website: www.totalpetrochemicals.biz

Polypropylene PPR 3221

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For other Regulations, please consult our Product Stewardship Certificate available on this website. We have included in our Polypropylene Product Stewardship Certificate the conformity to a number of regulations whenever it could be certified for all our European polypropylene products.

In case you might need additional technical or regulatory information, please contact your sales representative.

Technical data sheet
Polypropylene – Random Copolymer
Produced in Europe

Description

Polypropylene PPR 3221 is a high clarity, high impact resistance random copolymer especially designed for blow molding applications (mono and multi-layers) for food and non-food packaging of sauces, detergents and soaps, cosmetics and for sheets extrusion.

Characteristics

	Method	Unit	Typical Value
Rheological properties			
Melt Flow Index 230°C/2.16 kg	ISO 1133	g/10 min	1.8
Mechanical properties			
Elongation at Yield	ISO 527-2	%	<15
Flexural modulus	ISO 178	MPa	900
Izod Impact Strength (notched) at 23°C	ISO 180	kJ/m²	
at 23°C			22
at 0°C			3.6
Hardness Rockwell - R-scale	ISO 2039-2		82
Thermal properties			
Vicat Softening Point	ISO 306	°C	
50N-50°C per hour			67
10N-50°C per hour			130
Other physical properties			
Density	ISO 1183	g/cm³	0.902
Bulk Density	ISO 1183	g/cm ³	0.525

Safety and Product Stewardship

For safe use and handling, please refer to the Safety Data Sheet.

A Product Stewardship certificate giving the conformity to various regulations or statements on absence of certain chemicals is also availableon our web site www.polypropylene.totalpetrochemicals.com

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Rev: March 09

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STATEMENT OF COMPLIANCE FOR FOOD CONTACT APPLICATIONS:

In the EUROPEAN UNION

We confirm that the above-mentioned Product fulfils the harmonised requirements on materials used for articles or components of articles intended to come into contact with food as described in the European Directive 2002/72/EC amended by Directives 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC and its transposition into national laws as incorporated in the following contact regulations:

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 05/07/2006 (Moniteur Belge du 07/09/2006) modifiant l'Arrêté Royal du 3/07/2005.

in France:

- Décret Ministériel n° 73-138 du 12/02/73 et n° 2007-766 du 10/05/2007 ainsi que les lettres circulaires de la Répression des Fraudes et contrôle de la qualité (Recueil de textes: brochure n° 1227 "Matériaux au contact des aliments et denrées destinées à l'alimentation humaine" dernière édition: 15/07/2002);
- Instruction relative à l'emploi d'additifs dans les matières plastiques au contact des denrées alimentaires (Bulletin Officiel de la concurrence, de la consommation et de la répression des fraudes du 11/08/93):
- Arrêté du 19/10/2006 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.

in Germany:

- Gesundheitliche Beurteilung von Kunststoffen im Rahmen des Lebensmittel- und Bedarfsgegenständegesetzes (BfR): Empfehlung VII: Polypropylen Stand 01.06.2007 - 210 Mitteilung - B. Gesundh. Bl. 50 (2007) 1470,
- Bedarfsgegenständeverordnung (BGV) vom 23. Dezember 1997 (BGBI.I 1998 S. 5) und Änderung vom 16. Juni 2008 (BGBI. I S. 1170)

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in Italv

- Decreto Ministeriale 21/03/1973 (G.U. n° 104 20/4/1973) Disciplina igienica degli imballaggi, recipienti, ustensili, 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°411 of 1/12/2000 (G.U. N°11-15/01/2001)
- 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 imballagi, reciepienti, ustensili destinati a venire in contatto con le sostanze alimentari e con sostanze d'uso personale as updated up to D.M.H n° 82 of 18/04/2007 (G.U. N°151 02/07/2007).

in the Netherlands:

 Verpakkingen- en gebruiksartikelenbesluit (Warenwet) - Deel A, Hoofdstuk 1 : Kunststoffen, VGB, 27e suppl., December 2008.

in Spain:

- Orden SCO/ 983/ 2003 de 15 de abril (B.O.E. nº 99 de 25/04/2003) .
- Resoluciones del Ministerio de Sanidad de 04.11.1982 (B.O.E. nº 282 de 24.11.1982).
- Orden del Ministerio de Sanidad de 03.07.1985 (B.O.E. nº 166 de 12.07.1985).
- Real Decreto 2207/1994 de 16/11/1994 as updated to R.D. 442/2001.
- Real Decreto 118/2003 de 31/01/2003 as updated to R.D. 866/2008.

in the United kingdom:

- The Plastic Materials and Articles in Contact with Food Regulations 2008
- England: Statutory Instruments 2008/916
- Northern Ireland: Statutory Rules 2008/167
- Scotland: Statutory Instruments 2008/127
- Wales: Statutory Instruments 2008/1237 (W.124)

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Conditions:

- Regarding overall migration:

According to the Directives 82/711/EEC (and its amendments 93/8/EEC and 97/48/EEC), 85/572/EEC and 2002/72/EC, the overall migration limit, for which a maximum value of 10 mg/dm2 or 60 mg/kg is set (Directive 2002/72/EC, article 2), has to be controlled on the finished articles intended to come into contact with foodstuffs; consequently it is the responsibility of the end-user of the above-mentioned Product.

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

Restriction for Monomer a): none

Restriction for Additive(s) b):

We shall supply the TOTAL PETROCHEMICALS proprietary information needed to perform the migration measurements upon request.

The end-user must contact us for additional information, and you must inform the end-user accordingly.

It pertains also to end-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 PETROCHEMICALS RESEARCH FELUY and are a part of the responsibility of the user of the above-mentioned Product.

European Directive 2004/19/EC and its transposition into national laws.

We inform you that we do not use food additives as authorized by and subject to a restriction in the European Directive 89/107/EC and/or flavorings as authorized by the European Directive 88/388/EC during the manufacturing of the above-mentioned Product. However, since we do not perform specific tests to verify the potential presence of any of these food additives, we cannot guarantee that there is no trace amount of some of these substances, as impurity or otherwise, in the above-mentioned Product.

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REGULATION 1935/2004/EC

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.

REGULATION 2023/2006/EC (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 Regulation 2023/2006/EC.

in the UNITED STATES OF AMERICA:

- Code of Federal Regulations Food and Drugs Title 21- 2007- §177.1520: Olefins Polymers; For PPR: § 177.1520 (a) (3) (i) (c) (1) and (c) 3.1a. This product meets the criteria in § 176.170 (c) and the finished polymers may be used in contact with food of types I, II, IV-B, VI-B, VII-B and VIII as described in table 1 under conditions of use B through H as described in table 2 of §176.170(c) and/or with food of types III, IV-A, V, VI-A, VI-B, VI-C, VII-A and IX described in table 1 of §176.170(c) under conditions of use C through G as described in table 2 of §176.170(c) of this chapter.

GENERAL USE CONDITIONS:

it pertains to end-users of materials intended to come into contact with food, to ensure that the material does 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.

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STATEMENT ON TOYS - EUROPEAN STANDARD EN 71- 3.1994 and EN 71- 9.2005 :

We hereby confirm that the above-mentioned Product meets the requirements of European Standard EN 71-3 1994 its amendment EN 71-3/A1 2000 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.

STATEMENT ON NO COMPLIANCE WITH EUROPEAN PHARMACOPOEIA:

We **DO NOT** certify that the above-mentioned product would comply with the European pharmacopoeia.

STATEMENT ON NO COMPLIANCE WITH UNITED STATES PHARMACOPOEIA:

The above-mentioned product is **NOT** in compliance with the US pharmacopoeia because we **DID NOT** perform the required tests.

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STATEMENT ON TRANSMISSIBLE BOVINE SPONGIFORM ENCEPHALOPATHY (BSE):

Our suppliers provided us with documents addressing potential BSE/TSE concerns for additives which might be used in the above-mentioned Product and may themselves be derived from tallow/lard, or contain components derived from tallow/lard (tallow derivatives). Based on our supplier documentation and/or our own evaluation, we can confirm the following:

- 1) While Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSE) does <u>not</u> apply to components of packaging materials, we can confirm that none of the components potentially present in the above-mentioned Product qualify as Specified Risk Materials (SRMs) under said Regulation.
- 2) While Regulation (EC) No 1774/2002 laying down health rules concerning animal by-products not intended for human consumption does <u>not</u> apply to tallow derivative components themselves, which do not qualify as animal by-products subject to the Regulation, we can confirm that any animal by-product used to manufacture the tallow from which tallow derivative components in the above-mentioned Product are derived are exclusively Category 3 materials processed in compliance with said Regulation.
- 3) The tallow derivatives potentially present in the above-mentioned Product comply with the requirements of Section 6-4 ("Tallow derivatives") of Chapter 5.2.8 of the European Pharmacopoeia ("Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products") and the guidance document baring the same name issued by the European Medicines Agency (EMEA/410/01 Rev2 October 2003) and given the force of law by Directives 2001/82/EC and 2001/83/EC. We note that European Pharmacopoeia Chapter 5.2.8 is identical to the EMEA guidance document.

STATEMENT ON INVENTORIES:

We declare that the monomers and, if present, the additives ^{b)} of the above-mentioned Product are listed or exempted from listing on:

AICS, ECL, EINECS AND/OR ELINCS, ENCS, IECSC and TSCA.

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NOTE:

- a) Monomer as defined in the EC Directive 2002/72/EC up to 2008/39/EC.
- b) Additive as defined in the EC Directive 2002/72/EC up to 2008/39/EC.

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.

The present certificate is valid until end 2009. 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 PETROCHEMICALS RESEARCH FELUY

C. RAIMOND Regulatory Affairs

F. WYLIN Regulatory Affairs, Manager

Issued by an electronic system

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