



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

Purell GA7760

Product Manufacturer and/or Supplier

This product is supplied by Basell Sales & Marketing BV

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 June 18, 2012) 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/web/guest/candidate-list-table>

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.).

Food Contact

European Union (EU) Food Contact

This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation), applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 2023/2006/EC (GMP), applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 10/2011/EC (PIM) as amended, 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.

EU Regulation 10/2011/EC specifies 10 mg/dm² 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.

There are NO restrictions (SML/QMA) specified by the EU regulation 10/2011/EC for the components (monomers and additives) of this resin.

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.140/2009

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.579 (01/06/2011).

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- 07 February 2011 (BGBl I S.226)

GREECE: AXE Decision n.458/2003 modified by Decision n. 6/2011

IRELAND: S.I. No. 587 of 2007, as amended by S.I. No.301 of 2010

ITALY: "Decreto Ministeriale del 21/03/1973" amended on 26/4/1993 : D.M. N.220 and following updates (last update: D.M. of 16/02/2011).

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

NORWAY: Regulations 21 December 1993 No 1381 on materials and articles intended to come into contact with foodstuffs Chapter I General regulations, as amended.

PORTUGAL: Decreto-Lei n.º 62/2008 of 31/03/2008 and Amend. Decreto-Lei n.º 29/2009 of 02/02/2009

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

SWEDEN: Ordinance of the National Food Administration on materials and articles intended to come into contact with foodstuffs LIVSFS 2011:7.

THE NETHERLANDS: Staatscourant n.6861 of 06.05.2010.

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.

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 with no restrictions in specific migration limit (SML) or maximum quantity per area (QMA).

Tallow

Tallow derived additives may be used in the manufacture of this product.

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

STATEMENT ON THE USE OF TALLOW DERIVATIVES FOR FOOD CONTACT PLASTICS (AS AGREED UPON BY APME (NOW PIEUR) MEMBER COMPANIES)

The concerns relative to BSE/TSE in the context of plastics materials used in contact with food are

linked to the use of additives of animal origin: tallow derivatives. These products (fatty acids, fatty alcohols, metallic soaps, fatty amines, fatty amides, fatty acid esters, glycerine) are incorporated into plastics as lubricants, slip agents, anti-static agents as well as emulsifiers, anti-oxidants or corrosion inhibitors. They are primarily extracted from tissues of ovine or bovine origin. The tallow derivatives used for the production of our plastics materials undergo a series of severe process steps during manufacture:

Normally, pre-treatment of tallow and/or animal fat with strong acids

Hydrolytic cleavage at temperatures above 200 C, under pressure, for more than 20 minutes, yielding glycerine and fatty acids

Transesterification of the fatty acids with methanol at temperatures above 200 C, under pressure, for more than 20 minutes, yielding fatty acid methyl ester

Reduction of fatty acid methyl esters with hydrogen at temperatures above 200 C, under high pressure, for more than 20 minutes, yielding fatty alcohols

According to the revised opinion of the EU Scientific Steering Committee on the Safety of Tallow (June 2001) and the recommendation for inactivation of TSE included (among others) in the Commission Directive 2000/6/EC, in the updated report of APAG of April 2001 and also in the Regulation (EC) N.1774/2002, the above-mentioned treatments do ensure a complete inactivation of any TSE/BSE agent regardless of the source and type of material. The additional exposure of the plastic materials to temperatures ranging from 150 deg. C to 300 deg. C during 30 seconds up to several minutes, both at the compounding step and in the final conversion process, represents an additional safety factor ensuring the complete protection of people's health in respect of TSE/BSE for plastic materials used in contact with food.

The tallow derived raw materials used in this product fulfill the requirements laid down in the Note for Guidance, EMEA/410/01, rev.2, part 6.4 (Tallow Derivatives).

Our suppliers declare that the tallow derivatives are Category 3 materials and are manufactured under the conditions given in the aforementioned Note for Guidance.

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. 5654. Contact Basell for a DMF authorization letter to be sent to FDA.

ISO 10993

Biological reactivity evaluations have been performed on representative samples of this product, specifically the <88> USP Biological Reactivity Tests, In Vivo for a Class VI plastic (Systemic Injection Test, Intracutaneous Test, Implantation Test). These USP tests may fit the requirements of certain sections of 10993-10 (tests for irritation and skin sensitization) and 10993-11 (tests for systemic toxicity). 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. Results provided by Seller are intended to be representative in nature only and are not to be construed as a guarantee of future product performance. Seller makes no express or implied warranty by virtue of disclosing pass/fail status.

US Pharmacopeia (USP)

Representative samples of this product have passed the <88> USP Biological Reactivity Tests, In Vivo for a Class VI plastic (Systemic Injection Test, Intracutaneous Test, Implantation Test). In addition, Physico-chemical testing of this product met the USP limits.

Results provided by Seller are intended to be representative in nature only and are not to be construed as a guarantee of future product performance. Seller makes no express or implied warranty by virtue of disclosing pass/fail status.

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.

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.

Packaging and Packaging Waste - EU Directive 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.

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)

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

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.

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.

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-t-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.

Plasticizers (e.g. 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)

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:



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