

Compliance Statement for ALTROPOL products with regards to FDA 21 CFR 177.2600 Rubber articles intended for repeated use

This product is compositionally compliant with FDA 21 CFR 177.2600 - substances employed in the preparation of rubber articles intended for repeated use.

Accordingly, FDA regulations for rubber articles that are intended for repeated use allow the use of the products named below, in manufacturing rubber articles that are intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food provided such articles are manufactured in accordance with other applicable FDA requirements. These requirements include the following provisions:

1. Articles are manufacturing in accordance with good manufacturing practice, e. g. EN 9000 or similar quality management schemes.
2. The quantity of any substance employed in the production of rubber articles intended for repeated use shall not exceed the amount reasonably required to accomplish the intended effect in the rubber article and shall not be intended to accomplish any effect in food.
3. Finished rubber articles intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food.
4. Rubber articles intended for repeated use in contact with aqueous food and fatty foods meet their extractive limitations as specified in FDA 21 CFR 177.2600 (c).

Prior to the use of this product for the food contact application, it is the responsibility of the fabricator to determine that the end use product conforms to the specifications and limitations of this regulation, under their specific curing and post baking conditions of use.

(See FDA 21 CFR 177.2600)

Products

RTV 20 + VN A 117 olive green; RTV 20 + VN A 87; RTV 20 + VN A 1 + VN A 2 + VN A 26 all in colorless and blue; RTV 22F + VN A 142F orange; RTV 23 + VN A 7 colorless; RTV 25 + VN A 2 blue; RTV 25 + VN A 2 colorless; RTV 25 + VN A 1 blue; RTV 26 + VN A 18 colorless and blue; RTV 230 + VN A 149; PS RTV 250 A + B; RTV 27 + VN A 43

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Managing Board

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