Ipethene® 4140

Low Density Polyethylene

General Statement on Compliance with Food Contact Regulations

Based on information provided by our upstream raw material suppliers, publicly available regulatory sources, and to the best of our knowledge, we hereby declare that the above-mentioned product, as a plastic raw material intended to come into contact with food, complies with the applicable requirements of the following regulations governing materials and articles intended for food contact:

European Union

EC Regulation no. 1935/2004 on materials and articles intended to come into contact with food including all amendments up to and including **EC Regulation no. 2019/1381**.

EC Regulation no. 2023/2006 on good manufacturing practice (GMP) for materials and articles intended to come into contact with food, including all amendments up to and including **EC Regulation no. 2025/351**.

EC Regulation no. 10/2011 (PIM), on plastic materials and articles intended to come into contact with food, including all amendments up to and including **EC Regulation no. 2024/3190**.

Additional information:

- The product may contain residual levels of polymer production aids and catalysts, which may be present as impurities.
- This product does not contain substances subject to specific restrictions, including **specific migration limits (SMLs)** and **dual-use additives**.

In accordance with Regulation 10/2011/EC, the maximum allowable overall migration from finished plastic food contact articles is 60 mg/ kg food. Migration testing should be conducted using actual foodstuffs or the appropriate food simulants under the real time/temperature conditions of intended use, as specified in the regulation and its amendments.
Theoretical calculations and/or experimental testing performed on the above mentioned product or on a representative material, demonstrate that the overall migration limit of 60 mg/kg food was not exceeded under the following conditions: single-use application, 100% polymer used, thickness up to 250 µm, for any long-term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to 70°C for 2 hours or up to 100°C for 15 minutes (OM2), at food simulants A, B, and D2 demonstrating all food types.

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United States Food and Drug Administration (FDA)

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.152(a)(2)(i) and (c)2.2.

This product is suitable for food contact applications (including cooking), under conditions of use A through H as listed in 21 CFR §176.170(c), Table(*) 2, and is approved for contact with all food types listed in Table(*) 1 of the same section.

Additional information:

- The product may contain residual levels of polymer production aids and catalysts, which may be present as impurities.
- The product may contain adjuvant substances that are permitted for use in polymers intended for the manufacture of articles that come into direct contact with food and meet the requirements of their respective FDA regulations, and/or FCNs, and 21 CFR 177.1520(b).
- This product contains a polymer production aid (CAS no. 70955-14-5) listed in 21 CFR §178.3130(b), present at levels below 0.015% by weight and may be used in polypropylene articles intended for food contact, in accordance with specific conditions of use and food types.

(*) Tables referenced can be found on the FDA website:
https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

Responsibility of the Downstream User(s)

Please note that it is the responsibility of the manufacturer of the plastic food contact material and/or (semi-)finished article to follow good manufacturing practice and to follow relevant regulations.

Any potential health risks associated with the plastic food contact material and/or (semi-)finished article and compliance with both the technical and regulatory requirements of the intended application must be evaluated by its manufacturer in accordance with internationally recognized scientific principles of risk assessment. In the case of a multi-layer structure in the final article, the compliance of each individual layer with the applicable regulations and specifications must be independently verified. This declaration is based on information available at the time of issue and applies solely to the product as supplied. It does not replace the need for compliance verification under actual processing conditions and intended use.

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