



Effective Date: October 19th, 2017

REGULATORY INFORMATION PACKET

13R9A

POLYPROPYLENE COPOLYMER

Product Manufacturer

This product is manufactured by Flint Hills Resources in Longview, Texas, U.S.A.

Manufacturing Facility Certifications

Longview Polypropylene facility is certified to the ISO 9001:2008 Quality standard.
Longview manufacturing facility OSHA VPP (Voluntary Protection Program) Star Site certified.

Chemical Inventories

Please see SDS for chemical inventory listings.

Food Contact Status

US Food and Drug Administration (FDA): This material meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(3)(i) and (c)3.1a. 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, except for cooking, under conditions of use C through H as listed in 21 CFR 176.170(c), Table 2.

European Union (EU) Food Contact: 13R9A does not meet the requirements of EU Regulation 10/2011 for food contact as it contains an additive not included in Annex 1.

Food Allergens

This material does not contain allergens - as defined by FDA as Milk, Eggs, Fish, Crustaceans, Wheat, Soy, Peanuts, Tree Nuts - in the manufacture or formulation of this product.

US Pharmacopeia (USP)

This product has been certified as a USP Class VI Plastic (USP<88>, Biological Reactivity Tests, *In Vivo*). Transfusion and Infusion Assemblies and Similar Medical Devices (USP<161>) Physicochemical (USP<661> and Endotoxin (USP<85>)) testing have also been performed.

European Pharmacopoeia (EP)

This product does not pass the EP 3.1.3 or 3.1.6 monographs for Polyolefins and Polypropylenes due to the type and/or amount of additives in this product's formulation. The resin does pass all other testing of the 3.1.3 and 3.1.6 monographs.



Animal Derived Components (BSE/TSE)

Based on a review of the product composition, this product is not manufactured or formulated with ingredients of animal origin or associated with BSE/TSE infectivity.

Plant Derived Components

This product may contain one or more additives(s)/substances(s) synthesized from plant extracts, i.e. hydrolysis, etc. of plant oils into fatty acids and/or their derivatives, as per information from our raw material suppliers.

Kosher

The raw materials used in the manufacture of this product are derived from non-animal sources. There is no animal fat, no animal derived materials, grain derived, or fermentation products used in this product. The product is not certified as kosher but will comply with kosher dietary laws. Therefore, this product can be used with kosher products without compromising the status of the products.

Halal

This product has no animal fats or ingredients derived from animal or fermentation products; therefore, it will comply with the dietary laws of Halal; however, it is not Halal certified.

REACH 174 Substances (July 07, 2017)

The raw material manufacturer does not believe any of the chemicals as per the EU Candidate List of Substances of Very High Concern (SVHC) are present in our polypropylene products at levels greater than 0.1%.

Testing has indicated that some of our polypropylene products may contain trace residues (<5 ppm) of Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP), and Bis (2-ethylhexyl) phthalate (DEHP). Benzyl butyl phthalate (BBP) was below the detection limit of the instrument used to test.

EU Directive 2011/65/EU Restriction of Hazardous Substances (RoHS)

The resin manufacturer does not intentionally use (suggest to add: or add heavy metals) Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls (PBB's), or Polybrominated Diphenyl Ethers (PBDE's) or phthalates (DEHP, BBP, DBP, or DIBP) to any of the polypropylene products.

Testing has indicated that some of our polypropylene products may contain trace catalyst residues (<8 ppm) of Dibutyl phthalate, Diisobutyl phthalate, and/or Bis (2-ethylhexyl) phthalate. Benzyl butyl phthalate was below the detection limit of the instrument used to test.

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.

Heavy Metals (ELV Directive 2000/53/EC)

Coalition of Northeastern Governors (CONEG)

The raw material supplier does not use cadmium, chromium, lead, or mercury in the manufacture or 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.

European Directive (94/62/EC) Packaging and Packaging Waste

EU Directive 2012/19/EU Waste Electrical & Electronic Equipment (WEEE)

EU Directive 2012/19/EU on WEEE: Selective treatment of the waste (Annex VII). None of the substances listed in Annex VII are intentionally added or used in the formulation of this product with the following exception. This product is a hydrocarbon; however, liquid hydrocarbons are not present in this product.

This product conforms to the European Commission Directive 94/62/EC (Article 11) and its amendments on packaging and packaging waste. This product is recyclable according to the recycle code 5.

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

The resin manufacturer does not 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 manufacture or formulation of this product.

California Proposition 65

(Safe Drinking Water and Toxic Enforcement Act of 1986)

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.

Conflict Materials

(Dodd-Frank Wall Street Reform and Consumer Protection Act)

This product is not intentionally manufactured or formulated with the listed conflict Materials as per Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act; tin, tantalum, tungsten, or gold.

- Columbite-Tantalite – refined into Tantalum (Ta) (CAS# 7440-25-7)
- Cassiterite – refined into Tin (Sn) (CAS# 7440-31-5)
- Wolframite refined into Tungsten (W) (CAS# 7440-33-7)
- Gold (Au) (CAS# 7440-57-5)

We are disclosing the above information, to the best of our knowledge based upon data from our raw material supplier. We believe this information to be accurate and reliable as of the effective date of this Regulatory Data Sheet.



Ozone Depleting Chemicals (ODCs)

This material does not use Class I or Class II ODCs listed in the Resolution 1005/2009/EC in the manufacture or formulation of this product.

Phthalates

Although phthalates are not intentionally added in the formulation of this product, there are phthalates in the final resin as a result of catalyst residues. Analytical testing has been performed on several grades with specific phthalates determined to be in concentrations less than 5 ppm. Dibutyl phthalate, Diisobutyl phthalate, and Bis (2-ethylhexyl) phthalate. Benzyl butyl phthalate was below the detection limit of the instrument used to test.

Materials from Genetically Modified Organisms

13R9A utilizes a component produced from material of unknown genetic origin in its formulation.

Additional Substance Information

As with almost all polypropylenes, including 13R9A, anti-oxidants (preservatives) are used to some degree to protect the polymer during conversion/processing. A phenolic anti-oxidant (phenyl group containing) is used in the formulation.

This product is not intentionally manufactured or formulated with the following substances or compounds; however, we do not analyze for these substances or compounds.

- 2-Mercaptobenzothiazole (MBT)
- Aflatoxin-like compounds
- Aldehydes
- Azoxy compounds
- Bis(2-ethylhexyl) Adipate (DEHA)
- Bisphenol compounds, incl. but not limited to: BPA, BPB, BPC, BPE, BPF, BPS, and BPZ
- Butylated Hydroxyanisole (BHA)
- Butylated Hydroxytoluene (BHT)
- Dioxins and similar compounds
- Endocrine Disruptors (proven by the industry)
- Epoxy Resin
- Formaldehyde
- Halogenated (Brominated or chlorinated) or phosphorous based flame retardants
- Isocyanate
- Melamine
- Natural rubber latex, dry natural rubber, or synthetic latex
- Nitroso compounds
- Nitrosamines
- Novolac Glycidyl Ethers (NOGE)
- Organic phosphates



Parabens
Perfluorooctane Sulfonate (PFOS)
Phthalates / Phthalate esters
Plasticizers
Polybrominated Biphenyls (PBB's)
Polybrominated Diphenyl Ethers (PBDEs)
Polybrominated Terphenyls (PBTs)
Polychlorinated Biphenyls (PCBs)
Polycyclic aromatic hydrocarbon (PAH)
Polyurethane
Polyvinyl Chloride (PVC)
Polyvinylidene Chloride (PVDC)
Tris-nonylphenol Phosphite (TNPP)

Sterilization Methods

Gamma	25-40 kGY – Some discoloration may occur, but reverses over time. No significant effect on physical properties.
EtO	No issues. Can be safely used.
Autoclave	Limited to 121° C with no stress on part.

Shelf Life and Expiration Date

Eldon James has tight controls on inventory, so finished products are manufactured and sold quickly. Consequently, raw materials are stored for a relatively short time before use in the manufacturing process. Eldon James cannot commit to a shelf life on products, but we stand by the quality and use of new raw materials. Resin manufacturers usually make no commitment on shelf life. Eldon James does not make any claims regarding Expiration Date because our customers use our products in many different applications and conditions. Eldon James cannot make any assessment or claims regarding expiration. Each individual condition and application must be tested by the customer to determine the limits of each product, material, and use.

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 supplier knowledge and understanding. Eldon James Corporation 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.