
Regulatory Compliance Certificate***High Density Polyethylene grade***Eltex TUB121

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Drinking water applications

We obtained specific national approvals for this grade to be used for drinking water applications. Confirmation of these country specific approvals will be given on request. It is the responsibility of the converter to seek and obtain approvals of the finished product manufactured from this grade and intended to be used for drinking water applications.

Compliance with: Decreto Ministeriale 174 (Italy)

In relation to Decreto Ministeriale n°174 of 06/04/2004 on materials in contact with drinking water, we confirm that the monomers and additives used in the manufacture of the above grade are listed in the European Directive 2002/72/EC relating to plastics materials and articles intended to come in contact with foodstuffs, and corresponding Decreto Ministeriale of 21 March 1973 and their amendments, within the scope of these legislations.

Food-contact EU

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 (corrigenda of 02/04/2007), 2005/79/EC (18/11/2005), 2007/19/EC (30/03/2007), and 2008/39/EC (06/03/2008) or national legislations as listed below.

This grade also meets the relevant requirements of Regulation 1935/2004/EC (27/10/2004) on materials and articles intended to come into contact with food.

Migration tests carried on this type of polymer, under the conditions 10 days at 40°C, in the four standard food simulants show that the Overall Migration Limit of 60 mg/kg or 10 mg/dm² food is not exceeded.

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

This grade contains one additive subject to Specific Migration Limits (SML) (T) of 1 mg/kg. This grade contains zinc based additives subject to a Group Specific Migration Limit of 25 mg/kg (expressed as zinc). As the conversion process can affect migration, only the converter can guarantee to the food packer that above limits are not exceeded.

Calcium stearate is approved as direct food additive. It is present, as additive, in the above grade.

Modelling results, under the conditions 10 days at 40°C, in the four standard food simulants, and at a surface volume ratio of 6 dm⁻¹ indicate that when this grade is converted under Good Manufacturing Practice (GMP) to manufacture articles, the above SML(s) will not be exceeded.

Austria: Kunststoffverordnung Nr. 476/2003 und Änderungen 242/2005 und 452/2006

Belgium: Koninklijk Besluit - Arrêté Royal 3/07/2005 and Arrêté Royal 5/7/2006

Czech Republic: Vyhlaska Ministerstva zdravotnictvi c. 186/2003, c. 207/2006 and c. 551/2006

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: Bedarfgegenständeverordnung 23/12/1997 und Änderungen vom 21/12/2000, 07/04/2003, 13/07/2005 und 30/11/2006 sowie BfR Empfehlungen A - III, Polyethylene, Stand. 01/04/2006

Greece: AXE decision n° 458/2003

Ireland: Regulations 2005, Rule N°49

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. 197/2007 of 15/05/2007

Spain: Real Decreto 866/2008 of 23/05/08

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

Whereas Ineos Polyolefins supplies to its customers the adequate information to allow them to fulfil their own responsibilities, the converters do have to check and confirm that the final article meets both the technical and regulatory requirements of the application.

Phthalates

Phthalates are not used as additives or raw materials in the manufacture of the above grade.

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

This grade contains stearate as additive.

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 organism's 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 as amended
- 2002/95/EC (RoHS) as amended
- 2002/96/EC (WEEE) as amended
- 76/769/EEC as amended
- 94/62/EC (Packaging Waste Directive) as amended
- 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 (OCO) 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 also 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. None of the prohibited substances listed in Regulation 2037/2000/EC (Marketing and use of Ozone layer depleting substances) is used as additives or raw materials in the manufacture of the above 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 and Bisphenol-F
- Di(ethylhexyl) adipate
- Endocrine Disruptors listed in Japanese authority list "Strategic Programs on Environmental
- Endocrine Disruptors '98 (SPEED '98) - Table 3: Chemicals Suspected of Having Endocrine Disrupting Effects"
- Epoxidised Soya Bean Oil (ESBO)
- Formaldehyde (formol)
- Isopropyltioaxanthone (ITX)
- Latexes
- Nanoparticles
- Nonylphenol and its derivatives
- Perfluorinated tenside (PFT), Perfluorooctanoic acid (PFOA) & Perfluorooctane sulfonate (PFOS) listed in Directive 2006/122/EC
- Poly(aromatic hydrocarbons) according to US Environmental Protection Agency Method 610 (EPA 610)
- Polycyclic Aromatic Hydrocarbons (PAH)
- Recycled products according to Regulation 282/2008/EC
- Tert-butyl-4-hydroxyanisole (BHA) and 2,6-di-tert-butyl-p-cresol (BHT)
- Thiuram mix
- Titanium Acetyl Acetone (TAA)
- Tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds
- Vinyl chloride monomer and its polymers or copolymers
- Substances listed in:
 - California Proposition 65 State regulation
 - GADSL, "Global Automotive Declarable Substances List" 2008, version 1.0
 - IKEA Specification, IOS-MAT-0010, 2007-05-31, version AA-10911-8, chapter 3 & 6

Cosmetics

In compliance with the Directive 76/768/EC, as amended today, none of the substances subject to interdiction in that directive are used as raw materials or additives in the manufacture of the above grade.

GMP

The production and distribution processes of this grade have been submitted to a systematic review in regards to Good Manufacturing Practices as defined by the framework Regulation (EC) 1935/2004 and the "GMP" Regulation (EC) 2023/2006.

As a result of this review, INEOS Polyolefins can state that the production and distribution processes of this product are compliant with the here-above mentioned Regulations.

This certificate will be updated when appropriate. Therefore, it is recommended to revisit it 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.

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