
Regulatory Compliance Certificate

Polypropylene grade

200-CA40

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Food-contact EU

We confirm that monomers and additives used to manufacture this grade are listed in Directive 2002/72/EC (06/08/2002) relating to plastic materials and articles intended to come into contact with foodstuffs and its amendments 2004/1/EC (06/01/2004), 2004/19/EC (01/03/2004), 2005/79/EC (18/11/2005) and 2007/19/EC (30/03/2007) or national legislations as listed below, within the framework defined by the Regulation 1935/2004/EC (27/10/2004) on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

No monomers subject to restriction (Specific Migration Limit or Quantitative Maximum) are used.

No additives subject to restriction (Specific Migration Limit or Quantitative Maximum) are used.

Glycerol monostearate and calcium stearate are approved as direct food additives. They are present, as additives, in the above grade.

It is the responsibility of the converter to verify that the finished article meets both the technical and regulatory requirements of the intended application, and in particular does not modify the organoleptic properties of the food.

Austria	Kunststoffverordnung Nr. 476/2003 und Änderungen 242/2005 und 452/2006
Belgium	Koninklijk Besluit - Arrêté Royal 3/07/2005
Czech Republic	Vyhlaska Ministerstva zdravotnictvi c. 38/2001 Sb, c. 186/2003 Sb, c. 207/2006 Sb
Denmark	Fødevaredirektoratets Bekendtgørelse nr. 1102 af 09/11/2006
England	Statutory Instruments 2006 No. 2687 and BPF-BIBRA (1995)
Finland	KTM Asetukset 953/2002, 141/2005, 181/2005 ja 762/2006
France	Brochure N°1227 Edition 2002, Arrêté du 02/01/2003, Arrêté du 29/03/2005, Arrêté du 09/08/2005 et Arrêté du 19/10/06
Germany	Bedarfsgegenständeverordnung 23/12/1997 und Änderungen vom 21/12/2000, 07/04/2003, 13/07/2005 und 30/11/2006 sowie BfR Empfehlungen A - VII, Polypropylene, Stand. 01/04/2006
Greece	AXE decision n° 458/2002
Ireland	Statutory Instruments N. 542 of 2002
Italy	Decreto Ministeriale 21/03/1973 and subsequent amendments including last update D.M. No. 227
Netherlands	Warenwet (2006) Hoofstuk 1, Kunststoffen
Norway	Sosial-og helsedepartementets forskrift of 21/12/1993, n° 1381
Portugal	Decreto Lei N.4/2003 of 10/01/2003 and Corrigendum No 1-P/2003 of 28/2/2003
Spain	Resolucion of 04/11/1982 amended by Real Decreto 1262/2005, SCO/3508/2006 y ANAIP (1982), Anexo 1, Anexo 2
Sweden	Statens livsmedelsverks kungörelse LIVSFS 2003:2 och ändr. LIVSFS 2004:31, 2005:14, 2005:28, 2006:6, 2006:20.
Switzerland	Verordnung der EDI über Bedarfsgegenstände 23/11/2005, 3. Abschnitt Bedarfsgegenstände aus Kunststoff

Food contact US

This product is in compliance with Title 21 Code of Federal Regulations (CFR, 2006 Edition) Olefin polymers parts 177.1520 (c) Specifications 3.1a, 178.2010, and other regulations promulgated under the Federal Food, Drug and Cosmetic Act as may be applicable.

Phthalates

Phthalates are not used as additives or raw materials in the manufacture of the above-mentioned grade. However, as with most of polypropylene grades, a very low level (typically less than 12 ppm) of phthalates can be found in this grade arising from catalyst residues.

Bovine Spongiform Encephalopathy (BSE)
Transmissible Spongiform Encephalopathy (TSE)

This grade contains calcium stearate and glycerol monostearate as additives.

We received from our own suppliers the guarantee that even when these additives are produced from beef tallow, they are BSE free. The reasons given are:

The beef tallow is supplied together with a certificate from the authorities responsible, which confirms that the tallow originates from healthy animals (ante and post mortem).

It is claimed that BSE has never been found in beef tallow and the World Health Organisation (WHO) said that tallow does not represent a risk for both human and animal health (OMS/CDS/VPH/95.145).

The processing of beef tallow includes very high temperatures, which eliminate the risk of BSE contamination. Our suppliers also claimed that the raw materials that they use and the finished products they sell comply with the existing legislations.

Genetically Modified Organism (GMO)

Among the large variety of polymer additives that we are using, only a few of them may be genetically modified. We would like to comment on the relevance of gene modification techniques to plastic materials. The most significant fact is that the starting substances or additives possibly deriving from genetically modified organisms based materials are manufactured through multi-step conversion and / or purification processes, involving aggressive conditions like high temperature and pressure as well as action of chemically reactive substances. The final plastic materials themselves are produced under high temperature conditions and are further submitted during conversion processes (extrusion, moulding) to high temperature for a significant period of time.

On the basis of current scientific knowledge, it can be stated that no DNA and no proteins from a given organism (genetically modified or not) can resist to such a series of treatments. Therefore, their presence in our polymers and in plastic articles manufactured from them is unexpected.

In conclusion, we confirm that the above grade is safe to be manufactured, processed and used, even if it is manufactured from starting substances or contain additives which may be of genetically modified organisms origin.

End-of life vehicles

This grade meets the relevant requirements of Directive 2000/53/EC.

Heavy metals, RoHS, WEEE, Waste packaging, CONEG

This grade meets the relevant requirements of the following Directives or Regulations:

- 2003/11/EC
- 2002/95/EC (RoHS)
- 2002/96/EC (WEEE)
- 94/62/EC (Packaging Waste Directive)
- USA CONEG Regulation

“N” substances

None of the additives used in the manufacture of the above grade are classified as dangerous to the environment with the symbol “N” in Annex 1 of the Directive 67/548/EEC (adapted to technical progress for the 28th time by Directive 2001/59/EC).

Recovering, recycling and composting

The above grade can be valorised for energy recovery due to its high calorific gain of around 22 MJ/Kg.

It is recyclable, mechanical recycling being one option depending of the requirements of the application and the intended article specifications.

Polyolefins are neither biodegradable nor compostable.

Swiss VOC legislation

This product is without Volatile Organic Content (VOC) according to “Ordonnance sur la taxe d’incitation sur les composés organiques volatils (OCOV) du 12 novembre 1997”.

Toys (EN 71)

The above grade meets the requirements of the European Standard EN 71 part 3 (and 9), Edition 1995, Filing n° S51-214, Safety of Toys migration of certain elements. Since this grade also meets the requirements for food contact legislations, it is thus suitable for the manufacture of toys and parts of toys.

The above product meets the relevant requirements of Directive 2005/84/EC.

Dioxins and furans

Dioxins and furans are not used as raw materials or additives in the manufacture of this grade. These substances are also unlikely to be generated and released during the manufacture and processing of this grade.

Ozone layer-depleting agents

Chlorofluorocarbons (CFC's) and substances related to ozone depleting substances (as defined by the MONTREAL PROTOCOL and listed as class I & II substances by the US Clean Air Act) are not used as additives or raw materials in the manufacture of this grade.

BADGE, NODGE and BFDGE

In relation to the Directive 2002/16/EC, repealed by the Regulation 1895/2005/EC, BADGE [2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether], BFDGE [bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ether], and NOGE [novolac glycidyl ether] are not used as additives or raw materials in the manufacture of this grade.

Absence of substances and chemicals

None of the following substances are used as additives or raw materials in the manufacture of this grade:

- Allergens (as defined in Directive 2000/13/EC, as amended)
- Aromatic amines and colorants
- Azodicarbonamide or semi-carbazide compounds
- Asbestos
- Brominated flame retardants
- Bisphenol-A
- Di(ethylhexyl) adipate
- Epoxidised Soya Bean Oil (ESBO)
- Formaldehyde (formol)
- Latexes
- Nonylphenol and its derivatives
- Tert-butyl-4-hydroxyanisole (BHA) and 2,6-di-tert-butyl-p-cresol (BHT)
- Tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds
- Poly(aromatic hydrocarbons) according to US Environmental Protection Agency Method 610 (EPA 610)
- Vinyl chloride monomer and its polymers or copolymers

This certificate will be updated when appropriate. Therefore, it is recommended to revisit this certificate at least once a year.

It is the responsibility of the customer to check compliance of the final articles with the relevant legislation and applicable regulatory requirements including their restrictions.

For any further information, please post your request by means of Technical Services Online (TSO):
<http://www.innovene.com/technicalservices>.

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