Fyens Børste- & Kostefabrik

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DECLARATION OF COMPLIENCE

Manufakturer: **Fyens Børste- Kostefabrik**

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Phone: +45 66143661

Product covered by this declaration: 5782-/5783-/55060-/55061-/5779-/5780-/5781-/5920-/54434-/54454-/54234-/54254-/54334-/54354-/5902-/5775-/

Product description:	Small hand brushes
Material compounds:	Polypropylene: 97% - Masterbatch: 2% - Propellant: 1%
Filament:	Polyester (PBT) filament
Cramp:	Stainless steel (AISI 304)
Date of the declaration:	11-11-2024
Colour:	This document covers all available colours at FBK

Declaration of compliance with (EU)

- This product complies with Regulation (EC) NO. 10/2011 (with amendments up to and including Commission and Regulation (EU) – Subsequent amendments up to (EU) 2020/1245 are included.
- This product complies with Regulation (EC) NO. 1935/2004 (as amended)
- This product complies with Regulation (EC) NO. 2023/2006 (as amended)
- This Masterbatch complies with resolution AP 89(1)

This brush has been produced with monomers, if other substances has been used, they are authorised under Regulation (EC) 10/2011.

A risk assessment has been used for one or more colours according to Article 19 of Regulation (EC) No. 10/2011.

Information about the compliance of substances used that are subject to any restriction or specification

Compliance with overall and specific migration limit

- The results for overall migration **are below** the threshold value of 10 mg/ dm^2.
- The results for specific migration **are below** the specific migration limit.

Dual use additives

This product contains dual use additives which has been intentionally added.

These added substances are in accordance with the Regulations:

- (EC) 1333/2008
- (EC) 1334/2008
- Pigments in the Masterbatch comply with the resolution AP 89(1)

Danish Compliance

Denmark's Ministry of the Environment and Food has issued Order No. 1248: Executive Order on Food Contact Materials (Denmark) on October 30, 2018.Denmark's Ministry of the Environment and Food has issued Order No. 1248: Executive Order on Food Contact Materials (Denmark) on October 30, 2018.

- This Product complies with the Danish consolidation Act. No 1248 of 30/10/2018

FDA Compliance

Raw material in this brush are in compliance with Food and Drug Administration (FDA):

- FDA 21 CFR, Part 170 – 199.

Dual additives and Polymers are in compliance with:

- FDA 21 CFR Part_ 174, 175, 176, 177, 178, 181, 182, 184 or 186.

Polypropylene in this product are in compliance with:

- FDA 21 CFR 177.1520

Pigments used in the Masterbatch (colour) is listed under the FDA 21 CFR 178.3297

Migration tests

Test has been made from this product or products identical to this one, which mean products containing the exact same composition as the tested product will be seen as equals.

Products has been tested for overall migration according to the test conditions set by the EU – regulations 10/2011 for which the products comply with the overall migration limit of 10mg/dm^2 or 60 mg/kg.

Overall migration test condition is OM2 (10 days at 40 ^oC)

Food simulants used for overall migration where:

- Olive oil
- 3% acetic acid
- 10% Ethanol

Products are also in compliance with test conditions of specific migration.

Restrictions has been applied trough calculation, simulation or testing.

Any documentation relating to migration test can be send upon request under strict rules that the documentation will be handle with care and not forwarded to any third party without the knowledge and acceptance from FBK.

Types of foodcontact

This product is suitable for several different types of food when used as intended and under foreseeable conditions of use.

Suitable food contact types:

- Fatty
- Alcoholic
- Aqueous
- Dry
- Acidic

We recommend that usage time, temperature of food contact condition does not exceed 80 ^{o}C for 30 minutes.

For non-food contact:

- Minimum temperature: -20 ^{o}C
- Maximum temperature: 100 ^{o}C

Before and after use

Before use:

- It is recommended to clean, disinfect and/or sterilise the article before use.

After use:

- Clean, disinfect and sterilise the article after use according to the appropriate to its intended use, using the correct chemical, concentration time and temperature.
  Sterilise in an autoclave max temp. 120^{o}C (max temp for cleaning the article 134^{o}C).
  Disinfected; tolerate all approved disinfectants

Made by

Fyens Børste- & Kostefabrik

Signed by:
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Position: Executive Assistant
Address: Teknikvej 53, 5260 Odense S, Denmark