

Refining & Chemicals

Total Research & Technology Feluy
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CERTIFICATE N° 38894

Feluy, April 7, 2020

POLYPROPYLENE Aceso® PPM H250 grade as produced in Europe**Statement of compliance for food contact applications in Europe****1. Commission Regulation (EU) N° 10/2011:**

We confirm that the above-mentioned Product fulfills the harmonized requirements on plastic materials and articles intended to come into contact with food as described in the Regulation (EU) 10/2011 amended up to the Regulation (EU) 2019 1338 and can therefore be lawfully marketed and used throughout the EU, based on the principle of mutual recognition on the following elements:

- All the monomers, polymer production aids and additives used in the Product are included in the Union list in the Regulation (EU) 10/2011 amended up to the Regulation (EU) 2019/1338.
- For other substances (i.e. polymerization aids) used in the Product: they fall outside of the scope of harmonized Regulation (EU) 10/2011. According to article 19 they have been determined to be suitable for their intended use on the basis of the compliance with article 3 of the Framework Regulation (EC) N° 1935/2004 and potentially applicable national Member State Regulation (i.e. Germany – BfR ¹).

Restrictions and/or migration limits:

This Product contains no substance(s) with a specific migration limit and/or restrictions defined in Annex I of Regulation 10/2011/EU amended up to the Regulation (EU) 2019/1338 and in BfR (¹).

Experimental tests and/or theoretical calculation for migration carried out on the above mentioned Product (or a specimen representative of this material) covering long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100°C for up to 15 minutes with aqueous foodstuffs (i.e. simulants A and B) and fatty foodstuffs (Single use, polymer used at 100% and thickness up to 0.5 mm) have shown that the overall and if relevant the specific migration limit was not exceeded with aqueous foodstuffs (i.e. simulants A and B) and fatty foodstuffs including metals of annex II.

¹ Gesundheitliche Beurteilung von Kunststoffen im Rahmen des Lebensmittel- und Bedarfsgegenständegesetzes (BfR) : Empfehlung VII: Polypropylen Stand 01.09.2017 – 221 Mitteilung-B. Gesundh.BI.61(2018) 236

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For other specific conditions of use, not covered above, it pertains to downstream users to check by appropriate overall and/or specific migration tests on the final material or article the suitability for contact with different food-types and various end-use conditions. However these are beyond the control of TOTAL RESEARCH & TECHNOLOGY FELUY and are a part of the responsibility of the user of the above-mentioned Product.

We receive from some of our suppliers information regarding potential NIAS with restrictions as listed in commission Regulation (EU) N° 10/2011

We shall supply the TOTAL REFINING & CHEMICALS proprietary information needed to perform the migration measurements/analyses upon request.

For obtaining more information, please send directly an e-mail to: rc.fer-regaffairs@total.com

Dual use additive:

We inform you that the above-mentioned Product contains one or more substance(s) defined as 'dual use additive(s)'. The downstream user must contact us for additional information and you must inform the downstream user accordingly.

NIAS

Total is well aware of the legal requirements of Regulation 1935/2004/EC and 10/2011/EU, namely materials and articles coming into contact with food shall be manufactured so that they do not transfer their constituents to food in quantities that could endanger human health or bring about unacceptable change to the composition of the food. This does not only include constituents which are intentionally added but also non-intentionally added substances (NIAS)

2. Regulation (EC) N°1935/2004 of the European Parliament & of the Council (Framework Regulation)

We hereby confirm that the above-mentioned Product, when used under normal or foreseeable conditions of use, is expected to meet the relevant requirements laid down in Regulation 1935/2004/EC.

Moreover, we inform you that the organoleptic properties are influenced by the conditions of use i.e. temperature, type of packaged foodstuff, storage conditions. Consequently, the packaging has to be controlled by the downstream user following the specific end-use conditions of use.

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POLYPROPYLENE Aceso® PPM H250 grade as produced in Europe**3. Commission Regulation (EC) N° 2023/2006 (GMP)**

We inform you that the production of the above-mentioned Product is systematically reviewed with regards to good manufacturing practice (GMP) using our ISO 9001 System, and following the Plastics Europe guideline specifically dedicated to GMP.

Therefore we can state that the above-mentioned Product meets the relevant requirements laid down in Commission Regulation (EC) 2023/2006.

DISCLAIMER:

Our certificate is only valid for as far as above mentioned Product was bought from Total or its distributor and does not cover:

- Any modification of the above-mentioned Product by any addition of any other product or ingredient to it;
- Any prejudicial modification of the above-mentioned Product resulting from a processing of it;
- An inadequate use and/or storage of the above-mentioned Product and/or of the finished articles.

Unless specifically indicated in a regulatory certificate of compliance, the products mentioned herein are not suitable for applications in the pharmaceutical or medical sector. Under no circumstances are any products sold by Total Refining & Chemicals suitable for humans or animals in the following applications: (i) Implantable devices intended for human or animal body (ii) Devices intended to be used in contact with internal body fluids (iii) Devices intended to be used in contact with internal body tissues.

Information contained in this publication is true and accurate at the time of publication and to the best of our knowledge. The nominal values stated herein are obtained using laboratory test specimens. Before using one of the products mentioned herein, customers and other users should take all care in determining the suitability of such product for the intended use.

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The present certificate is valid for a period of eighteen months starting from the date first above written and replaces any earlier certificate relating on this subject which should be considered as null and void. Upon the expiration of this certificate, we can issue a new one at your request. In case of change during this period a new certificate will be issued automatically; kindly forward it to any recipient of the present certificate.

TOTAL RESEARCH & TECHNOLOGY FELUY

C. RAIMOND
Regulatory Affairs

F. RADERMACHER
Regulatory Affairs, Manager

Issued by an electronic system