

COMPLIANCE SUMMARY GUIDE

Pumpsil® Issue 1



1. Regulation compliance statements

1a. Gluten

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

1b. Animal Derivative Content Free (ADCF) – Tallow/BSE/TSE

Watson Marlow works closely with our raw materials suppliers to ensure traceability of our raw materials and production process. We can confirm that Pumpsil and its raw materials are manufactured from ADCF components. As such Pumpsil is considered Animal Derivative Component Free.

1c. Melamine

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

1d. Phthalates

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

1e. Bisphenol A (BPA)

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

1f. Latex

Latex is not used in the raw material or manufacture of Pumpsil. This includes contact materials during the manufacturing process.

1g. Allergens

Pumpsil 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 finished Pumpsil product 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 Pumpsil.

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

1i. Restriction of Hazardous Substances (RoHS) Eu Directives 2002/95/EC

No hazardous substances as defined by the RoHS directive have been added in the manufacture or the raw materials of Pumpsil.

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

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

Pumpsil does not contain any Substance of Very High Concern (SVHC) as established by the European Commission HA Candidate list posted in December 2012.