

## **Declaration of Compliance**

Business Operator Vikan A/S

Rævevej 1 DK-7800 Skive (+45) 96 14 26 00

Product name Mixer, Ø31 mm, 1180 mm, White

Item Number 70095

Plastic Material Polyamide (nylon), 97 %

Colour masterbatch White, 3 %

**EU Compliance** 

AP(89)1

Regulation (EC) No 1935/2004 In accordance with EU Commission Regulation no. 1935/2004 article 3, 11(5), 15 and 17

the product is intended for food contact. The product is marked with the "glass & fork"

symbol on the packaging or on the product itself through moulding.

All pigments in the masterbatch comply with resolution AP 89(1)

Regulation (EC) No 2023/2006 The product is produced according to EU Commission Regulation no. 2023/2006 of 22.

December 2006 on good manufacturing practices for materials and articles intended to

come into contact with food (GMP).

Regulation (EU) No 10/2011 Monomers and intentionally added additives used to manufacture this product are listed in Annex I of Commission Regulation (EU) No. 10/2011 of 14. January 2011 on plastic

materials and articles intended to come into contact with foodstuffs. Subsequent

amendments up to (EU) 2023/1442 are included.

Monomers and/or additives with specific migration limit (SML) are used. The substances with a SML will not migrate in quantities that will exceed the SML, under the specified conditions of use. Upon request we will supply relevant information regarding these

substances on a confidential basis.

Vikan A/S does not use multi-layer materials or articles with a functional barrier.

Regulations (EC) No 1333/2008 and (EC) No 1334/2008

This material contains intentionally added "dual use" additives for which restrictions or purity criteria are in place in accordance with Regulations (EC) 1333/2008 and (EC) 1334/2008. Upon request we will supply relevant information regarding these substances

on a confidential basis.



## **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".

**UK Compliance** The product complies with The Materials and Articles in Contact with Food (Amendment)

(EU Exit) Regulations 2019 No. 704

**Danish Compliance** The product complies with the Danish consolidation Act no. 681 of 25/05/2020.

Japanese Compliance All substances (polymers, monomers and additives) used in Vikan products comply with

Article 18(3) of the Japanese Food Sanitation Act and are listed in Tables 1 and 2 of

Appendix 1 of the Positive List.

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, and the article comply with the overall migration limit of 10 mg/dm<sup>2</sup> or 60 mg/kg.

Test conditions for overall migration were OM7 (2 h at 175 °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

2.1 dm<sup>2</sup>/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

Any food contact conditions up to 175  $\,^{\circ}\text{C}$  with aqueous, alcoholic, fatty and dry foods

for up to 1 hour.

Any food contact conditions that include heating up to 70 °C for up to 2 hours, or up to

100 °C for up to 15 minutes with acidic foods.

Non-food contact usage

temperature

Minimum temperature: -20 °C Maximum temperature: 175 °C

**General** Equipment should be cleaned, disinfected and sterilised, as appropriate to it's 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.

Date 4/18/2024

Made By

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Materials & Compliance Specialist