

DECLARATION OF COMPLIANCE

Product: HD-PE LITEN MB 73

This product fulfils the requirements on plastic materials and articles intended to come into contact with foodstuffs, as described in:

EU:

Regulation (EC) No 1935/2004 of the European Parliament and of the Council,

Commission Regulations (EC) No 1895/2005, 2023/2006,

Commission Regulations (EU) No 10/2011 as amended by regulations (EU) 1282/2011, 1183/2012, 202/2014, 865/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/988, 2019/1338, 2020/1245 and Commission Implementing Regulation (EU) No 321/2011. The monomer(s) and the intentionally added additive(s) are listed in the Table 1 of Annex I of this regulation.

Indicative migration tests performed on the product on thin plate under test conditions OM5 (100°C/2 hours, migration ratio 100 cm²/100 ml in food simulants A, B and D2 and SM tests in food simulants A,B and D2 (60 °C/10 days, migration ratio 60 cm²/100 ml) show that limits are not exceeded.

The converter is thus advised to run a simulation with his own specific parameters (S/V ratio, time, temperature conditions, type of food) or perform a real migration test to verify the compliance of his own articles.

Intentionally added substances with a restriction or a Specific Migration Limit according to EU Regulation 10/2011 (SML):

Ref. No 68320, CAS 2082-79-3 with SML,

Ref. No 89040, CAS 557-05-1, (Zn salt) with SML.

This product contains the intentionally added dual use additives (Food additives/flavourings): none.

Primary Aromatic Amines are not intentionally added to this product nor expected to be present.

The SML limits set out in Table 1 of Annex II, are not exceeded. Compliance has been checked by either testing (food simulant B), modelling or assessed by calculation.

This product does not contain any intentionally added substance identified as a potential genotoxic compound that would be expected to migrate from product in excess of 0.00015 mg/kg in food or food simulant to cause genotoxic effect.

This product does not contain any Substances of Very High Concern (SVHC) or substances restricted under REACH Annex XVII in a concentration above 0.1% w/w.

Regarding composition, chemical reactions and the closed manufacturing process, we are not aware of the presence of any non-intentionally added substances (NIAS) in our product, which might subsequently be transferred into foodstuff in an amount, which could cause concern for human health

The traceability of the product is guaranteed under Article 17 of Regulation (EC) No 1935/2004 by issuing a Certificate of Inspection for each product according to EN 10204 cl. 3.1, as well as by placing an individual code on each package in case of bagged product.

USA:

FDA, CFR, Title 21 (4/2022) 177.1520 (a)(2)(i), (b) and (c) 2.1a Olefin polymers.

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Disclaimer:

End users must make their own determination that their use of our product is safe, lawful and technically suitable in their intended applications. No liability can be accepted in respect of the use of ORLEN Unipetrol RPA products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials. To fully comply with food regulations on plastic materials and articles is the responsibility of the manufacturer of final article.

