

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

Adflex X 100 G

Product Manufacturer

This product is manufactured by Basell Europe.

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: European Inventory of Existing Chemical Substances (EINECS)

Australia: Australian Inventory of Chemical Substances (AICS)

Korea: Korean Existing Chemicals List (KECL)

Japan: Japanese Inventory (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

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

AUSTRIA: "K.V.O." N.775, 23/09/1994 as amended at last by BGBl 1.8.2005 - Teil. II - n.242

BELGIUM: "Arrete royal du 10 decembre 2002 (amending Arrete royal du 11 mai 1992).

DENMARK: Foededirektorates Bekendtgorelse N. 111 (20/02/2003).

FINLAND: "KTM", Paatos 953/2002 of 12.11.2002.

FRANCE: "Materiaux au contact des aliments et de denre destine a l'alimentation humaine" Brochure n.1227 edition Janvier 1994 as updated.

Arrete du 14 Septembre 1992 (as modified at last by Arrete 09/08/2005).

GERMANY:

Bedarfsgegenstandeverordnung- 7 April 2003

BfR is no longer applicable for this resin

GREECE: AXE Decision n.458/2002

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.123 of 28/03/2003).

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

NORWAY: "Kongelig resolusjon" of 11 March 1976 and updated 21/12/1993.

PORTUGAL: "Decreto Lei" N.4/2003 of 10/01/2003 and following Corrigendum nº 1-P/2003 of 28/2/2003.

SPAIN: Resolucion de 04/11/1982 amended by Real Decreto 442/2001.

SWEDEN: Food regulation SLV FS 1993:18 as updated by SLV FS 2003:2.

THE NETHERLANDS: " Staatscourant n.67 of 4.04.2003.

UNITED KINGDOM: "Plastics for food contact applications" Revised Ed.1986. Statutory Instruments, 1998/1376 and followings updates (last update: S.I. 2005/325).

SWITZERLAND: KsV, 26 June 1995 as modified by KsV, 30/01/1998.

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

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

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

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

There are NO SMLs specified by the regulations for the components (monomers/additives) of this resin.

Processing aid

There are two processing aids used in this product which have SMLs.

EU Directive 2002/72/EC and amendments, 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 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/EC) and 85/572/EC.

This resin should be used in contact with aqueous and partially fatty food

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)(3)(iii) and (c)3.4 for olefin polymers. 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. However, this product can only be used in contact with food types I, II, III, IV-B, VI, VII, VIII and IX listed in 21 CFR 176.170(c), Table 1.

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.2600 (rubber articles for repeated use) (a) through (c).

To comply with 21CFR 177.2600, the finished article must meet certain criteria as listed in CFR 21 177.2600 (d),(e) and (f) and be thoroughly cleansed prior to its first use (21 CFR 177.2600 (g)).

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 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, 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 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.

Heavy metals (ELV Directive 2000/53/EC)

The quantity (statistically evaluated) of Cd, Pb, Cr, Hg present in this grade is deemed below the limits given in Annex II (Note) of the Decision 2002/525/EC of June 27th (amending Annex II of Directive 2000/53) which establishes:

0.1% Lead

0.1% Chromium

0.1% Mercury

0.01% Cadmium

Coalition of Northeastern Governors (CONEG)

Cadmium, chromium, 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, 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, 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" 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(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 article 1 of Decision 1999/815/EC 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), di-n-octyl phthalate(DNOP) and butylbenzyl phthalate(BBP).

Phthalates

The phthalates listed in Italian Ministry of Health Decree no538, dated December 17, 1999, 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), di-iso-octyl phthalate(DIOP), di-ethyl phthalate(DEP), di-cyclo-hexyl phthalate(DCHP), di-methyl-cyclo-hexyl phthalate(DMCHP) and di-methoxy-ethyl phthalate(DMEP).

Basell 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 Basell 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. Basell is a firm supporter of the chemical industry's Responsible Care® program and the Product Stewardship code. Basell supplies polypropylene resins that are safe when used properly for their intended applications.

In keeping with the principles of Responsible Care®, Basell 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 general conditions of use as established in EC Directives 2002/72/EC and 97/48/EC, as amended) has resulted in phthalates not detected at a sensitivity of 20 parts per billion (0.02 parts per million).

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.

Nonylphenol

Nonylphenol and Nonylphenol etoxylate 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), Polybrominated Biphenyls (PBBs), Polychlorinated Terphenyls (PCTs), Polybrominated Diphenyl Ethers (PBDEs) and Polybrominated Terphenyls (PBTs)

Polychlorinated biphenyls (PCBs), polybrominated biphenyls (PBBs), polychlorinated terphenyls (PCTs), 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

Vinyl chloride (CAS number 75-01-4) is not used in the manufacture of or the formulation of this product. However, we do not test this product for vinyl chloride.

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

At the light of our aknowledge,

- PBDE
- PBB

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

- Chromium (VI)
- Lead
- Mercury
- Cadmium

are not used 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 100 parts per millions by weight

Composting - CEN Standard prEN 13432

Certified for Basell by:



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