

DuPure[®] R 01 NP

Polypropylene

General Statement on Compliance with Food Contact Regulations

Food contact – European Union

This product meets the relevant requirements of Regulation 1935/2004/EC, so far applicable for plastic raw materials, used for articles or components of articles intended to come into contact with food. This product is a plastic raw material for which specific measures are adopted as foreseen in article 5 of Regulation 1935/2004/EC. For plastic materials and articles, specific measures are adopted through Regulation 10/2011/EC as amended (see below).

This product is manufactured in line with the relevant requirements of Regulation 2023/2006/EC, so far applicable to plastic raw materials, on good manufacturing practice for materials and articles intended to come into contact with food.

The monomers and additives used to manufacture the above-mentioned polypropylene grade are listed in Regulation 10/2011/EC and amendments 1282/2011/EC, 1183/2012/EC, 202/2014/EC, 174/2015/EC, 1416/2016/EC, 752/2017/EC, 79/2018/EC, 213/2018/EC, 831/2018/EC, 37/2019/EC, 1338/2019/EC, 1245/2020/EC, 1442/2023/EC & 1627/2023/EC, relating to plastic materials and articles intended to come into contact with foodstuffs. This product contains one or more components which are regulated with a specific migration limit (SML). The identity of this/these component(s) can be disclosed for testing purposes, upon special request and under maintaining secrecy. Furthermore, dual use additives may be used in the formulation of the above mentioned product. The identity of those substances can also be disclosed upon special request and under maintaining secrecy.

For full compliance an overall migration limit of 10 mg/dm² and specific migration limits apply to the final article intended to come in contact with food, which shall be measured from the finished food contact article by using real food or appropriate food simulants at the time/temperature conditions as applicable, according to the rules as specified in Regulation 10/2011/EC and subsequent amendments. It is the responsibility of the converter to check and confirm that the final article meets both the technical and regulatory requirements of the application. To avoid any misunderstandings: we remind you that the manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food.

Food contact – US Food and Drug Administration (FDA)

The base resin in this product meets the FDA (Food and Drug Administration) requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(1)(i) and (c)1.1a.

This product may contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. According to our information these substances used in this product meet the requirements of their respective FDA regulations, (FCNs), and 21 CFR 177.1520(b).

This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, listed under conditions of use A through H in 21 CFR 176.170 (c), Table^(#) 2, and can be used in contact with all food types as listed in 21 CFR 176.170 (c), Table^(#) 1.

^(#) These tables can be found on the FDA website:

<https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>

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