OriGen BIOMEDICAL

WHITE PAPER

DMSO COMPATIBILITY WITH MEDICAL PLASTICS

Testing demonstrating DMSOresistance of common polymers used in medical devices

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DMSO Compatibility with Medical Plastics

GENERAL

OriGen Biomedical CryoPur™ and CryoPur-D are cryo-protectant solutions containing the solvent DMSO (dimethyl sulfoxide) in varying concentrations, up to 100%. DMSO is a strong, polar aprotic solvent used to displace the water inside the cell membranes prior to freezing which protects the cells during the transition to liquid nitrogen temperatures. Due to the high solubility potential of DMSO, it can react with some plastic polymers used to manufacture medical devices. The solvent can negatively impact the plastics in a variety of ways: degradation of the polymer, discoloration, swelling, etc; all failure modes are marked with a distinctive visual change. The solubility potential of DMSO decreases as the concentration of DMSO in solution decreases; at concentrations of 80% (w/w) DMSO in water and below, the solution does not visually impact any of the plastics studied in any appreciable way.

EXPERIMENT

OriGen has tested all plastics used in the manufacture of products that might come into contact with DMSO solutions, specifically used in the following product lines:

- **CryoStore (CS)**
- **CryoPur™ (CP)**
- **Accessory Sets (Acc)**
- **Evolve™ (EV)**
- **O-Wrap™ (OW)**
- **TissueVault™ (TV)**
- **PermaLife™ (PL)**

To determine short-term compatibility, the polymer was exposed to DMSO solutions for up to 24 hours and inspected for visual changes. The part was deemed resistant if there were no signs of change after exposure. If the polymer showed any sign of change (cracking, splitting, whitening, discoloration, swelling, sweating, etc.), the plastic was labeled non-compatible with that solution concentration of DMSO. The table below lists each plastic polymer, where the polymer is used, and the compatibility with solutions of 100% and 80% DMSO. Where appropriate, both the abbreviation and the common name of the plastic are given; additionally, the use of the plastic (molded, tubing, or film) is given.

Resistance is based on a 24-hour exposure of the plastic to DMSO and, unless noted, does not indicate that the plastic may be used as a vessel to store DMSO for longer periods. For materials used for DMSO solution storage, long-term compatibility has been established and is indicated in the table. The following codes are used to indicate the failure mode of the plastic:

- **R = Resistant (No Visual Change)**
- **NR/C = Non-resistant, Color Change**
- **NR/D = Non-resistant, Degradation**
- **NR/S = Non-resistant, Swelling and Sweating of DMSO**

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RESULTS

Polymer Abbreviation (use) Polymer common name	Where Used	Short-term, Resistance to 100% DMSO	Resistance to ≤80% DMSO
EVA (film and tubing) *Ethylene-vinyl acetate*	CS, Acc	R	R
EVO (film and tubing) *Ethylene-vinyl olefin*	EV, OW, TV	R	R
FEP (film and tubing) *Fluorinated ethylene propylene*	PL	R	R‡
PC (molded and barbs) *Polycarbonate*	Acc, CP, PL	NR/D & NR/C	R‡
PPL (molded) *Polypropylene*	Acc	R	R‡
PE (molded) *Polyethylene*	Acc	R	R‡
Nylon (molded)	Acc, CP	R‡	R‡
Acetal (molded)	Acc	R	R
PVC (tubing) *Poly vinyl chloride*	CS, Acc, EV, PL	NR/C	R
PVC (molded) *Poly vinyl chloride*	CS, Acc, EV	NR/C	R
COP (molded) *Copolyester*	CS, Acc, EV, PL	R	R
ABS (molded) *Acrylonitrile Butadiene Styrene*	Acc	NR/D	R
PVDF (molded) *Polyvinylidene fluoride, Kynar*	Acc	NR/S	R
Butyl (stoppers)	CP	R‡	R‡
COC (molded) *Cyclic-olefin copolymer*	CP	R‡	R‡

‡ These polymers were also tested for long-term storage of DMSO solutions.

CONCLUSIONS

All OriGen bag films (CryoStore, Evolve, O-Wrap, TissueVault, and PermaLife) are rated for short-term exposure to any concentration of DMSO solution.

Many Accessory Set and tube set components are rated for short-term exposure to any concentration of DMSO solution. To prevent confusion, OriGen has labeled compatible accessory sets as "Resistant to 100% DMSO" in marketing literature and product labels. If you have any questions regarding resistance, please do not hesitate to contact technical support for further explanation.

All components currently used in OriGen product lines are rated for exposure to solutions containing a concentration of 80% DMSO or less.