



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

Purell PE 1840 H

Product Manufacturer

This product is manufactured by Basell Europe.

This product is produced by Equistar Chemicals, L.P.

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

This product is defined as a preparation under REACH. All components of this preparation as supplied in the European Union are compliant with the pre-registration requirements of REACH. All members of the supply chain are affected by REACH, and we recommend that you seek additional advice, in the event that you need further clarification concerning your own obligations related to the REACH legislation.

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)

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. 1102 (09/11/2006).

FINLAND: "KTM", Paatos 953/2002 of 12.11.2002 (amended by 181/2005 of 10.03.2005)

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 19/11/2008).

GERMANY:

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

BfR is no longer applicable for this resin

GREECE: AXE Decision n.458/2003 modified by Decision n.330/2005

IRELAND: Statutory Instruments N.542 of 2002.

ITALY: "Decreto Ministeriale del 21/03/1973" amended on 26/4/1993 : D.M. N.220 and following updates (last update: D.M. N.174 of 07/11/2008).

LUXEMBOURG: "Reglement Grand-Ducal" du 27/01/2001.

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.866/2008 of 23/05/2008.

SWEDEN: Food regulation LIVSFS 2003:2 as amended by LIVSFS 2006:20.

THE NETHERLANDS: " Staatscourant n.114 of 15.06.2006.

ENGLAND: "The Plastic Materials and Articles in Contact with Food (England) Regulations 2008," Statutory Instrument 2008 No. 916"

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 Directive 2008/39/EC.

The additives used to produce the resin are listed in EU Directive 2002/72/EC and amendments up to Directive 2008/39/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 Directive 2008/39/EC, which applies to all EU Member States, specifies 10 mg/dm² 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 Directive 2008/39/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 - 6th Edition of European Pharmacopeia

Drug Master File (DMF)

Information on this product is listed in DMF N. 8410. 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)

Class I and Class II ODCs listed in the US Clean Air Act Amendments of 1990 are not used in the manufacture of or formulation of this product.

Class I and Class II ODCs(as defined in Montreal Protocol)dealt in the Regulation 2037/2000/EC and following amendments, 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

Phthalates are not used in the manufacture of or the formulation of this product. However, we do not test this product for phthalates.

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.

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.

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.

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.

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

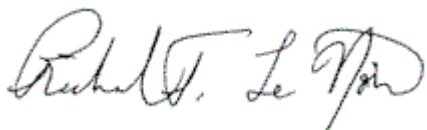
This product is not suitable for composting.

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. Because of possible changes in the law and in regulations, Basell recommends that customers continuing to use our product verify status every year from the issue date of the RAPIDS.

Certified by:



Richard T. LeNoir
Product Stewardship Manager - N.A.
Basell USA Inc.
a LyondellBasell Industries company
Delaware Corporate Center II
2 Righter Parkway

Suite 300
Wilmington, DE 19803
USA
Phone: 302-683-8125
FAX: 302-731-6480
email: rich.lenoir@lyondellbasell.com



Patrizia Busi
Regulatory Affairs Manager - Europe
Basell Poliolefine Italia S.r.l
a LyondellBasell Industries company
Centro Ricerche "G.Natta"
P.le Donegani, 12
44100 - Ferrara (I)
Phone: +39- 0532-468653
Fax : +39-0532-776726
E-mail: patrizia.busi@lyondellbasell.com
