

## Certificate of conformity

### HDPE 52518 (JAM Petrochemical)

Certificate N°: 2010A024 (under testing/certification by PIRA labs (UK))

Date of issue: estimated date of completion 2010.08.01

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For any additional technical or regulatory information, please contact your sales representative.

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## Statements of compliance

### **1. Food contact applications**

It is the responsibility of our customers to check if the materials supplied by PCC and articles made out of it are suitable for the intended use and comply with all applicable regulations and requirements.

#### **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, 2008/72/EC and its transposition into national laws as incorporated in the following contact regulations:

in AT:

- Kunststoffverordnung (KVO), BGBl. II Nr. 476/2003 of 14/10/2003. Änderung der Kunststoffverordnung 2003 BGBl. II Nr. 242/2005 of 01.08.2005. Grade-specific approval of the «Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH.»

in BE:

- Arrêté Royal du 02/07/2005 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 03/07/2005.

in BG: refer to EC (page 5)

in CH:

- Bundesgesetz über Lebensmittel und Gebrauchsgegenstände (Lebensmittelgesetz, LMG). Status: März 2004.
- Verordnung des EDI über Materialien und Gegenstände aus Kunststoff (Kunststoffverordnung, KsV). Status Januar 2004.
- Non-objection letter of the Federal Office for Public Health (Bundesamt für Gesundheitswesen).

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in CZ: refer to EC (page 5)

in DE:

- 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 vom 10. April 1992 (BGBl.I.S.866) und Änderungen vom 11. April 1993 (BGBl. I. S.1886), vom 7. April 2003 (BGBl.I.S.486) und vom 6. September 2005 (BGBl.I.S.2618).

in DK:

- Fødevarestyrelsens Bekendtgørelse nr. 426 af 10/05/2006 om materialer og genstande bestemt til kontakt med fødevarer. Ministeriet for Familie- og Forbrugeranliggender.

in FI:

- Kauppa- ja teollisuusministeriön asetus elintarvikkeen kanssa kosketukseen joutuvista muivisista tarvikkeista (953/2002) 12.11.2002.
- Kauppa- ja teollisuusministeriön asetus 141/2005, 25.02.2005 elintarvikkeen kanssa kosketukseen joutuvista muovisista tarvikkeista.
- Kauppa- ja teollisuusministeriön asetus 181/2005, 10.03.2005 elintarvikkeen kanssa kosketukseen joutuvista muovisista tarvikkeista.

in FR:

- 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 11/08/2002);
- 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 IT:

- Decreto Ministeriale 21/03/1973 (G.U. n° 104 – 20/04/1973) Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto

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con le sostanze alimentari o con sostanze d'uso personale as amended by Decree of the Ministry of Health n° 411 of 01/12/2000 (G.U. n° 11-15/012001)

- Decreto Ministeriale 26/04/1993, n° 220 (G.U. n° 162 – 13/07/1993) 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 D.M.H n° 82 of 18/04/2007 (G.U. n° 151 – 02/07/2007).

in NL:

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

in NO:

- Forskrift om materialer og gjenstander i kontakt med næringsmidler.

in PL: refer to EC (page 5)

in RO: refer to EC (page 5)

in SI: refer to EC (page 5)

in ES:

- Orden SCO/983/2003 de 15 de abril (B.O.E. n° 99 de 25/04/2003).
- Resoluciones del Ministerio de Sanidad de 04.11.1982 (B.O.E. n° 282 de 24.11.1982).
- Orden del Ministerio de Sinidad de 03.07.1985 (B.O.E. n° 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 SE:

- Statens livsmedelsverks kungörelse om ändring i kungörelsen (SLV FS 1993:18) med föreskrifter och allmänna råd om material och produkter avsedda att komma i kontakt med livsmedel.

in UK:

- The Plastic Materials and Articles in Contact with Food Regulations – 2008

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- England: Statutory Instruments 2008/916
  - Northern Ireland: Statutory Rules 2008/167
  - Scotland: Statutory Instruments 2008/127
  - Wales: Statutory Instruments 2008/1237 (W.124)

**EC:**

- EC Commission Directive 2002/72/EC of August 6, 2002, as amended by 2004/1/EC, 2004/19/EC, 2005/79/EC and 2008/39/EC of March 6, 2008.
- This material contains no monomers which are regulated with a specific migration limit.
- This material contains no additives which are regulated with a specific migration limit.
- This material does not contain intentionally added dual use additives which are subject to disclosure of adequate information as described in Annex VIa of Directive 2007/19/EC.
- This material has been manufactured in accordance with the relevant requirements of Commission Regulations EC No. 2023/2006 on good manufacturing practice of materials and articles intended to come into contact with food.
- Migration estimates calculated with an EU recognised mathematic migration model or migration experiments with test samples and carried out in the presence of the standard food stimulants during 10 days at 40°C, have shown that under these conditions migration limits were not exceeded: With non-fatty food (according to tests with water, 3% acetic acid and 10% ethanol as food stimulants) and with all types of fatty food (according to EC Council Directive 85/572/EEC).

**1.1. Note on Additives**

**SML (Specific Migration Limits)**

The above polymer grade does contain some additives that are listed in Annex III Section B of the EC Directive 2002/72/EC, as amended up to EC Directive 2007/19/EC and that are subject to a Specific Migration Limit (SML).

However, be informed, that for SML-subjected additives listed in Annex III Section B the verification of compliance with the specific migration limits in stimulant D or in test media of substitute tests as laid down in Article 3(1), second subparagraph of Directive 82/711/EEC – as amended – and Article 1 of Directive 85/572/EEC shall apply from 1<sup>st</sup> April 2008.

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### **OML (Overall Migration Limits)**

According to the Directives 82/711/ECC (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 10mg/dm<sup>2</sup> 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.

Typical samples produced from this resin have been tested against OML using standards B.C. & D., in exposure condition of 10 days at 40°C. These tests met the requirements that OML specify in 2002/72/EC.

Restriction for Monomer: none

Restriction for Additives: none

#### **1.2. Directive (EC) 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs**

We inform you, that the above-mentioned product contains one or more food additives authorised and subject of a use restriction in food under Directive 95/2/EC. We received from the concerned additives suppliers' information demonstrating, that applicable restriction in food under Directive 95/2/EC will be met in the finished products. The end-user must contact us for additional information, and you must inform the end-user accordingly.

#### **1.3. Regulation (EC) 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC**

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.

#### **1.4. Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice (GMP) for materials and articles intended to come into contact with food**

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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.

**1.5. Directive (EC) 94/62/EC of 20 December 1994 on packaging and packaging waste (incl. Heavy Metals)**

This product conforms to the Coalition of North-Eastern Governors (CONEG) and the European Directive 94/62/EC, as amended, on Packaging and Packaging Waste, Article 11. Any incidental levels of lead, cadmium hexavalent chromium, and mercury do not exceed 100 ppm total.

**1.6. In the United States of America (FDA)**

According to Food and Drug Administration (FDA) code paragraph 21 CFR 177.1520 (olefin polymers), extraction experiments with test samples have shown that extraction limits specified for use in articles used for packing or holding food during cooking (specification 177.1520 §3.2a) were not exceeded.

The additives are cleared according to Part 178 (indirect food additives) or are generally recognized as safe, or are prior-sanctioned food additives.

**1.7. Statement on transmissible Bovine Spongiform Encephalopathy (BSE)**

Our suppliers have 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:

- 1.7.1** While Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathy (TSE) does not 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.

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**1.7.2** While Regulation (EC) No 1774/2002 laying down health rules concerning animal by-products not intended for human consumption does not 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 products are derived are exclusively Category 3 materials processed in compliance with said regulation.

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 Pharmacopeia ("Minimising the Risk of Transmitting Animal Spongiform Encephalopathy same name issued by the European Medicines Agency (EMA/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 EMA guidance document.

## **1.8 Consumer Product Safety Improvement Act of 2008 (CPSIA)**

This product is not manufactured or formulated with lead, di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). To the best of our knowledge, it does not contain these materials above the limits set in the Consumer Product Safety Improvement Act of 2008, Title 1, Sections 101 and 108.

### **1.8.1 Phthalate Esters**

The above mentioned products are not intentionally manufactured or formulated with phthalate esters; however, we do not analyze for these specific substances or compounds.

### **1.8.2 Bisphenol A**

This product is not manufactured or formulated with Bisphenol A (CAS# 80-05-7).

### **1.8.3 Fluorotelomers, Perfluorooctanoic acid (PFOA) and Derivatives**

This product is not intentionally manufactured or formulated with Fluorotelomers, Perfluorooctanoic acid (PFOA), or Perfluorooctane sulfonate (PFOS); however, we do not analyze for these specific substances or compounds.

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## **1.9 Statement on Genetically Modified Organisms (GMO)**

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 Genetically Modified Organisms (GMO).

### **1.10 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 deterioration in the organoleptic characteristics which render it unfit.

## **2. Disclaimer of compliance in Pharmacopoeia**

### **2.1 European Pharmacopoeia**

We do not certify that the above-mentioned product would comply with the European pharmacopoeia.

### **2.2 United States Pharmacopoeia**

As the required tests were not performed, the above-mentioned product cannot be confirmed as in compliance with US pharmacopoeia.

## **3. Statement on toys – European Standard EN 71-3.1994 and EN 71-9.2005 (ASTM F 963-95)**

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 – Pat 3: Migration of certain elements" and EN 71-9, September 2005 "Organic chemical compounds – requirements". This product is not formulated with antimony, arsenic, barium, cadmium, chromium, mercury, lead or selenium.

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

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#### **4. Statement on inventories**

We declare that the monomers and, if present, the additives of the above-mentioned product are AICS, DSL, ECL, EINECS and/or ELINCS, IECSC, IECSC, PICCS and TSCA.

**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.*

#### **5. Classification, labelling and packaging of dangerous substances (CLP)**

Classification, packaging and labelling of dangerous substances and preparations is harmonized in order to protect health and the environment and ensure the free movement of such products. The provisions on classification, packaging and labelling of dangerous substances and preparations have been amended with the entry into force of the new Regulation (EC) No 1272/2008 and the creation of the European Chemicals Agency

##### **5.1. Safety Data Sheet (SDS)**

Current SDS are available on <http://www.petrochem-ir.net/product-en.html>

##### **5.2. Labelling (under preparation)**

##### **5.3. Iconograms (under preparation)**

##### **5.4. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)**

PCC confirms officially, via the appointed Only-Representative, PCC UK compliance with the European REACH regulation (1907/2006/EC) [which includes pre-registration with the firm intention to carry out registration (evaluation and authorisation) of those chemicals subject to REACH].

PCC also confirms compliance to the Chemicals Agency (ECHA), on request of the European Commission, may prepare Annex XV dossiers for Substances of Very High Concern (SVHC), as defined in Article 57 of Regulation (EC) No 1907/2006.

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This product is not manufactured or formulated with any of the Substances of Very High Concern (SVHC) as per the candidate list that was current as of the effective date of this certificate of conformity.

## 6. RoHS

This product complies with the requirements of Article 4.1 of EU Directive 2002/95/EC (RoHS), as amended; it is not intentionally manufactured or formulated with cadmium, lead, mercury, polybrominated biphenyls, or polybrominated biphenyl ethers and is not expected to contain hexavalent chromium.



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### Disclaimer

We wish to stress that the migration- and extraction- test results may differ significantly from the performance of the final plastic material or article under the actual and foreseeable conditions of use.

It is the responsibility of the converter or food packager that markets the final material or article to guarantee its compliance under actual and foreseeable conditions of use, and to check it on a regular basis.

The recommendations or regulations mentioned above refer to the final materials and articles that directly contact the food.

This declaration however, is restricted to PCC as it leaves the production facilities.

This declaration does not cover:

- any substance subsequently added by the converter
- poor material or end product due to inexpert manufacture by the converter
- any negative influence of the finished article on the organoleptic properties of the packaged food

We therefore advise the receivers to obtain an updated declaration periodically.

This declaration replaces all previous ones relating to this subject.

### Validity

The present certificate is valid for a period of 2 years from issue date. 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.

Petrochemical Commercial Company (PCC)

*M. J. Rahimi*



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