ThermoFisher SCIENTIFIC

November 30, 2022

GENERAL QUALITY STATEMENT – TRANSFER PIPETTES

Molecular BioProducts Inc., a part of Thermo Fisher Scientific Inc. (TFS), hereby certifies that all sterile and non-sterile products have been manufactured in accordance with established manufacturing guidelines and product specifications. The product conforms to the following quality requirements:

ISO REGISTRATION

ISO 9001:2015
Registration No.: FM 640638. Valid until November 17, 2025.

ISO 13485:2016
Registration No.: FM 640641. Valid until November 17, 2025

FDA REGISTRATION

Our facilities in Mexico and San Diego, Ca. are registered with the FDA regarding Transfer Pipettes products as Medical Devices Class I, in compliance with CGMP.

Tijuana, MX: FDA Registration #: 3006190736
San Diego, CA: FDA Registration #: 3007284190

MATERIALS

Products are produced with low density polyethylene and polypropylene resins. No latex or asbestos are intentionally used in any product or packaging material manufactured by Molecular Bio Products Inc. No mold release substances are used during the manufacturing of transfer pipettes.

COMPLIANCE WITH REACH AND RoHS DIRECTIVES

a) **REACH:** Our resin suppliers have indicated that the material they supply is complies with the REACH Directives 552/2009, 1907/2006, 197 SVHC and does not contain any SVHC in amounts greater than 0.1% (w/w).
b) **Restriction of Hazardous Substances (RoHS):** Our resin suppliers have indicated that the material they supply is complies the with revised RoHS Directive 2002/95/EC and 2011/65/EU, which restricts the use of heavy metals, PBB and PBD.

This REACH and RoHS statement does not constitute legal or business advice. It is for informational purposes only; and is based on information provided by our suppliers at the time this document was published. This compliance information is subject to change at any time.

BSE/TSE IN THE RAW MATERIALS

Our resin suppliers have indicated that the LDPE resin is produced using synthetically derived chemicals and does not contain any animal-derived materials, including BSE/TSE (Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy).

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CALIFORNIA PROPOSITION 65

Our resin suppliers have indicated that the material they supply is compliance with California's "Safe Drinking Water and Toxic Enforcement Act of 1986" (Proposition 65).

For more material declarations please contact: ROCreg.materials@thermofisher.com
Conflict Minerals Statements: Conflict.Minerals@thermofisher.com

STERILIZATION

Molecular Bio Products Inc. certifies every lot of sterilized products. Bioburden measurement is used to determine the applied dosage e-beam irradiation for sterilization. Product sterility is validated by an independent laboratory that follows ISO11137 (last revision) guidelines for sterilization validation.

The SAL level requirement may vary depending on the product requirements, the SAL level is specified on each individual COC (Certificate of Conformity).

COC can be provided upon request to Support.Info.Sandiego@thermofisher.com.

STORAGE

It has been determined that a large range of storage conditions are considered acceptable. Due to the nature of the materials used (polypropylene/high density polyethylene) and the type of construction/assembly of Molecular Bio Products Inc. product, we do not currently disclose storage conditions on any packaging or label but recommend storage at ambient temperature.

SHELF LIFE/EXPIRATION

Molecular BioProducts Inc. does not publish an expiration date on finished good labeled product. When product does not have a shelf life specified on the product label, a four(4) year shelf life from the date of manufacture is recommended.

Sterility expires sooner when sterile product packaging is compromised and/or sterile technique is not followed opening the package. Please practice FIFO (first in, first out) to ensure that your stock is rotated properly.

RECORD RETENTION

Records are maintained in accordance with Thermo Fisher Scientific's corporate record retention policy and FDA requirements. Molecular Bio Products Inc. makes no warranties or representations either express or implied with respect to the compliance information provided in this document.

- Thermo Fisher Scientific will not enter into Customer Quality Agreement and/or Quality Audits if the product(s) are classified as non-regulated catalog (non-custom) item. Thermo Fisher Scientific does have a standard response package that satisfies and answers many of the customers' queries in order to evaluate Thermo Fisher Scientific as a supplier.

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