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R.E.A. FC n. 233925  
C. F./Reg. Imp. 09211800157  
socio unico Freedom SPA

Forlì, 27/01/10

Oggetto: Idoneità Alimentare

In accordo con quanto dichiarato dai nostri fornitori, le materie prime utilizzate nella produzione del seguente compound:

**LAPRENE 83F000969**

rispettano i requisiti stabiliti dalla Direttiva Europea 2002/72/CE e successivi aggiornamenti fino al 2008/39/CE. La lavorazione di materiali presso So.F.Ter. avviene al meglio delle nostre capacità e delle nostre conoscenze al fine di assicurare una qualità costante della produzione.

I prodotti/articoli plastici finiti destinati al contatto con alimenti realizzati o contenenti il prodotto in oggetto, devono essere conformi al limite complessivo di migrazione (OML) e, come previsto dalla direttiva 2002/72/CE, la migrazione dovrebbe essere misurata sugli articoli finiti messi a contatto con l'alimento o con prodotti simulanti appropriati per un periodo e ad una temperatura scelti in riferimento alle condizioni di contatto nell'uso effettivo in conformità alle regole contenute nelle direttive UE 97/48/CE (emendamento 82/711/CEE) e 85/572/CEE.

Questa responsabilità è a carico dei produttori di manufatti o componenti di manufatti fabbricati con (o contenenti) il compound in oggetto.

**SO.F.TER SPA**

*Dr. Bellomo Leonardo*  
*Manager of Research Center*



Certificate n. 890 concerning the design, production and sale of Technical Thermoplastic Elastomers (TPE Division) and Engineering Thermoplastics (ETP Division).  
Certificazione n. 890 relativa alla progettazione, produzione e vendita di Elastomeri Termoplastici Tecnici (div. TPE) e Tecnopolimeri (div. ETP).



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Forlì, 19/05/09

Oggetto: Idoneità Alimentare

In accordo con quanto dichiarato dai nostri fornitori, le materie prime utilizzate nella produzione del seguente compound:

**LAPRENE 83F000969**

rispettano i requisiti stabiliti dalla “Food and Drug Administration” General regulation ed in particolare:

FDA 21 CFR 177.1520 (a) (c)

FDA 21 CFR 177.1810 (b) (3)

FDA 21 CFR 172.878

La lavorazione di materiali presso So.F.Ter. avviene al meglio delle nostre capacità e delle nostre conoscenze al fine di assicurare una qualità costante della produzione.

I produttori di manufatti o componenti di manufatti fabbricati con o contenenti i compounds in oggetto devono assicurarsi che i prodotti finiti soddisfino tutte le leggi, direttive e norme vigenti e che i manufatti stessi non portino a cambiamenti inaccettabili alla composizione dell’ alimento o al deterioramento delle caratteristiche organolettiche.

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*Dr. Bellomo Leonardo*  
*Manager of Research Center*



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produzione e vendita di Elastomeri Termoplastici  
Tecnici (div. TPE) e Tecnopolimeri (div. ETP).



## **Regulatory Affairs Product Stewardship Information / Certification Data Sheet (RAPIDS)**

### **Moplen EP300H**

#### **Product Manufacturer and/or Supplier**

This product is manufactured by HMC Polymers Company, Ltd.

#### **REACH (Regulation (EC) No. 1907/2006)**

This product is manufactured by affiliates and subsidiaries of the LyondellBasell group of companies around the world.

Under the EC Regulation REACH this product is classified as a preparation.

If the product has been purchased from Basell Sales & Marketing Company B.V. (BSM), we confirm that all substances of this preparation are compliant with the pre-registration requirements of REACH, and that we have the intentions to proceed with the registration of these substances, or to procure substances only from suppliers from which confirmation has been received that the suppliers are aware of their REACH requirements, that they have pre-registered and/or will timely register their substances, and that they will supply the relevant Safety Data Sheets (SDS) with REACH registration numbers as soon as the registrations occur. BSM shall in no event be liable for any non compliance deriving from false or incorrect statements of its suppliers.

We remind you, if this product is purchased from any supplier other than BSM, including other companies of the LyondellBasell group, the importer into the European Economic Area (EEA) is responsible for compliance with the requirements of the REACH Regulation. Please contact our helpdesk if you need to discuss the potential compliance with REACH before importing this product into the EEA.

#### Substances of Very High Concern (SVHC)

This product does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern (List as of December 15, 2010) above the 0.1% threshold as stated in REACH (Article 57, Regulation No. 1907/2006) determined either through (i) non-use of the substance, (ii) mass balance calculation, or (iii) specific testing.

The current list of all SVHCs can be found at the following link to the ECHA website:

[http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

#### **Chemical Inventories**

All ingredients in this product are in compliance with the following chemical inventories:

United States: Toxics Substances Control Act Inventory (TSCA)

Canada: Domestic Substances List (DSL)

Europe: EINECS/ELINCS replaced by REACH

Australia: Australian Inventory of Chemical Substances (AICS)

Korea: Korean Existing Chemicals List (KECL)

Japan: Japanese Inventory of Existing and New Chemical Substances (ENCS)

The Philippines: Philippines Inventory of Chemicals and Chemical Substances (PICCS)

China: Inventory of Existing Chemical Substances Manufactured or Imported in China (IECSC)

This product has no special requirements under US TSCA (e.g. consent orders, test rules, 12(b) requirements, etc.).

### **Regulation 1935/2004/EC**

This product is suitable to come into contact with food as provided below in our statement related to Directive 2002/72/EC. Basell maintains purchase, sales and manufacturing records adequate to meet the requirements of Traceability (art.17).

### **Regulation 2023/2006/EC (GMP)**

This product has been produced in line with GMP requirements as for:

- Awareness maintained at all levels
- Contamination prevention
- Effective Management of Change procedures
- Measures applied to ensure that the product is consistently suitable for the intended use

### **Food Contact**

European Union (EU) Food Contact

This product complies with the relevant requirements of Regulation 10/2011/EC (PIM), applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

The monomers and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EC.

Dual Use Additives

Dual use additives subject to restrictions in food as defined in Regulation 10/2011/EC are not intentionally used in the manufacture of or formulation of this product.

Specific Migration Limit (SML)

There is one or more process aid that has a specific migration limit (SML).

DNBP (see phthalate section below for more information) is an impurity of a "technical support agent" used in this product. It has a SML equal to 0.3 mg/kg (300 ppb) established in Regulation 10/2011/EC (Substance PM/REF: 74880). The concentration of DNBP in this product is <0.05%.

In order to obtain the identity of the component(s) that are dual additives or that have a SML, a secrecy agreement will need to be established with LyondellBasell (or one of its joint venture or subsidiary companies).

EU Regulation 10/2011/EC specifies 10 mg/dm<sup>2</sup> as the maximum overall migration (OML) from the finished plastic food contact material or article. The OML and SMLs (when applicable) should be determined according to the requirements specified in EU Regulation 10/2011/EC. The OML and SML determinations are the responsibility of the manufacturer of the finished plastic food contact material or article. In addition, we remind you that the manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food.

The composition of this product complies with the following National Legislations, Recommendations or Communications for the production of food packaging.

AUSTRIA: "K.V.O." N.476/2003 as amended at last by BGBl - Teil. II - N.325/2007

BELGIUM: "Arrete royal du 5 juillet 2006 (amending Arrete royal du 11 mai 1992 and modifying "Arrete royal du 3 juillet 2005")

DENMARK: Bekendtgørelse N. 1068 (13/11/2009).

FINLAND: "KTM", Paatos 953/2002 of 12.11.2002 (amended by 107/2009 of 03/03/2009)

FRANCE: "Materiaux au contact des aliments et de denre destine a l'alimentation humaine"  
Brochure n.1227 edition Janvier 1994 as updated.  
Arrete du 02 Janvier 2003 (as modified at last by Arrete 03/09/2010).

GERMANY:

Bedarfsgegenstaendeverordnung- 30 November 2006 (BGBl I S.2730)

GREECE: AXE Decision n.458/2003 modified by Decision n. 454/2008

IRELAND: S.I. No. 587 of 2007, as amended by S.I. No.88 of 2009

ITALY: "Decreto Ministeriale del 21/03/1973" amended on 26/4/1993 : D.M. N.220 and following updates (last update: D.M. of 23/04/2009).

LUXEMBOURG: "Reglement Grand-Ducal" n. 163 du 05/11/2008.

NORWAY: "Kongelig resolusjon" of 11 March 1976 and updated 21/12/1993 N.1381 (Chapter II, Section 11)

PORTUGAL: Decreto-Lei n.º 197/2007 de 15 de Maio, amended by Decreto-Lei n.62/2008 de 31 de Março

SPAIN: Real Decreto N.118 31/01/2003 modified by Real Decreto N.103/2009 of 06/02/2009.

SWEDEN: Food regulation LIVSFS 2003:2 as amended by LIVSFS 2009:2.

THE NETHERLANDS: Staatscourant n.1659 of 10.12.2008.

ENGLAND: "The Plastic Materials and Articles in Contact with Food (England) Regulations 2009" , Statutory Instrument 2009 n.205

SWITZERLAND: BGVO 817.023.21 of 23 November 2005, as amended.

CZECH REPUBLIC: Regulation of the Ministry of Health N.551/2006 modifying N.38/2001

US Food and Drug Administration (FDA)

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(3)(i) and (c)3.1a, 3.2a. According to our information, all other ingredients used in this product meet the requirements of their respective FDA regulations and 21 CFR 177.1520(b). This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2 and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

Canada Health Protection and Food Branch (HPFB)

A letter of "no objection" for food contact use of this product has not been obtained from HPFB. If a "no objection" letter is needed, contact your company representative.

China Food Contact Regulations

GB9685-2008 "The Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials"

All additives used in this product comply with the requirements of GB9685-2008.

### **Tallow**

Tallow derived additives are not intentionally used in the manufacture of or formulation of this product.

### **Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)/"Mad Cow"**

The additives in this product are not derived from animal sources. However, our operations are continuous and our Good Manufacturing Practices call for transitions between product types to be of sufficient length in order to prevent cross contamination. So there could be a very small amount of an additive that is derived from an animal source present in this product. The bovine material can be any part of the animal.

**Kosher**

We do not certify our resins to be Kosher or in compliance with Kosher requirements.

**Genetically Modified Organisms (GMO)**

Additives are used that may be manufactured from vegetable sources. Therefore, we have to assume that GMO could have been used in the growing of the vegetable material.

**European Pharmacopeia (EP)**

This product cannot be certified for compliance to EP requirements.

**Drug Master File (DMF)**

Information on this product is not listed in a DMF.

**US Pharmacopeia (USP)**

This product has not been tested for USP Class VI.

**Latex**

"Natural rubber latex", "dry natural rubber", "synthetic latex" or "rubber that contains natural rubber" are not used in the manufacture of or the formulation of this product.

**Coalition of Northeastern Governors (CONEG)**

Cadmium, chromium (VI), lead and mercury are not used in the manufacture of or the formulation of this product. In addition, this product meets the CONEG requirements of less than 100 ppm for total incidental cadmium, chromium, lead and mercury.

**European Union (EU) Directive - Packaging and Packaging Waste - 94/62/EC (as amended)**

Cadmium, chromium (VI), lead and mercury are not used in the manufacture of or the formulation of this product. This product meets the year 2001 requirements of less than 100 ppm for total incidental cadmium, chromium (VI), lead and mercury. In addition, this product has the potential to be recycled according to these requirements.

**Heavy Metals testing results**

Testing of resins similar to this product by the Inductively Coupled Argon Plasma Spectrometry method (reference EN71.3 for Toys) has shown the following metals are not present at the sensitivities listed in parenthesis: antimony(5 ppm), arsenic(5 ppm), barium(25 ppm), cadmium(5 ppm), chromium(5 ppm), lead(5 ppm), mercury(5 ppm) and selenium(25 ppm).

**California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)**

This product presents "no significant risk" for cancer to the people of California. This product contains no substances known to the State of California to cause reproductive toxicity at a level of exposure subject to the requirements of Proposition 65.

**BHT [butylated hydroxytoluene] (CAS number 128-37-0)/BHA [butylated hydroxyanisole] (CAS numbers 121-00-6 and 25013-16-5)**

BHT and BHA are not used in the manufacture of or formulation of this product. However, this product has not been tested for these chemical substances.

**Ozone Depleting Chemicals (ODCs)**

ODCs listed in "The Montreal Protocol on Substances that Deplete the Ozone Layer" are not used in the manufacture of or formulation of this product.

**Toys**

This product complies with the requirements in CEN Standard EN71.3.

The chemicals listed in CEN Standard EN71.9, Tables 2D, 2E and 2I are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

**Phthalates**

The phthalates for which opinions have been given by EFSA ( European Food Safety Authority) and TDI's ( Tolerable Daily Intake) established for use in plastics for containers in food applications. are  
...lyondellbasell.com/.../com.vignette....

...phthalates (DEHP, DINP, DBP, DIDP, BBP) are not intentionally added in the manufacture of or the formulation of this product. The phthalates are di-iso-nonyl phthalate(DINP), di-(2-ethylhexyl)phthalate(DEHP), di-n-butyl phthalate(DBP), di-iso-decyl phthalate(DIDP), butylbenzyl phthalate(BBP).

In addition, di-iso-butyl phthalate (DIBP) has recently been classified by TC C&L of ECB (Commission Working Group on Classification & Labelling - European Chemicals Bureau) in accordance with the requirements of Directive 67/548/EC (Classification and labelling of dangerous substances), taking into account a NOAEL (No Observed Adverse Effect Level) supplied by European Industry. Based on the NOAEL, the toxicity of DIBP is more than 100 times lower than DNBP's (product assessed by EFSA for use in plastics in contact with food).

HMC is aware of the publicity about phthalate plasticizers. Phthalate plasticizers are in general used in specific non-olefinic resin systems to soften these resins and make them flexible. When phthalate plasticizers are added, they can constitute up to 50% of the resultant plastic material. Basell does not use any plasticizers in the resins it supplies. Polyolefins do not require the use of plasticizers to make them soft and flexible. Those phthalate plasticizers that have been associated with potential health issues, specifically di(2-ethylhexyl) phthalate (DEHP), diisononyl phthalate (DINP), dioctyl phthalate (DOP) and butyl benzyl phthalate (BBP), are not used by Basell in the manufacture of or formulation of its resins.

All HMC operations are guided by our commitment to be a responsible supplier, always respecting the health and safety of our employees, our contractors, our customers and the community, as well as the quality of the environment in which we live and operate. HMC is a firm supporter of the chemical industry's Responsible Care program and the Product Stewardship code. HMC supplies polypropylene resins that are safe when used properly for their intended applications. In keeping with the principles of Responsible Care, HMC is supporting industry efforts to study chemicals for their potential to cause endocrine disruption.

As for this product, a phthalate compound, diisobutyl phthalate (DIBP), is a minor component of the catalyst system used to manufacture some of the base polyolefin resins. This is typical of polypropylene resins produced with high mileage catalysts. An impurity in the DIBP is di-n-butyl phthalate (DNBP), sometimes referred to as dibutyl phthalate(DBP). During processing, DIBP reacts and converts to two related phthalate compounds diethyl phthalate (DEP) and ethyl isobutyl phthalate. None of the four phthalates has been determined to be human carcinogens or endocrine disrupters at the low levels as suggested by environmentalists. Testing of several resins has resulted in the identification of residual phthalate content no more than 25 parts per million.

To put these results in perspective, plastic materials that require phthalate plasticizers, referred to above, can have up to 500,000 parts per million (50%) of the phthalate plasticizer in them. Further testing with food simulants (per European Union Regulation 10/2011) has resulted in phthalates not detected at a sensitivity of 20 parts per billion (0.002 parts per million).

#### **Acrylamide (CAS number 79-06-1)**

Acrylamide is not used in the manufacture of or the formulation of this product. However, we do not test this product for acrylamide.

#### **Aromatic Amines**

Aromatic amines are not used in the manufacture of or formulation of this product. However, this product has not been tested for these chemical substances.

#### **Asbestos**

Asbestos is not used in the manufacture of or formulation of this product. However, we have do not test this product for asbestos.

#### **Bisphenol A [chemical name: 2,2-bis(4-hydroxyphenyl)propane] (CAS# 80-05-7)**

Bisphenol A is not used in the manufacture of or the formulation of this product. However, this product has not been tested for this chemical substance.

#### **Dioxin**

Dioxin is not used in the manufacture of or formulation of this product. Dioxin is not known to be formed during processing of this product.

#### **Epichlorohydrin (CAS number 106-89-8)**

Epichlorohydrin is not used in the manufacture of or the formulation of this product. However, we do not test this product for epichlorohydrin.

### **Nonylphenol (CAS number 25154-52-3)/Nonylphenol ethoxylates**

Nonylphenol and Nonylphenol ethoxylates are not used in the manufacture of or the formulation of this product. However, this product has not been tested for these chemical substances.

### **Alkylphenol**

### **Organo-tin Compounds**

Tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds are not used in the manufacture of or the formulation of this product. However, this product has not been tested for these chemical substances.

### **Fluorocarbons**

Fluorotelemers, Zonyl fluoroadditives (DuPont trade name), perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA), perfluorochemicals (PFC) or other fluorocarbon substances are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

The PFOA issue has definitely been a "hot" one. It is recommended that customers look at the following websites for information about the safety of PFOA and certain PFOA products. Information from these sources may help alleviate concerns about using PFOA products.

[http://www2.dupont.com/PFOA/en\\_US/](http://www2.dupont.com/PFOA/en_US/)  
<http://www.pfoa-facts.com/>

### **Polychlorinated Biphenyls (PCBs), Polychlorinated Terphenyls (PCTs), Polychlorinated Naphthalenes (PCNs), Polybrominated Biphenyls (PBBs), Polybrominated Diphenyl Ethers (PBDEs) and Polybrominated Terphenyls (PBTs)**

Polychlorinated biphenyls (PCBs), polychlorinated terphenyls (PCTs), polychlorinated naphthalenes (PCNs), polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs) and polybrominated terphenyls (PBTs) are not used in the manufacture of or formulation of this product. However, this product has not been tested for these chemical substances.

### **Styrene (CAS number 100-42-5) and Polystyrene**

Styrene (chemical name: ethenylbenzene) and polystyrene resins are not used in the manufacture of or the formulation of this product. However, we do not test this product for these chemical substances.

### **Vinyl Chloride (CAS number 75-01-4) and Polyvinyl Chloride (PVC)**

Vinyl chloride and PVC resins are not used in the manufacture of or the formulation of this product. However, we do not test this product for these chemical substances.

### **Benzotriazole and 2-Mercaptobenzothiazole (MBT)**

2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol [also called 2-(2'-Hydroxy-3',5'-di-tert-butylphenyl)benzotriazole] (CAS No. 3846-71-7) and 2-Mercaptobenzothiazole [also called 2(3H)-Benzothiazolethione or Benzothiazole-2-thiol or MBT] (CAS No. 149-30-4) are not used in the manufacture of or formulation of this product. However, this product is not tested for these substances.

### **Regulation (EC) N.1895/2005**

BADGE, NOGE and BFDGE are not used in the manufacture of or the formulation of this product according to requirement of Regulation N.1895/2005.

### **Polycyclic Aromatic Hydrocarbons (PAHs)**

We do not intentionally use the following polycyclic aromatic hydrocarbons (PAHs) in the manufacture of or formulation of this product:

1,2-dihydro-acenaphthene (CAS# 83-32-9)  
acenaphthylene (CAS# 208-96-8)  
9H-fluorene (CAS# 86-73-7) anthracene (CAS# 120-12-7)  
benz(a)anthracene (CAS# 56-55-3)

benzo(a)pyrene (CAS# 50-32-8)  
benzo(b)fluoranthene (CAS# 205-99-2)  
benzo(e)pyrene (CAS# 192-97-2)  
benzo(ghi)perylene (CAS# 191-24-2)  
benzo(j)fluoranthene (CAS# 205-82-3)  
benzo(k)fluoranthene (CAS# 207-08-9)  
chrysene (CAS# 218-01-9)  
dibenz(a,h)anthracene (CAS# 53-70-3)  
fluoranthene (CAS# 206-44-0)  
fluorene (CAS# 86-73-7)  
indeno(1,2,3-cd)pyrene (CAS# 193-39-5)  
naphthalene (CAS# 91-20-3)  
phenanthrene (CAS# 85-01-8)  
pyrene (CAS# 129-00-0)

However, we do not test our resins for these substances.

#### **Thailand Hazardous Substances Act**

The chemical substances in List #4 (Prohibitive Substances) of the Thailand Hazardous Substances Act (21 November 2003) are not used in the manufacture of or formulation of this product. However, this product is not tested for these substances.

#### **Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS) - Directive 2002/95/EC, as amended.**

The information for RoHS can be found in the "Heavy Metals" (cadmium, chromium, lead, mercury) and the "Polychlorinated Biphenyls (PCBs), Polybrominated biphenyls (PBBs), etc." (PBBs, PBDEs) sections above.

#### **Energy Recovery - CEN Standard prEN 13431**

The calorific gain from polypropylene in an energy recovery process is 24 MJ/kg.

**Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications. Because of possible changes in the law and in regulations, HMC recommends that customers continuing to use our product verify status every year from the issue date of the RAPIDS.**

Certified by:



Dr. Andreas Goedel  
Business Innovation Manager  
HMC Polymers CO., Ltd.  
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Approved on Wednesday, May 25, 2011. Valid for 1 year.



## **Regulatory Affairs Product Stewardship Information / Certification Data Sheet (RAPIDS)**

# **Purell PE 1810 E**

### **Product Manufacturer**

This product is manufactured by Basell Europe.

### **REACH (Regulation (EC) No. 1907/2006)**

This product is manufactured by affiliates and subsidiaries of the LyondellBasell group of companies around the world.

Under the EC Regulation REACH this product is classified as a preparation.

If the product has been purchased from Basell Sales & Marketing Company B.V. (BSM), we confirm that all substances of this preparation are compliant with the pre-registration requirements of REACH, and that we have the intentions to proceed with the registration of these substances, or to procure substances only from suppliers from which confirmation has been received that the suppliers are aware of their REACH requirements, that they have pre-registered and/or will timely register their substances, and that they will supply the relevant Safety Data Sheets (SDS) with REACH registration numbers as soon as the registrations occur. BSM shall in no event be liable for any non compliance deriving from false or incorrect statements of its suppliers.

We remind you, if this product is purchased from any supplier other than BSM, including other companies of the LyondellBasell group, the importer into the European Economic Area (EEA) is responsible for compliance with the requirements of the REACH Regulation. Please contact our helpdesk if you need to discuss the potential compliance with REACH before importing this product into the EEA.

Substances of Very High Concern (SVHC)

This product does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern (List as of December 15, 2010) above the 0.1% threshold as stated in REACH (Article 57, Regulation No. 1907/2006) determined either through (i) non-use of the substance, (ii) mass balance calculation, or (iii) specific testing.

The current list of all SVHCs can be found at the following link to the ECHA website:

[http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

### **Chemical Inventories**

All ingredients in this product are in compliance with the following chemical inventories:

United States: Toxics Substances Control Act Inventory (TSCA)

Canada: Domestic Substances List (DSL)

Europe: EINECS/ELINCS replaced by REACH

Australia: Australian Inventory of Chemical Substances (AICS)

Korea: Korean Existing Chemicals List (KECL)

Japan: Japanese Inventory of Existing and New Chemical Substances (ENCS)

The Philippines: Philippines Inventory of Chemicals and Chemical Substances (PICCS)

China: Inventory of Existing Chemical Substances Manufactured or Imported in China(IECSC)

New Zealand: New Zealand Inventory of Chemicals (NZIoC)

This product has no special requirements under US TSCA (e.g. consent orders, test rules, 12(b) requirements, etc.).

### **Regulation 1935/2004/EC**

This product is suitable to come into contact with food as provided below in our statement related to Directive 2002/72/EC. Basell maintains purchase, sales and manufacturing records adequate to meet the requirements of Traceability (art.17).

### **Regulation 2023/2006/EC (GMP)**

This product has been produced in line with GMP requirements as for:

- Awareness maintained at all levels
- Contamination prevention
- Effective Management of Change procedures
- Measures applied to ensure that the product is consistently suitable for the intended use

### **Food Contact**

European Union (EU) Food Contact

The composition of this product complies with the following Legislations, Recommendations or Communications for the production of food packaging.

AUSTRIA: "K.V.O." N.476/2003 as amended at last by BGBl - Teil. II - N.325/2007

BELGIUM: "Arrete royal du 5 juillet 2006 (amending Arrete royal du 11 mai 1992 and modifying "Arrete royal du 3 juillet 2005")

DENMARK: Bekendtgørelse N. 1068 (13/11/2009).

FINLAND: "KTM", Paatos 953/2002 of 12.11.2002 (amended by 107/2009 of 03/03/2009)

FRANCE: "Materiaux au contact des aliments et de denre destine a l'alimentation humaine" Brochure n.1227 edition Janvier 1994 as updated.  
Arrete du 02 Janvier 2003 (as modified at last by Arrete 03/09/2010).

GERMANY:

Bedarfsgegenstaendeverordnung- 30 November 2006 (BGBl I S.2730)

GREECE: AXE Decision n.458/2003 modified by Decision n. 454/2008

IRELAND: S.I. No. 587 of 2007, as amended by S.I. No.88 of 2009

ITALY: "Decreto Ministeriale del 21/03/1973" amended on 26/4/1993 : D.M. N.220 and following updates (last update: D.M. of 23/04/2009).

LUXEMBOURG: "Reglement Grand-Ducal" n. 163 du 05/11/2008.

NORWAY: "Kongelig resolusjon" of 11 March 1976 and updated 21/12/1993 N.1381 (Chapter II, Section 11)

PORTUGAL: Decreto-Lei n.º 197/2007 de 15 de Maio, amended by Decreto-Lei n.62/2008 de 31 de Março

SPAIN: Real Decreto N.118 31/01/2003 modified by Real Decreto N.103/2009 of 06/02/2009.

SWEDEN: Food regulation LIVSFS 2003:2 as amended by LIVSFS 2009:2.

THE NETHERLANDS: Staatscourant n.1659 of 10.12.2008.

ENGLAND: "The Plastic Materials and Articles in Contact with Food (England) Regulations 2009" , Statutory Instrument 2009 n.205

SWITZERLAND: BGVO 817.023.21 of 23 November 2005, as amended.

CZECH REPUBLIC: Regulation of the Ministry of Health N.551/2006 modifying N.38/2001

The monomers used to produce the resin are listed in EU Directive 2002/72/EC and amendments up to Regulation 975/2009/EC.

The additives used to produce the resin are listed in EU Directive 2002/72/EC and amendments up to Regulation 975/2009/EC or in the relevant national legislations.

The additives/monomers for which a QM was imposed by Regulations (if any) are under our own responsibility.

No dual use additives subject to a restriction in food are used to produce this resin.

There are NO restrictions (SML;QMA) specified by the regulations for the components (monomers/additives) of this resin.

EU Directive 2002/72/EC and amendments up to Regulation 975/2009/EC, which applies to all EU Member States, specifies 10 mg/dm<sup>2</sup> as the maximum overall migration from finished plastic food contact articles. This is the responsibility of the converter.

In accordance with EU Directive 2002/72/EC and amendments up to Regulation 975/2009/EC the migration should be measured using the actual foodstuff or the appropriate food simulants at the real time/temperature conditions of use, according to the rules specified in EU Directives 97/48/EC (amending 82/711/EEC) and 85/572/EEC.

We remind you that the users must verify that the finished items, manufactured according to good technology practice, must not modify the organoleptic properties of the food.

US Food and Drug Administration (FDA)

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(2)(i) and (c)2.1, 2.2. According to our information, all other ingredients used in this product meet the requirements of their respective FDA regulations and 21 CFR 177.1520(b). This

product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2 and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

### **Tallow**

Tallow derived additives are not intentionally used in the manufacture of or formulation of this product.

### **Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)/"Mad Cow"**

We do not use components derived from animal sources in the manufacture of or formulation of this product.

### **Kosher**

We do not certify our resins to be Kosher or in compliance with Kosher requirements.

### **European Pharmacopeia (EP)**

This product meets the EP requirements for 3.1.3, Polyolefins - 7th Edition of European Pharmacopeia

### **Drug Master File (DMF)**

Information on this product is listed in DMF N. 8412. Contact Basell for a DMF authorization letter to be sent to FDA.

### **ISO 10993**

Biological reactivity tests have been performed on this product. The test results showed that this product passed, and provides evidence that this product meets the requirements of certain sections of ISO 10993-6, 10993-10 and 10993-11. Despite this, the manufacturer of a medical device made with this product must still evaluate the medical device to show that it fully meets the requirements of the applicable sections of ISO 10993.

### **US Pharmacopeia (USP)**

This product has passed the USP tests for a Class VI plastic. In addition, Physico-chemical testing of this product met the USP limits.

### **Latex**

"Natural rubber latex", "dry natural rubber", "synthetic latex" or "rubber that contains natural rubber" are not used in the manufacture of or the formulation of this product.

### **Heavy metals (ELV Directive 2000/53/EC and its following amendments)**

The quantity (statistically evaluated) of Cd, Pb, Cr(VI), Hg present in this grade is deemed below the limits given in Annex II (Note) of the Decision 2005/673/EC of September 20th (amending Annex II of Directive 2000/53/EC) which establishes:

0.1% Lead  
0.1% Chromium  
0.1% Mercury  
0.01% Cadmium

### **Coalition of Northeastern Governors (CONEG)**

Cadmium, chromium (VI), lead and mercury are not used in the manufacture of or the formulation of this product. In addition, this product meets the CONEG requirements of less than 100 ppm for total

incidental cadmium, chromium, lead and mercury.

#### **European Union (EU) Directive - Packaging and Packaging Waste - 94/62/EC (as amended)**

Cadmium, chromium (VI), lead and mercury are not used in the manufacture of or the formulation of this product. This product meets the year 2001 requirements of less than 100 ppm for total incidental cadmium, chromium (VI), lead and mercury. In addition, this product has the potential to be recycled according to these requirements.

#### **California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)**

This product presents "no significant risk" for cancer to the people of California. This product contains no substances known to the State of California to cause reproductive toxicity at a level of exposure subject to the requirements of Proposition 65.

#### **Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)**

BHT and BHA are not used in the manufacture of or formulation of this product. However, this product has not been tested for these chemical substances.

#### **Ozone Depleting Chemicals (ODCs)**

The ozone-depleting substances (ODS), listed in the Annexes I & II of the Regulation ( EC ) No 1005/2009 of 16 September 2009, are not used in the manufacture of or formulation of this product.

#### **Toys**

This product complies with the requirements in CEN Standard EN71.3.

The phthalates listed in Annex of Directive 2005/84/EC ( Annex I of Directive 76/769/EEC) are not intentionally added in the manufacture of or the formulation of this product in a concentration above the given limits.

#### **Phthalates**

The phthalates for which opinions have been given by EFSA ( European Food Safety Authority) and TDI's ( Tolerable Daily Intake) established for use in plastics for containers in food applications, are not intentionally added in the manufacture of or the formulation of this product. The phthalates are di-isobutyl phthalate(DINP), di-(2-ethylhexyl)phthalate(DEHP), di-n-butyl phthalate(DBP), di-iso-decyl phthalate(DIDP), butylbenzyl phthalate(BBP).

In addition, di-iso-butyl phthalate (DIBP) has recently been classified by TC C&L of ECB ( Commission Working Group on Classification & Labelling - European Chemicals Bureau) in accordance with the requirements of Directive 67/548/EC (Classification and labelling of dangerous substances), taking into account a NOAEL (No Observed Adverse Effect Level) supplied by European Industry. Based on the NOAEL, the toxicity of DIBP is more than 100 times lower than DNBP's (product assessed by EFSA for use in plastics in contact with food).

Phthalates are not used in the manufacture of or the formulation of this product.

#### **Acrylamide**

Acrylamide (CAS number 79-06-1) is not used in the manufacture of or the formulation of this product. However, we do not test this product for acrylamide.

#### **Aromatic Amines**

Aromatic amines are not used in the manufacture of or formulation of this product. However, this product has not been tested for these chemical substances.

### **Asbestos**

Asbestos is not used in the manufacture of or formulation of this product. However, this product has not been tested for this chemical substance.

### **Bisphenol A**

Bisphenol A is not used in the manufacture of or the formulation of this product. However, this product has not been tested for this chemical substance.

### **Dioxin**

Dioxin is not used in the manufacture of or formulation of this product. Dioxin is not known to be formed during processing of this product.

### **Epichlorohydrin**

Epichlorohydrin (CAS number 106-89-8) is not used in the manufacture of or the formulation of this product. However, we do not test this product for epichlorohydrin.

### **Nonylphenol**

Nonylphenol and Nonylphenol ethoxylates are not used in the manufacture of or the formulation of this product. However, this product has not been tested for these chemical substances.

### **Alkylphenol**

### **Organo-tin Compounds**

Tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds are not used in the manufacture of or the formulation of this product.

### **Polychlorinated Biphenyls (PCBs), Polychlorinated Terphenyls (PCTs), Polychlorinated Naphthalenes (PCNs), Polybrominated Biphenyls (PBBs), Polybrominated Diphenyl Ethers (PBDEs) and Polybrominated Terphenyls (PBTs)**

Polychlorinated biphenyls (PCBs), polychlorinated terphenyls (PCTs), polychlorinated naphthalenes (PCNs), polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs) and polybrominated terphenyls (PBTs) are not used in the manufacture of or formulation of this product. However, this product has not been tested for these chemical substances.

### **Styrene and Polystyrene**

Styrene (chemical name: ethenylbenzene) (CAS number 100-42-5) and polystyrene resins are not used in the manufacture of or the formulation of this product. However, we do not test this product for these chemical substances.

### **Vinyl Chloride and Polyvinyl Chloride (PVC)**

Vinyl chloride (CAS number 75-01-4) and PVC resins are not used in the manufacture of or the formulation of this product. However, we do not test this product for these chemical substances.

### **Benzotriazole and 2-Mercaptobenzothiazole (MBT)**

2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol [also called 2-(2'-Hydroxy-3',5'-di-tert-butylphenyl)benzotriazole] (CAS No. 3846-71-7) and 2-Mercaptobenzothiazole [also called 2(3H)-Benzothiazolethione or Benzothiazole-2-thiol or MBT] (CAS No. 149-30-4) are not used in the manufacture of or formulation of this product. However, this product is not tested for these substances.

### **Regulation (EC) N.1895/2005**

BADGE, NOGE and BFDGE are not used in the manufacture of or the formulation of this product according to requirement of Regulation N.1895/2005.

### **Nanomaterials**

NANOMATERIALS (insoluble or biopersistent and intentionally manufactured materials with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm ) are not used in the manufacture of or the formulation of this grade.

However, this product has not been tested for these chemical substances.

### **Polycyclic Aromatic Hydrocarbons (PAHs)**

We do not intentionally use the following polycyclic aromatic hydrocarbons (PAHs) in the manufacture of or formulation of this product:

1,2-dihydro-acenaphthene (CAS# 83-32-9)  
acenaphthylene (CAS# 208-96-8)  
9H-fluorene (CAS# 86-73-7) anthracene (CAS# 120-12-7)  
benz(a)anthracene (CAS# 56-55-3)  
benzo(a)pyrene (CAS# 50-32-8)  
benzo(b)fluoranthene (CAS# 205-99-2)  
benzo(e)pyrene (CAS# 192-97-2)  
benzo(ghi)perylene (CAS# 191-24-2)  
benzo(j)fluoranthene (CAS# 205-82-3)  
benzo(k)fluoranthene (CAS# 207-08-9)  
chrysene (CAS# 218-01-9)  
dibenz(a,h)anthracene (CAS# 53-70-3)  
fluoranthene (CAS# 206-44-0)  
fluorene (CAS# 86-73-7)  
indeno(1,2,3-cd)pyrene (CAS# 193-39-5)  
naphthalene (CAS# 91-20-3)  
phenanthrene (CAS# 85-01-8)  
pyrene (CAS# 129-00-0)

However, we do not test our resins for these substances.

### **Dimethyl Fumarate (DMF) - EU Commission Decision 2009/251/EC**

Dimethyl fumarate [2-butenedioic acid (2E)-, dimethyl ester] (DMF) (CAS#: 624-49-7) is not used in the manufacture of or formulation of this product. However, we do not test this product for DMF.

### **DEHA, DINCH, BTHC, TOTM, etc.**

The following chemical substances are not used in the manufacture of or formulation of this product:

DEHA bis(2-ethylhexyl) adipate – Cas. N.103-23-1  
DINCH 1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester, Cas N. 166412-78-8  
BTHC butyryl tri-n-hexyl citrate CAS 82469-79-2;  
TOTM tris(2-ethylhexyl)benzene-1,2,4-tricarboxylate CAS 3319-31-1  
Glycerides, castor-oil mono-, hydrogenated, acetates CAS. N.736150-63-3

However, we do not test our resins for these substances.

### **Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) - Commission Decision of 19 March 2010 - (2010/169/EU)**

Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) Cas. N.3380-34-5 is not used in the manufacture of or formulation of this product. However, this product has not been tested for this substance.

### Switzerland "VOC-LENKUNGSABGABE"

This product contains less than 3% VOC's of the substances in the positive lists of the above Regulations.

### Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS) - Directive 2002/95/EC, as amended.

At the light of our aknowledge,

- PBDE
- PBB
- Chromium (VI)
- Lead
- Mercury
- Cadmium

are not used nor intentionally added in the production of the resin.

For a coloured grade, pigments/colourants may contain traces of the above heavy metals.

The incidental sum of their concentrations does not exceed the limits established by Decision 2005/618/EC

### Composting - CEN Standard prEN 13432

This product is not suitable for composting.

### Energy Recovery - CEN Standard prEN 13431

The calorific gain from polyethylene in an energy recovery process is 22 MJ/Kg

**Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications.**

**This certificate shall continue in effect for 1 year from its effective date unless it is modified before. If, during such 1 year period, Basell changes the product formulation such that the RAPIDS is no longer accurate, Basell will notify you ( normally by e-mail). Basell shall not notify you in case changes in the regulations occur.**

**Basell recommends that customers continuing to use our product verify status frequently and at least every year from the issue date of the RAPIDS.**

Certified by:



Alessandro Medri  
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Approved on Tuesday, March 15, 2011. Valid for 1 year.