



Declaration of Compliance

Business Operator

Vikan A/S
Rævevej 1
DK-7800 Skive
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Product Name

Mixer w/Holes, Metal Detectable, Ø31 mm, 1200 mm, Red

Item Number

70144

**Plastic Material**

Polypropylene with metal and x-ray detectable additive

Colour masterbatch

Red

EU Compliance**Regulation (EU) No 10/2011**

The monomers and additives used in the manufacture of this product are listed in Annex I to Regulation (EU) No 10/2011 of the European Parliament and of the Council of 14 January 2011 on plastic materials and articles intended to come into contact with food, as amended.

(EU) 2024/3190

The product has been manufactured and assessed in compliance with the criteria established by Regulation (EU) 2024/3190.

US FDA Compliance

All raw materials in this product are in compliance with FDA (Food and Drug Administration in the USA) 21 CFR parts 170 to 199.

The polymers and additives complies with FDA 21 CFR part 174, 175, 176, 177, 178, 181, 182, 184, or 186. Additives are cleared according to FDA 21 CFR Part 178 (Indirect food additives), are generally recognised as safe (GRAS), are prior-sanctioned food ingredients, or are cleared on basis of regulations for food additives of before 1958.

The polypropylene complies with FDA 21 CFR 177.1520 "olefin polymers".

The pigments in the masterbatch are listed under FDA 21 CFR 178.3297 „Colorants for Polymers“.

Migration analysis plastics

Samples of the product, or a similar product made from identical plastic material, have been tested for overall migration according to the test conditions specified in (EU) 10/2011 for repeated use, and the article comply with the overall migration limit of 10 mg/dm² or 60 mg/kg.

Test conditions for overall and specific migration were OM2 (10 days at 40 °C)

Food simulants used for overall migration were 10 % ethanol (simulant A), 3 % acetic acid (simulant B) and olive oil (simulant D2).

Compliance with specific migration limits, and other restrictions, has been documented through testing, calculation or simulation.

Max ratio of food contact surface area to volume 1.1 dm²/100 ml

Food contact types

The product is suitable for contact with the following types of food under the intended and foreseeable conditions of use:

- ☒ Aqueous
- ☒ Acidic
- ☒ Alcoholic
- ☒ Fatty
- ☒ Dry

Food contact usage time and temperature

Storage at room temperature or below up to 30 days, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

Non-food contact usage temperature

Minimum temperature: -20
Maximum temperature: 100

**General**

Equipment should be cleaned, disinfected and sterilised, as appropriate to its intended use, before use.

It is also important to clean, disinfect and sterilise equipment as appropriate after use, using the appropriate decontamination chemicals, concentrations, times and temperatures.

Appropriate equipment decontamination will minimise the risk of microbial growth and cross contamination and will maximise the efficiency and durability of the equipment.

Recommended sterilisation temperature (Autoclave): 121 °C

We will make the relevant background documentation available to the competent authorities, at their request.

Vikan A/S is registered with the Danish Veterinary and Food Administration (DVFA), and our mandatory Own Control System is subject to inspection by the DVFA.

The product is suitable for repeated use under the conditions specified in this Declaration of Compliance. Reuse does not affect the product's compliance with applicable food contact regulations, provided it remains intact, undamaged, and is cleaned appropriately between uses.

Date

2026-08-25

Made By

Marta Sztuka
Materials and Compliance Specialist