



STATEMENT

KAROLEE POLYURETHANE SIFTER CLEANING BALLS USA AND EU COMPLIANCE WITH FDA REGULATIONS

TO WHOM IT MAY CONCERN

Subject

Base material in compliance with FDA regulations: 21 CFR 177.1680 governing repeated contact with dry foods, and FDA 21 CFR 177.2600 governing repeated contact with dry-, aqueous- and fatty foods regulation (EU) No. 10/2011 and good manufacturing practise for materials and articles intended to come into contact with food concerning commission regulation (EU) No. 2023/2006.

PRODUCT DESCRIPTION

Trade name

Karolee Polyball sifter cleaning balls.

Description

Circular spheres ranging from Ø 13 mm to Ø 50 mm, white translucent.

Material

Thermoset Polyurethane Elastomer 80° Shore A.

Statement of compliance

- 01 | Muller Beltex BV certify that the starting compounds, or monomers, that are used in moulding these prepolymers are on the list of approved and authorized monomers and exceeds the 1,000 dalton molecular point threshold for substances that can typically be absorbed into the body and therefore meet regulations CFR 177.1680, FDA 21 CFR 177.2600 and (EU) No. 10/2011.
- 02 | Muller Beltex BV certify good manufacturing practise for materials and articles intended to come into contact with food concerning commission regulation (EU) No. 2023/2006. Our supplier is an ISO 9001 certified company. Therefore, it is reasonably expected that all GMP (=Good Manufacturing Practice) criteria will be in compliance.

Muller Beltex
Authorised official,

L.M. Muller
January 2017