REGULATORY INFORMATION DATA SHEET
PRODUCT STEWARDSHIP

P4C5Z-027

POLYPROPYLENE HOMOPOLYMER

Product Manufacturer

This product is manufactured by INV Polypropylene, LLC (INVISTA Polypropylene) in Longview, Texas, U.S.A.

Manufacturing Facility Certifications

The Longview Polypropylene facility is certified to the ISO-9001:2015 Quality standard. Certificate is available upon request.

The Longview manufacturing facility is certified as an OSHA VPP (Voluntary Protection Program) Star Site.

Chemical Inventories

Please see SDS for chemical inventory information.

Food Contact

US Food and Drug Administration (FDA):

> This material meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(1)(i) and (c)1.1a. According to our information, all other ingredients used in the formulation meet their respective FDA regulations and 21 CFR 177.1520(b). Specifically, this product meets the FDA criteria for food contact, including cooking applications. This product can be used under conditions of use A through H as listed in 21 CFR 176.170(c), Table 2.

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European Union (EU) Food Contact:

> P4C5Z-027 conforms to sections of Regulation (EC) 1935/2004 on materials intended to come into contact with food. The monomers and additives used to produce this resin are listed in EU Regulation 10/2011 and/or amendments. No monomers with a restriction are used. This product contains substances subject to a Specific Migration Limits (SML's) of 1, 3.6 and 5 mg/kg. This product also contains a dual-use additive (CAS 1592-23-0) in its formulation. Migration can be affected by the conversion process so only the converter to the final item can guarantee the limit is not exceeded.

Ultimately, customers must make their own determination that their use of our product(s) is safe, lawful, and technically suitable for their intended application(s).

Drug Master File (DMF)

This product is listed in DMF #9988. Letters of Authorization to reference this DMF can be obtained by request.

European Pharmacopoeia (EP)

This product has not been tested to EP 3.1.6 - Polypropylene for Containers for Parenteral Preparations.

US Pharmacopeia (USP)

This product has been certified as a USP Class VI Plastic (USP<88>, Biological Reactivity Tests, *In Vivo*). Certificate is available upon request.

Bioterrorism Act of 2002

The facility manufacturing this product is not required to register with the Bioterrorism Act of 2002 because it is not a food facility.

Tallow/BSE/TSE

INVISTA Polypropylene does not intentionally use tallow or any other animal derived materials in the formulation of this product.

Kosher

INVISTA Polypropylene does not certify this resin to be Kosher or in compliance with Kosher requirements.

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Heavy Metals (ELV Directive 2000/53/EC)

The quantity of Pb, Hg, Cd, and Cr 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% Pb, 0.1% Cr, 0.1% Hg, and 0.01% Cd.

Coalition of Northeastern Governors (CONEG)

INVISTA Polypropylene does not intentionally use cadmium, chromium, lead, or mercury in the formulation of this product. In addition, this product meets the CONEG limitation of 100 ppm for the total incidental content of cadmium, chromium, lead, and mercury.

Restriction of Hazardous Substances (RoHS)

This product conforms to the RoHS Directive (2011/65/EU) and/or amendments restricting the use of Heavy Metals, PBB's, PBDE's, and phthalates.

European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)

INVISTA Polypropylene does not intentionally use 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE), bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers (BFDGE) or novolac glycidyl ethers (NOGE) in the formulation of this product. We do not test this product for these substances.

Ozone Depleting Chemicals (ODCs)

INVISTA Polypropylene does not intentionally use any compounds listed in Annex I of EU Regulation (EU) 2024/590 in the formulation of this product.

California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)

Based on available information this product does not contain any components or chemicals currently known to the State of California to cause cancer, birth defects or reproductive harm at levels which would be subject to Proposition 65. Reformulation, use, or processing of this material may affect its composition and require re-evaluation.

Allergens

INVISTA Polypropylene does not intentionally use allergens - as defined by FDA as Milk, Eggs, Fish, Crustaceans, Wheat, Sesame, Soy, Peanuts, Tree Nuts - in the formulation of this product.

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Genetically Modified Organisms (GMO)

This product may utilize a component partially produced from plant material of unknown genetic origin in its formulation.

Additional Substance Information

INVISTA Polypropylene does not intentionally use any of the following substances in the formulation of this product: “natural rubber latex”, “dry natural rubber”, “synthetic latex”, “rubber that contains natural rubber”, Tin, Tantalum, Tungsten, Gold, Cobalt, Natural Mica, Asbestos, Bisphenol A (BPA), Bisphenol S (BPS), Butylated Hydroxyanisole (BHA), Butylated Hydroxytoluene (BHT), Dimethyl Fumarate (DMF), Triclosan**,** Tris-nonylphenol Phosphite (TNPP), Melamine, Per- and polyfluoroalkyl substances (PFAS) or any other fluorinated compounds, Perfluorooctanoic Acid (PFOA), Perfluorooctane Sulfonate (PFOS), Polyvinyl Chloride (PVC), Vinylidene chloride, Alkylphenols (nonyl- or octyl-) or Alkylphenol ethoxylates (nonyl- or octyl-), Phthalates, Nitrosamines, Dioxins, Polycyclic Aromatic Hydrocarbons (PAH), Polybrominated Biphenyls (PBB’s), Polychlorinated Biphenyls (PCB’s), Polybrominated Diphenyl Ethers (PBDE’s), Polybrominated Terphenyls (PBT’s), Polychlorinated Terphenyls (PCT’s), Brominated compounds, Tributyl-tin (TBT), Dibutyl-tin (DBT), Monobutyl-tin (MBT) or any other Organo-tin compounds. We do not test this product for these substances.

Shelf Life

Although INVISTA Polypropylene does not warranty our resins within any specific length of time, we recommend a shelf life of approximately two years, provided the material has been stored in dry conditions at temperatures below 50°C (122°F) and protected from UV and nitrous oxide exposure. Improper storage conditions can initiate premature degradation of color, odor and physical properties.

European Regulation (EU) 2025/40 Packaging and Packaging Waste Regulation (PPWR)

INVISTA Polypropylene does not intentionally use any fluorinated compounds (including per and polyfluoroalkyl – PFAS) or heavy metals (Pb, Cr (VI), Cd, or Hg) in the formulation of this grade. INVISTA Polypropylene does not test each raw material or product we produce for trace amounts of these substances. INVISTA Polypropylene recommends proper recycling of our polypropylene as opposed to disposal of plastic products into landfills.

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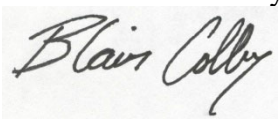
Use of this Regulatory Information Data Sheet

The information provided as requested is intended to be used for informational purposes only. The information is provided on a without prejudice basis and should not be viewed as giving technical advice, instruction, or otherwise. The information is furnished free of charge and is based on INVISTA Polypropylenes' knowledge and understanding. INVISTA Polypropylene makes no representation or warranty as to the completeness or accuracy of the information contained herein. It is intended for use by persons having technical skill, at their own discretion and risk, who will make their own determination as to its suitability for their purposes prior to use. As with any material, evaluation of any compound under end-use conditions prior to specification is essential. Ultimately, customers must make their own determination that use of this product is safe, lawful, and technically suitable for their intended applications.

The document is effective for one year. If a product formulation revision should change the information provided in this Regulatory Information Data Sheet (RIDS), INVISTA Polypropylene will notify customers to whom this regulatory sheet was provided. INVISTA Polypropylene will not notify you should a change in regulation(s) require a change to this RIDS. INVISTA Polypropylene recommends updating your files with a new RIDS on a yearly basis.

Verified for INV Polypropylene, LLC by:



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