# Technical Bulletin
# 1203.30

Subject: OriGen PVC Tubing Resistance to DMSO, Experimental Results
Date: March 2012
To: All CryoStore, Acessory Sets, and Evolve users & distributors

OriGen Biomedical has recently completed an experiment to investigate the results of exposure of our medical grade PVC tubing to different concentrations of DMSO. This was done to determine the concentration of DMSO at which our blend of medical grade PVC tubing is fully resistant and whether any leachables are present in solution after contact with the tubing. The summary of the experiment is as follows. Note that all concentrations listed are calculated based on volume.

**Hypothesis:**
OriGen medical grade PVC tubing used in our products is resistant to DMSO solutions at concentrations of 80% DMSO and lower (diluted with water for injection).

**Method:**
*Test 1*
To determine if the tubing degrades when exposed to DMSO, segments of OriGen PVC tubing were weighed and then submerged in four concentrations of DMSO (100%, 90%, 80%, and 55%) for 30 minutes. The mass of the tubing post-exposure was compared to the mass of the tubing pre-exposure to determine the percent of mass lost during submersion.

*Test 2*
To determine if DMSO is affected by exposure to OriGen PVC, segments of the tubing were flushed with four concentrations of DMSO (100%, 90%, 80%, and 55%). The effluent was captured and analyzed to determine its chemical composition. First, the solution was separated into individual compounds using gas chromatography. Then, each compound was identified and quantified using mass spectrometry. The purity of the DMSO and the total percent of PVC compounds found in the solution were recorded; the presence of trace amounts of any PVC compound was also noted.

**Results:**
*Test 1: Submersion Results*

| Concentration of DMSO | Average Percent Loss | Notes |
|---|---|---|
| 100% | 0% | Tubing whitens to 100% opacity after exposure; “sweats” as it dries, opacity is reduced |
| 90% | 0% | Tubing whitens to ~50% opacity after exposure; “sweats” as it dries, opacity is reduced |
| 80% | 0% | No change in tubing appearance |
| 55% | 0% | No change in tubing appearance |

*Test 2: Flush Results*

| Concentration of DMSO | DMSO purity | PVC Compounds Present? | Sum of PVC compounds |
|---|---|---|---|
| 100% | 99.87% | Yes | 0.05% |
| 90% | 99.94% | No | 0.00% |
| 80% | 99.95% | No | 0.00% |
| 55% | 99.95% | No | 0.00% |

**Discussion:**
The submersion results indicate that OriGen PVC does not degrade when exposed to any concentration of DMSO. The whitening experienced by the tubing at concentrations of 100% and 90% DMSO is likely due to absorption of DMSO into the PVC matrix structure which then sweats out as the tubing is allowed to dry, which restores the clarity of the tubing.

The flush results indicate that very small amounts of PVC compounds are soluble in solutions of only 100% DMSO. The identity of this compound was found to be a derivative of the non-toxic plasticizer used to manufacture OriGen's medical grade PVC. The other analysis results demonstrate that all other concentrations of DMSO remain pure to >99.9% and do not contain trace amounts of PVC compounds when flushed through the tubing.

These results are supported with a review of the chemical structures of water, DMSO, and PVC. At concentrations of 80% DMSO in water, the solution achieves a 1:1 molar ratio, meaning for every 1 molecule of DMSO, there is one molecule of water. The water molecules stabilize the DMSO molecules via hydrogen bonding, which as this experiment proves, prevents the absorption of DMSO into the tubing and reduces the solubility of the plasticizers used in OriGen PVC to zero. Furthermore, the backbone structure of the PVC polymer is comprised entirely of carbon to carbon bonds which require a tremendous amount of energy to break. This explains why the tubing segments did not degrade when exposed to any concentration of DMSO.

**Conclusion:**
OriGen Biomedical medical grade PVC tubing used in our products is chemically resistant to solutions containing 80% DMSO or less.