

REF. 610057

DATE 9 April 2021

Detectable Products for Contact with Food

Declaration of Compliance Statement

Applicable article number: 610057
Applicable Products: Reusable earplug – 2 flange – 200/pack
Available colors : Blue, red

Regulations and Standards

We confirm that the above mentioned products are suitable for use in contact with all food types and are in conformity with the applicable requirements of the following regulations and standards:

- Regulation (EC) no.1935/2004 on Materials and Articles intended to come into contact with food.
 - Commission Regulation (EU) No.10/2011 on Plastic materials intended to come into contact with food including its updates Regulation 1282/2011 and Regulation 1183/2012.
 - Regulation (EC) no. 2023/2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food.
 - Council of Europe Resolution AP 89/1 on the use of Colorants in Plastic Materials coming into contact with food.
 - US FDA 21 CFR 177.1520 (Olefin polymers) with colorants and additives cleared for use through listing in 178.3297 (Colorants for polymers), 178.2010 (antioxidants and/or stabilizers for polymers, or other respective parts of the FDA regulations.
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Migration test data obtained under short-term repeat use test conditions (6dm²/kg food) has demonstrated that levels of overall migration and specific migration of additives from these products will not exceed the legal limits with all food types.

Test Simulants:

A-C, D1, D2 of Regulation No. 10,2011 for Plastic Materials and Articles in contact with food.

Food Types:

All dry, aqueous, acidic, alcoholic and fatty foods.

Testing Condition:

2 hours at 70C, Repeat use. Test OM3 of regulation 10/2011



Dual-use food additives may be present but any migration into food will be minimal. This compliance statement is based on information supplied by the polymer and pigment manufacturers, migration testing according to Regulation 10/2011, migration modelling and quality control systems in place at manufactory.

General information (for guidance)

Usage temperature:

Maximum use temperature: 100°C

Max. wash temperature: 121°C

Minimum use temperature: Do not store at deep freeze temperature prior to use

Cleaning:

It is recommended that prior to and after use, material us cleaned, disinfected & sterilized as appropriate to their intended use (to minimize risk of microbial growth and cross contamination, maximizing their efficiency and durability)

Supporting documents are available and can be disclosed to the competent authority on request.

REACH – No substances of very high concern (SVHC) above the 0.1% weight (w/w) threshold limit are present in the materials.

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