

Compliance Summary

ReNu SU Technology cartridge

1. Regulatory compliance statements

1a. Gluten

Gluten is not used in the raw material or manufacture of the ReNu SU Technology cartridge. As such it would not be expected to be present in the ReNu SU Technology cartridge tubing or extracted solutions from the ReNu SU Technology cartridge.

1b. Declaration of minimised risk of TSE/BSE

Watson-Marlow works closely with our raw materials suppliers to ensure traceability of our raw materials and production process.

The processing conditions of the materials used in ReNu SU Technology cartridge exceeds the temperatures stated in EMEA 410/01 rev 3 regulations on the minimisation of risk from TSE/BSE prions. Therefore, it is deemed that these materials comply with EMEA 410/01 rev 3 regulations.

1c. Melamine

Melamine is not used in the raw material or manufacture of the ReNu SU Technology cartridge. As such it would not be expected to be present in the ReNu SU Technology cartridge tubing or extracted solutions from the ReNu SU Technology cartridge.

1d. Phthalates

Phthalates are not used in the raw material or manufacture of the ReNu SU Technology cartridge. As such it would not be expected to be present in the ReNu SU Technology cartridge tubing or extracted solutions from the ReNu SU Technology cartridge.

1e. Bisphenol A (BPA)

BPA is not used in the raw material or manufacture of the ReNu SU Technology cartridge. As such it would not be expected to be present in the ReNu SU Technology cartridge tubing or extracted solutions from the ReNu SU Technology cartridge.

1f. Latex

Latex is not used in the raw material or manufacture of the ReNu SU Technology cartridge. This includes contact materials during the manufacturing process.

1g. Allergens

The ReNu SU Technology cartridge does not contain allergens such as milk, eggs, crustaceans, wheat, soy, corn, peanuts, tree nuts (as defined by the FDA CFR 21.164.110). The ReNu SU Technology cartridge does not come into contact with any allergens during the manufacturing process.

1h. Presence of heavy metals

Lead, mercury, cadmium and arsenic are not used in the raw material or manufacture of the ReNu SU Technology cartridge.

Extraction solutions obtained after prolonged contact (7 days at 40C) with the ReNu SU Technology cartridge were analysed using Inductively Coupled Plasma - Mass Spectrometry (ICP-MS) and have shown these elements were not present.

1i. Restriction of Hazardous Substances (RoHS) EU Directives

No hazardous substances as defined by the RoHS directive have been added in the manufacture or the raw materials of the ReNu SU Technology cartridge.

1j. Registration, Evaluation, Authorisation of Chemicals Hazardous to Health (REACH)

Watson-Marlow Fluid Technology Group products comply with the REACH regulations. Furthermore no substances are intentionally released as a result of using our products for their intended purpose.

The ReNu SU Technology cartridge does not contain any Substance of Very High Concern (SVHC) as established by the European Commission HA Candidate list.