
FCX HDPE Pipe Product Stewardship Information

The following food contact compliance stewardship information refers to the inner layer of our FCX HDPE pipes.

Please note that compliance with these regulations should not be interpreted to guarantee that the product, will, in fact, perform in a particular application. Our Technical Service Representative can help you determine that the characteristics of the product are compatible with the desired conditions of use.

Global Food Contact Status:

European Union

This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation) as 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 and subsequent amendments.

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 and subsequent amendments. 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.

Dual use additives subject to restrictions in food as defined in Regulation 10/2011/EC are not intentionally used in the manufacture or formulation of this product.

This product contains one or more components with Specific Migration Limit (SMLs)

EU National Legislations

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 foostuffs Chaper I General regulations, as amended.
Portugal: Decreto-Lei No. 62/2008 of 31/03/2008, and Amend. Decreto-Lei No. 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.

Allergen Statements

The food ingredients listed in the Annex IIIa of European Directive 2007/68/EC, are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

Biomedical Policy

This product may not be used in the manufacture of any of the following applications: U.S. FDA Class III medical devices; Health Canada Class IV medical devices; European Class III medical devices; applications involving permanent implantation into the body; life-sustaining medical applications; and lead, asbestos or MTBE related applications.

This product may not be used in any U.S. FDA Class I, Health Canada Class I, and/or European Union Class I medical devices, without prior notification to Seller for each specific product and application.

This product may not be used in the manufacture of any of the following, without prior written approval by Seller for each specific product and application: U.S. FDA Class II medical devices; Health Canada Class II or III medical devices; European Union Class II medical devices; or any equivalent U.S. FDA, Health Canada, or European Union regulations pertaining to medical devices; packaging in direct contact with a pharmaceutical active ingredient and/or dosage form; and tobacco-related products and applications.

All references to the U.S. FDA, Health Canada and European Union regulations include all other country's equivalent regulatory classifications.

Animal Based Raw-Materials (BSE/TSE)

Europe - BSE/TSE - "Mad Cow"

Tallow derived materials used in this product fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMEA/410/01 rev3

Tallow

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

Epoxy Derivatives

The materials BADGE, BFDGE or NOGE are not intentionally added in this product as referenced in Commission Regulation 1895/2005/EC, on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs as plasticizers, additives or raw materials.

California Prop 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.

Drinking Water Certifications

National Regulations for plastics to produce pipes and fittings in contact with drinking water are in place in various EU Countries, including:

Italy (e.g. Decreto N. 174/2004 as amended); Germany (e.g. DVGW – Deutsche Vereinigung des Gas und Wasserfaches / KTW – Kunststoff Trinkwasser Empfehlungen); Netherlands (e.g. ATA – Attestation of Toxicological Aspects); France (e.g. ACS - Attestation de Conformité Sanitaire). In regards to the composition of plastics used to produce the above articles, specific reference to positive lists of food contact materials is provided within national regulations. As a preliminary conformity check on product's composition, please refer to the certification of compliance with Regulation 10/2011/EC on plastic materials and articles intended to come into contact with food, provided in another part of this document, and is in place in all EU Countries.

Halal Certification

This product is not certified as Halal.

Kosher Certification

This product is not certified Kosher.

Latex

No materials containing latex or natural rubber are used in the manufacturing, handling and packaging processes for this product.

Metals Content

US CONEG

Based on the available documentation provided by our raw material suppliers, this product complies with the CONEG Model Legislation for requirements regarding the defined limit for the sum of heavy metals (lead, mercury, cadmium and hexavalent chromium).

EU Packaging and Packaging Waste

Based on the available documentation from raw materials suppliers, this product complies with the directive 94/62/EC and its following amendments concerning the defined limit(s) of heavy metals.

Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS)

RoHS Regulation refers to electrical and electronic equipment and not specifically to plastic raw materials. However, based on the available documentation from raw materials suppliers, this product complies with the requirements of the Directives 2002/95/EC, as amended, and 2011/65/EU concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE).

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.

Other Chemicals

The chemical materials listed below are not used in the manufacture or the formulation of this product and are not expected to be present. However, this product has not been tested for these chemical materials.

2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol; (Benzotriazole); CAS# 3846-71-7;
2,4,4'-trichloro-2'-hydroxydiphenyl ether; (Triclosan); CAS# 3380-34-5;
2-mercaptobenzothiazole; MBT; CAS# 149-30-4;
Acrolein; (propenal); (CAS# 107-02-8);
Acrylamide; CAS# 79-06-1;
Aromatic amines;
Asbestos;
Azo Dyes and Pigments;
Polyaromatic Hydrocarbons - PAHs:
1,2-dihydro-acenaphthene; (CAS# 83-32-9); 9H-Fluorene; (CAS# 86-73-7); Acenaphthylene; (CAS# 208-96-8); 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); 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);
Bisphenol A; (BPA); CAS# 80-05-7; Bisphenol A diglycidyl ether; (BADGE); CAS# 1675-54-3;
Bisphenol F diglycidyl ether; BFDGE; CAS# 2095-03-6; Butylated hydroxyanisole; (BHA); CAS# 121-00-6 & 25013-16-5; Butylated hydroxytoluene; (BHT); CAS# 128-37-0 Chlorinated paraffins; Cyanuric acid; (Isocyanuric Acid or CYA); CAS# 108-80-5; Dimethyl fumarate; (DMF); CAS# 624-49-7; Dioxins; Epichlorohydrin; (ECH); CAS# 106-89-8; Fluorocarbons; Fluorotelomers Formaldehyde; CAS# 50-00-0; Formaldehyde in specific conditions could be formed during the resin processing (see MSDS)
Gold; CAS# 7440-57-5;
Halogenated Flame Retardants
Melamine; (1,3,5-Triazine-2,4,6-triamine); CAS# 108-78-1;
Nonylphenol; CAS# 25154-52-3;
Nonylphenol ethoxylates; Novolac glycidyl ether;
Organotin compounds;
Perfluorochemicals; (PFCs); Perfluorooctane sulfonate; (PFOS); CAS# 1763-23-1; Perfluorooctanoic acid; (PFOA); CAS# 335-67-1; Polybrominated biphenyls; (PBBs); Polybrominated diphenyl ethers; (PDBEs); Polybrominated terphenyls; (PBTs); Polychlorinated biphenyls; (PCBs); Polychlorinated naphthalenes; (PCNs); Polychlorinated terphenyls; (PCTs); Polystyrene; Polyvinyl chloride; (PVC); CAS# 9002-86-2; Radioactive substances; Radon; CAS# 10043-92-2; Styrene monomer; CAS# 100-42-5; Sulphur dioxide; CAS# 7446-09-5; Tin oxide (SnO₂); (Cassiterite); CAS# 8062-08-6; Tris-nonylphenol phosphite; (TNPP); CAS# 26523-78-4; Vinyl chloride; CAS# 75-01-4; Wolframite; CAS# 1332-08-7;

Ozone Depleting Substances

European Union

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.

United States

Materials listed in the Clean Air Act Amendments of 1990 (Class I, CFC's and Class II, HCFC's, Halons and the solvents, carbon tetrachloride and 1,1,1-trichloroethane) are not intentionally used in the production of this product.

Phthalate Free

Phthalates are not used in the manufacture or the formulation of this product. However, this product has not been tested for phthalates.

REACH Information

Under the EC Regulation REACH this product is classified as a preparation. If the product has been purchased from PESTEC, 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.

REACH 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 20, 2013) 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 ECHA website link listed below:

<http://echa.europa.eu/web/guest/candidate-list-table>

Global Chemical Control Regulations

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)

China: Inventory of Existing Chemical Substances Manufactured or Imported in China (IECSC) This product has no special requirements under US TSCA (e.g. consent orders, test rules, 12(b) requirements, etc.).

VOC Content Switzerland VOC Declaration

This product contains less than 3% VOC's of the substances in the positive lists of the Switzerland Regulations "VOC-LENKUNGSABGABE."

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.

Disclaimer

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(i) any U.S. FDA Class I, Health Canada Class I, and/or European Union Class I medical devices, without prior notification to Seller for each specific product and application; or
(ii) the manufacture of any of the following, without prior written approval by Seller for each specific product and application: U.S. FDA Class II medical devices; Health Canada Class II or III medical devices; European Union Class II medical devices; or any equivalent U.S. FDA, Health Canada, or European Union regulations pertaining to medical devices; packaging in direct contact with a pharmaceutical active ingredient and/or dosage form; and tobacco-related products and applications.

This product(s) may not be used in the manufacture of any of the following applications: U.S. FDA Class III medical devices; Health Canada Class IV medical devices; European Class III medical devices; applications involving permanent implantation into the body; life-sustaining medical applications; and lead, asbestos or MTBE related applications. All references to the U.S. FDA, Health Canada and European Union regulations include another country's equivalent regulatory classification.