

## Refining & Chemicals

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**CERTIFICATE N° 37303**

Feluy, June 12, 2017

**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) 2017/752 and its application into national laws

in Belgium :

- Arrêté Royal du 10/02/2011 amending l'Arrêté Royal du 03/07/2005.

in France :

- Arrêté du 01/04/2011 modifiant l'Arrêté du 02/01/2003

- Brochure n° 1227- édition: 15/07/2002.

in Germany :

- Bedarfsgegenständeverordnung in der Fassung vom 23. Dezember 1997 (BGBl. I 1998 S. 5), zuletzt geändert durch Art. 1 der Verordnung vom 24. Juni 2013 (BGBl. I S. 1682).

in Italy :

- Decreto Ministeriale 21/ 03/1973 and amended by Decreto Ministeriale 26/04/1993, n°220 and following updates (last update Decree of the ministry of Health of 16/02/2011).

in the Netherlands :

- Verpakkingen- en gebruiksartikelenbesluit (Warenwet) - Deel A, Hoofdstuk 1 : Kunststoffen, VGB, 44e suppl., 2016.

in Spain :

- Real Decreto 103/2009 de 06/02/2009 modifying R.D. 866/2008.

- Real Decreto 847/2011, de 17/06/2011.

in the United Kingdom :

- The Plastic Materials and Articles in Contact with Food Regulations - 2012

- England: Statutory Instruments 2012/2619

- Northern Ireland: Statutory Rules of Northern Ireland 2012/384

- Scotland: Scottish Statutory Instruments 2012/318

- Wales: Welsh Statutory Instruments 2012/2705 (W.291)

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### **POLYPROPYLENE Aceso® PPM H250 grade as produced in Europe**

#### **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) 2017/752.

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 all types of food (Single use, polymer used at 100% and thickness 0.5 mm) have shown that the overall and if relevant the specific migration limit was not exceeded with all food types including metals of Annex II.

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 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)

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**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 e.g 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.

**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 human or animal 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.

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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. The Companies within Total Refining & Chemicals do not accept any liability whatsoever arising from the use of this information or the use, application or processing of any product described herein. No information contained in this publication can be considered as a suggestion to infringe patents. The Companies disclaim any liability that may be claimed for infringement or alleged infringement of patents.

The present certificate is valid for a period of five years starting from the date first above written. 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

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Issued by an electronic system