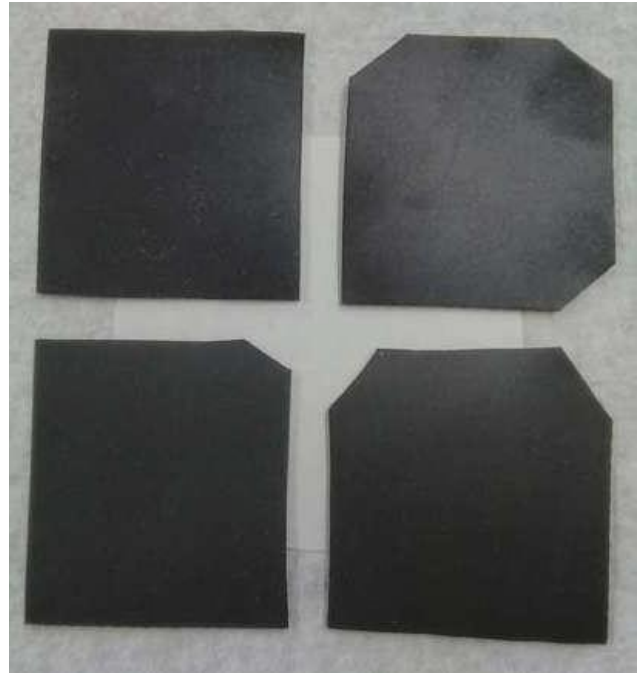
27: Anodized Aluminum control and test replicates after treatment



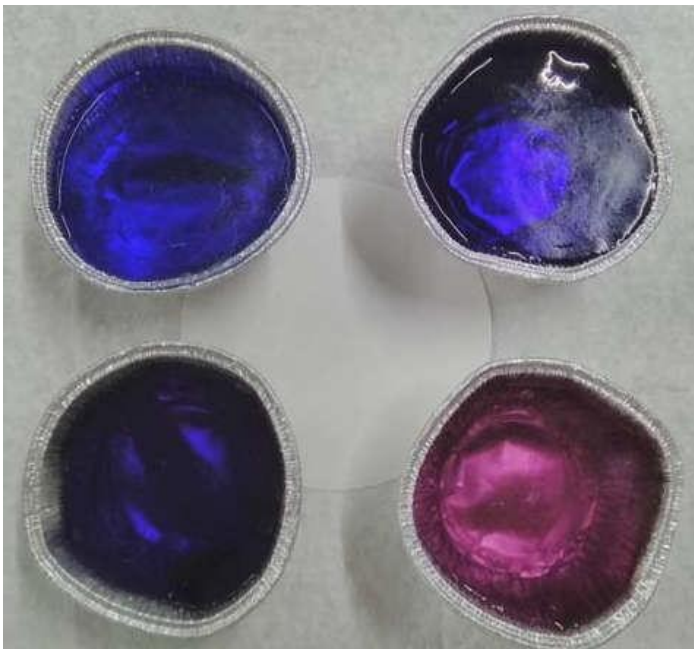
28: Fiberglass control and test replicates after treatment



*29: Delrin control and test replicates after treatment*



*30: Santoprene control and test replicates after treatment*



*Photo 31: Blue Siloxane Gel control and test replicates after treatment*



*Photo 32: Pink Siloxane Gel control and test replicates after treatment*





*Photo 33: Yellow Siloxane Gel control and test replicates after treatment*

## Appendix 2: ClorDiSys Study Photos

