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WaterSep Membrane and Cartridge
Regulatory and Bio-Compatibility Summary

Rev. 0 - AH

March 20, 2009

I. Materials of Construction

- Membrane:
  - Polyethersulfone – complies with Title 21 CFR Part 177.2440 promulgated under the Federal Food, Drug and Cosmetic Act (FFDCA). It is, therefore, permitted by FDA for use as articles or components of articles intended for repeated use in contact with food.
  - Glycerine USP (Kosher) – added as storage agent – see removal procedures
  - Sodium Azide – 0.05-0.1% added as bacteriastat – see removal procedures

- Housing, Header, End Connections
  - Polysulfone white – complies with Title 21 CFR Part 177.1655 promulgated under the Federal Food, Drug and Cosmetic Act (FFDCA). It is, therefore, permitted by FDA for food contact applications intended for repeated use under conditions of use A through H in Table 2 of 21 CFR Part 176.170 (c).

- Encapsulant – Components may appear in one or more of the following sections:
  - Meets extraction requirements of CFR 21.175.300

II. BioCompatibility Summary

WaterSep has conducted the following Biocompatibility studies on our hollow fiber membranes and cartridges:

- **USP Class VI test – GLP compliance.**
  Study Summary: "the test article, WaterSep hollow fiber cartridge meets the requirements of USP guidelines, for class VI test – 70^{o}C." See full report in Appendix below
- **USP Physicochemical test for plastics – GLP compliance**
  Study Summary: "the purified water extract of the test article, WaterSep hollow fiber cartridge, meets the test criteria described in the USP Physicochemical test for plastics guidelines."

III. Regulatory Filing

WaterSep does not have a regulatory filing with the FDA at this time.

Rev schedule:

0. Initial publication
1.

IV. Reports Available (pdf):

1. USP class VI test – GLP compliance
2. USP Physicochemical test for plastics – GLP compliance