General Quality Statement

Transfer Pipettes – Pastette®

ISO REGISTRATION:
ISO 9001:2015, Registration no.: FM-640638 valid until November 17th 2022
ISO 13485:2016, Registration no.: FM-640641 valid until November 17th 2022

FDA REGISTRATIONS:
Our manufacturing facilities in Mexico and the San Diego site are registered with FDA only as the manufacturer and distributor of Transfer Pipettes products (Class I Medical Devices), in compliance with current Good Manufacturing Practices (cGMP). FDA registration numbers; 3007284190 and 3006190736.

MATERIALS:
Products are produced with low density polyethylene and polypropylene resins. No latex or asbestos is used in any product or packaging of products manufactured by Alpha Laboratories Ltd. No mould release substances are used during the manufacturing of transfer pipettes.

COMPLIANCE WITH REACH AND ROHS DIRECTIVES
REACH: While we don't test the composition of our resin, based on information from our resin suppliers, we believe that our products meet the REACH directives 552/2009, 1907/2006, 197 SVHC and do not contain any SVHCs in amounts greater than 0.1% (w/w).

Restriction of Hazardous Substances (RoHS): While we don't test the composition of our resin, based on information from our resin suppliers, we believe that our products are compliant with revised RoHS directive 2011/65/EC restricting the use of Heavy Metals, PBB's, and PBDE's.

This REACH and RoHS statement does not constitute legal or business advice. This statement is provided for information purposes only; they are based upon information available at this time. Alpha Laboratories makes no warranties or representations either expressed or implied with respect to the information provided by this statement.

BSE/TSE IN RAW MATERIALS
According to the information we have received from our raw resin supplier, the LDPE resin is produced with chemicals that are synthetically derived and is free from animal derived materials, including bovine derived materials. Thus, it is free from BSE/TSE (Bovine Spongiform Encephalopathy / Transmissible Spongiform Encephalopathy).

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CALIFORNIA PROPOSITION 65
According to the information we have received from our raw resin supplier, the LDPE resin may be used in compliance with California's "Safe Drinking Water and Toxic Enforcement Act of 1986" (Proposition 65).

STERILISATION:
Alpha Laboratories certifies every lot of sterilised product. The measurement of bioburden is used to determine the applied dosage e-beam irradiation for sterilisation. The sterility of product is validated by an independent laboratory that follows the ISO11137:2006 guidelines for sterilisation validation. Upon request, Alpha Laboratories provides a certification of sterility that includes SAL (Sterility Assurance Level) and the date of irradiation. Sterility expires when the product packaging is compromised and/or sterile technique is not followed after opening.

STORAGE:
It has been determined that a large range of storage conditions are considered acceptable. Given the nature of the material used (polypropylene/polyethylene) and the type of construction/assembly of Alpha Laboratories' product, Alpha Laboratories does not currently report storage conditions on any packaging or labelling, but we recommend storage at ambient temperature.

EXPIRATION:
Alpha Laboratories does publish expiration dates on these products. A four (4) year shelf life for sterile product and a five (5) shelf life for non-sterile product. Please practice FIFO (first in, first out) to ensure that your stock is rotated properly.

QUALITY AUDITS:
Alpha Laboratories will allow customers the opportunity to audit our facilities and review quality information related to the purchased products and corresponding processes. An agreed-upon audit plan /agenda will be needed prior to the audit.

RECORD RETENTION:
Records regarding batch traceability, quality control testing and independent laboratory test results are retained per Alpha Laboratories corporate record retention policy and FDA requirements.

Certified by: _____ Date: 05 March 2020
Robert Vint, Managing Director