

**Refining & Chemicals**

Total Research & Technology Feluy  
IP & Regulatory Affairs Department  
Regulatory Affairs  
Tel. : +32 (0)64 51 41 04  
Fax.: +32 (0)64 51 41 49  
petrochemicals.felr-regaffairs@total.com

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**CERTIFICATE N° 35684**

Feluy, February 25, 2015

**POLYPROPYLENE PPH 9020 grade as produced in Europe****1.STATEMENT OF COMPLIANCE FOR FOOD CONTACT APPLICATIONS :****1.1Statement of compliance for food contact in EUROPE****1.1.1 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) 2015/174 and its application into national laws

in Belgium :

- Arrêté Royal du 03/07/2005 concernant les matériaux et objets destinés à entrer en contact avec les denrées alimentaires (Moniteur Belge du 29/07/2005).
- Arrêté Royal du 10/02/2011 (Moniteur Belge du 18/02/2011) modifiant l'Arrêté Royal du 03/07/2005.

in France :

- Arrêté du 01/04/2011 modifiant l'Arrêté du 02/01/2003 relatif aux matériaux et objets en matière plastique mis ou destinés à être mis au contact avec les denrées, produits et boissons alimentaires.
- Autres textes relatifs aux matières plastiques (circulaires, lettres-circulaires, instructions etc.) de la Répression des Fraudes et contrôle de la qualité regroupés dans la brochure n° 1227 du journal officiel : "Matériaux au contact des aliments et denrées destinées à l'alimentation humaine" - 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).

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in Italy :

- Decreto Ministeriale 21/ 03/1973 (G.U. n° 104 - 20/4/1973) Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale as amended by Decree of the Ministry of Health N° 270 of 12/12/2007 (G.U. N° 33- 08/02/2008).
- Decreto Ministeriale 26/04/1993, n°220 (G.U. n° 162 - 13/7/1993) Regolamento recante aggiornamento del decreto ministeriale 21/03/1973, concernente la disciplina igienica degli imballaggi, recipienti, utensili destinati a venire in contatto con le sostanze alimentari e con sostanze d'uso personale as updated up to Aggiornamento del Decreto ministeriale 21 marzo 1973, concernente la disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale. Recepimento della direttiva 2011/8/UE (materia plastiche) (Decree of the Ministry of Health of 16/02/2011 (G.U. N° 63 del 18/03/2011).

in the Netherlands :

- Verpakkingen- en gebruiksartikelenbesluit (Warenwet) - Deel A, Hoofdstuk 1 : Kunststoffen, VGB, 39e suppl., December 2013.

in Spain :

- Real Decreto 866/2008 de 23/05/2008 (B.O.E de 30/05/2008), por el que se aprueba la lista de sustancias permitidas para la fabricación de materiales y objetos plásticos destinados a entrar en contacto con los alimentos y se regulan determinadas condiciones de ensayo (corrigendum (BOE de 07/06/2008).
- Real Decreto 103/2009 de 06/02/2009 as updated to R.D. 866/2008 (B.O.E de 17/02/2009).
- Resoluciones del Ministerio de Sanidad de 04.11.1982 (B.O.E. n° 282 de 24.11.1982) modified by Orden del Ministerio de Sanidad y consumo de 03.07.1985 (B.O.E. n° 166 de 12.07.1985) .
- Real Decreto 847/2011, de 17 de junio, por el que se establece la lista positiva de sustancias permitidas para la fabricación de materiales poliméricos destinados a entrar en contacto con los alimentos. (BOE de 11/07/2011).

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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)

**Conditions:**

- Overall Migration Limit:

According to Regulation (EU) 10/2011 (Annex III and Annex V) , the overall migration limit, for which a maximum value of 10 mg/dm<sup>2</sup> or 60 mg/kg is set ( Regulation (EU) 10/2011 , article 12) , has to be controlled on the finished articles intended to come into contact with foodstuffs; consequently it is the responsibility of the downstream user of the above-mentioned Product.

We inform you that some overall migration tests according to EN 1186-1, EN 1186-3 and EN 1186-14 were carried out on the Product (or a specimen representative of this material ) ( 100%)-single use conditions –

contact period : 10 days at 40°C– overall migration limit : 10 mg/dm<sup>2</sup>. i) 3% acetic acid (w/v) in aqueous solution (sheet 0.5 mm ) - < 1 mg/dm<sup>2</sup>– passed –ii) 10% ethanol (v/v) in aqueous solution (sheet 0.5 mm ) – < 1 mg/dm<sup>2</sup> - passed- iii) olive oil (sheet 0.5 mm) – 2 mg/dm<sup>2</sup> – passed –

The here above standardised testing condition is intended for the following food contact conditions : a 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- thickness 0.5 mm)

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contact period : 2 hours at 100°C – overall migration limit : 10 mg/dm<sup>2</sup>. i) olive oil (sheet 0.5 mm) – 6 mg/dm<sup>2</sup> – passed.

The here above standardised testing condition is intended for the following food contact conditions: high temperature applications up to 121 °C with food with lipophilic character. (single use- thickness 0.5 mm)

Moreover we inform you that the overall migration result is influenced by the conditions of use e.g. temperature, type of packaged foodstuff (fatty food, aqueous food, thickness). Consequently the packaging has to be controlled following the specific end-use conditions of use as described in Regulation (EU) 10/2011 (Annex III and Annex V).

- Specific Migration Limit(s) and/or other restrictions :

1. Restriction for Monomer <sup>a)</sup>: no
2. Restriction for Additive(s) <sup>b)</sup>: no.
3. Restriction for polymer production aids and/or aids to polymerisation: yes

We inform you that certain experimental tests and/or theoretical calculation for specific migration were carried out on the above mentioned Product ( or a specimen representative of this material) (used at 100%) – thickness of the sheet 250 µm – contact period 10 days at 60 °C – in the four standard food simulants- Passed.

The here above standardised condition is intended for the following food contact conditions : for 10 days at 60°C covers long storage times above 6 months at room temperature and 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- thickness 250 µm )

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For other specific conditions of use, it pertains to downstream users to check by appropriate 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 upon request. The downstream user must contact us for additional information, and you must inform too downstream users accordingly.

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.

**1.1.2 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, meets the relevant requirements laid down in Regulation 1935/2004/EC.

We inform you that some sensory tests according to DIN 10955 were carried out on the above-mentioned Product (or a specimen representative of this material) (100%) in the following BfR conditions of test- water, (sheet 1 mm ; ratio 6 dm<sup>2</sup>/l) - 10 days at 40°C days – passed.

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The here above standardised condition is intended for the following food contact conditions:  
covers a long-term contact at 40°C valid for mineral water and refreshing drink bottles.(single use – thickness 1 mm )

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.

**1.1.3 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.

**1.2 Statement of compliance for food contact in the UNITED STATES OF AMERICA**

- Code of Federal Regulations, Food and Drugs (FDA) Title 21- 2014 - §177.1520 : Olefins Polymers; For PPH : (a) (1) (i), (b) and (c) item 1.1a, §176.170(c), Food Types I through IX of Table 1, under conditions of use A through H of Table 2 .

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**POLYPROPYLENE PPH 9020 grade as produced in Europe****1.3 General use conditions (food contact) :**

It pertains to downstream users of materials intended to come into contact with food, to ensure that the final materials or articles do not bring about an unacceptable change in the composition of the food, or bring about a deterioration in the organoleptic characteristics which render it unfit.

For other specific conditions of use not covered in the DoC (Declaration of Compliance) (item 1), it pertains to downstream users to check by appropriate migration tests on the final material or article the suitability for contact with different food-types and various end-use conditions. For high temperature applications tests shall be carried out under the worst foreseeable conditions of use in which physical or other changes do not take place. The maximum testing temperature is governed by the phase transition temperature of the polymer.

**2. STATEMENT OF COMPLIANCE FOR TOYS - EUROPEAN STANDARDS EN 71- 3.1994 and EN 71- 9.2005 :**

We hereby confirm that the above-mentioned Product meets the relevant requirements of European Standards EN 71-3 1994, its amendment EN 71- 3/ A1 2000, its corrigendum AC: 2002 entitled "Safety of Toys - Part 3 : Migration of certain elements" and EN 71-9, September 2005 "Organic chemical compounds- requirements".

The above-mentioned Product meets this standard because every time analyses were performed on this product, results were below the prescribed limits.

**3. STATEMENT OF NO COMPLIANCE WITH EUROPEAN PHARMACOPOEIA :**

We **DO NOT** certify that the above-mentioned Product would comply with the European Pharmacopoeia.

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**POLYPROPYLENE PPH 9020 grade as produced in Europe****4. STATEMENT OF NO COMPLIANCE WITH UNITED STATES PHARMACOPOEIA :**

We **DO NOT** certify that the above-mentioned Product would comply with the United States Pharmacopoeia.

**5. STATEMENT OF NO COMPLIANCE WITH CANADIAN PHARMACOPOEIA:**

The above-mentioned Product has **NOT** a DMF in Canada.

**6. STATEMENT OF TRANSMISSIBLE BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) :**

We hereby confirm that we did receive an indication from our suppliers of additives used in the above-mentioned Product mentioning the absence of any substances which are of animal origin.

Based on the above, we are confident that the above-mentioned Product is free of SRM (Specified Risk Materials).

**7. STATEMENT OF GENETICALLY MODIFIED ORGANISMS (GMO).**

We hereby confirm that we did receive an indication from our current additive suppliers.

- 1) The majority of additives <sup>b)</sup> used in the above-mentioned Product are not GMO derived
- 2) Whilst the others derive from Genetically Modified Organism (GMO).

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**POLYPROPYLENE PPH 9020 grade as produced in Europe****8. STATEMENT OF INVENTORIES:**

We declare that the monomers <sup>a)</sup> and, if present, the additives <sup>b)</sup> of the above-mentioned Product are listed or exempted from listing on the inventories of the following countries:

- Australia: AICS (Australian Inventory of Chemical Substances)
- China: IECSC (Inventory of Existing Chemical Substances Manufactured or Imported in China)
- Canada: DSL (Domestic Substances List) and NDSL (Non Domestic Substances List)
- Europe: EINECS AND/OR ELINCS (Replaced by REACH)
- Japan: ENCS (Japanese inventory of Existing and New Chemical Substances)
- Korea: KECL (Korean Existing Chemicals List)
- New Zealand: TSA (Toxic Substances Act)
- The Philippines: PICCS (Philippines Inventory of Chemicals and Chemical Substances)
- United States: TSCA (Toxic Substances Control Act Inventory)

**NOTE :**

<sup>a)</sup> Monomer as defined in the Regulation (EU) 10/2011.

<sup>b)</sup> Additive as defined in the Regulation (EU) 10/2011.

**DISCLAIMER :**

Our certificate 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.

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### **POLYPROPYLENE PPH 9020 grade as produced in Europe**

The present certificate is valid for a period of eighteen months 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

C. RAIMOND  
Regulatory Affairs

F. WYLIN  
Regulatory Affairs, Manager

Issued by an electronic system

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**Total Research & Technology Feluy**  
Zone Industrielle Feluy C – B-7181 Seneffe – Belgique.  
Tel. : +32 (0)64 51 41 11  
Fax.: +32 (0)64 54 08 45  
E-mail: research-feluy@total.com