

US FDA, RoHS, and CE Compliance in Electropure™ EDI Modules

SnowPure, LLC manufactures Electropure™ and Zapwater™ electrodeionization (EDI) modules which are suitable for use in a variety of applications.

All of the wetted materials within the modules have been identified by the United States FDA in Title 21 of the Code of Federal Regulations (CFR21). None of the materials used in Electropure™ modules are of animal origin, or contain TSE/BSE. SnowPure maintains files from its suppliers as to their CFR21 compliance. SnowPure does no independent testing of component materials and solely relies on its suppliers to be in compliance with FDA requirements. If necessary for validation, SnowPure can provide to its customers, under a non-disclosure agreement, a list of the wetted materials in its modules and their specific CFR21 compliance letters.

RoHS (2011/65/EC Directive): No Electropure™ products use asbestos, lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, or polybrominated diphenyl ethers. They are also free of perfluorooctane sulfonates (PFOS) and deca bromodiphenyl ethers (Deca-BDE). All EDI modules conform to CE: meeting the 2014/35/EU Directive.

Included EDI Products:

This applies to all of the following Electropure™ EDI Products: EXL, XL, EPM, and Zapwater™.

List of Wetted Materials:

Water on the product side of SnowPure's electrodeionization products (EXL, XL, EPM, and Zap product lines) contacts the following materials. All are certified by our vendors to be compliant with US CFR 21 and RoHS.

Wetted component	Material	US FDA Code Section
Manifold	Polyphenylene Oxide(PPO)/Polystyrene (Noryl®)	21 CFR 177.2460 177.1640
Manifold	Acetal (Acetron®)	21 CFR 177.2470
Resin Chamber	Polypropylene(PP)	21 CFR 177.1520
Resin Chamber	Acetal (Acetron®)	21 CFR 177.2470
Resin Chamber	Polyphenylene Oxide(PPO)/Polystyrene (Noryl®)	21 CFR 177.2460 177.1640
John Guest® Fittings	Acetal	21 CFR 177.2470
Sanitary Seals	EPDM or Nitrile	21 CFR 177.2600
Anion Exchange Membrane	Anion Exchange Membrane	21 CFR 173.20
Cation Exchange Membrane	Cation Exchange Membrane	21 CFR 173.20
Anion Exchange Resin	Anion Exchange Resin, Strong Base	21 CFR 173.25
Cation Exchange Resin	Cation Exchange Resin, Strong Acid	21 CFR 173.25