

Makrolon® Rx1805

Effective Date: August 23rd, 2021

POLYCARBONATE**Product Manufacturer**

This product is manufactured by Covestro in Pittsburgh, PA U.S.A.

Manufacturing Facility Certifications

USP Class VI and FDA-modified ISO 10993-1.

Chemical Inventories

Please see SDS for chemical inventory listings.

Food Contact Status

has met the requirements of the FDA-Modified ISO 10993, Part 1 “Biological Evaluation of Medical Devices” tests with human tissue contact time of 30 days or less. These tests are conducted under Good Laboratory Practices as defined by the FDA in 21 CFR Part 58.

Food Allergens

No information available.

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.

USP Physicochemical Tests for Elastomeric Closures – Isopropanol and Water Extracts

USP Physicochemical Tests for Plastics

Analysis for Metals by ICP

Rabbit Pyrogen Test – ISO 10993-11

Systemic Injection, 4 Extracts – ISO 10993-11

In Vitro Hemocompatibility – ISO 10993-4

Intramuscular Implantation – ISO 10993-6

Hemolysis, Human Blood – ISO 10993-4

Hemolysis, Rabbit Blood – ISO 10993-4

L929 MEM Elution Test – ISO 10993-5

Kingman Maximization Test, Saline and CSO – ISO 10993-10

Intracutaneous Injection Test, 4 Extracts – ISO 10993-10

Ames Reverse Mutation Assay, Saline and Ethanol, - ISO 10993-3

European Pharmacopoeia (EPHC)

In the EU Framework Regulation (EC) 1935/2004 defines basic requirements for materials and articles intended for contact with food. The EU Directive 2002/72/EC (and amendments) provides specific provisions on plastic materials and articles intended to come into contact with foodstuffs. It contains for example lists of monomers and additives exclusively allowed for the manufacture of the plastic materials or articles. Monomers and additives may have restrictions on the permitted quantity of residuals in the article or on the specific migration into food.

The Commission Regulation (EU) No. 10/2011 does not regulate the use of colorants and therefore national provisions apply. For example, Germany’s Federal Institute for Risk Assessment (BfR) has issued recommendations on colorants for food contact applications

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Animal Derived Components (BSE/TSE)

This product is not manufactured or formulated with ingredients of animal origin.

REACH 219 Substances (July 8, 2021)

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 polycarbonate products at levels greater than 0.1%.

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

Directive 2011/65/EU restricts the use of certain hazardous substances in electrical and electronic equipment per (EU) 2015/863 RoHS3 (amending directive 2011/65/EU), above the specific thresholds have not been intentionally added and therefore, these substances are not expected to be present:

- Cadmium (0.1%)
- Lead (0.1%)
- Mercury (0.1%)
- Hexavalent chromium (0.1%)
- Flame retardants PBB polybrominated biphenyls (0.1%) and PBDE polybrominated diphenyl ethers (0.1%); including pentabromodiphenyl ether (CAS-No. 32534-81-9), octabromodiphenyl ether (CAS-No. 32536-52-0) and deca-bromodiphenyl ether (CAS-No. 1163-19-5)
- Bis(2-Ethylhexyl) phthalate (DEHP): 0.1% (added in 2015);
- Benzyl butyl phthalate (BBP): 0.1% (added in 2015);
- Dibutyl phthalate (DBP): 0.1% (added in 2015);
- Diisobutyl phthalate (DIBP): 0.1% (added in 2015).

The resin manufacturer and Eldon James comply with the requirements of Directive 2011/65/EU and its amending directive (EU) 2015/863 regarding substance restriction.

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.

Phthalates

This product is not intentionally manufactured or formulated with phthalate esters; however, we do not analyze for these specific substances or compounds

Additional Substance Information

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

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2-Mercaptobenzothiazole (MBT)
Aflatoxin-like compounds
Aldehydes
Azoxy compounds
Bis(2-ethylhexyl) Adipate (DEHA)
Butylated Hydroxyanisole (BHA)
Butylated Hydroxytoluene (BHT)
Dioxins and similar compounds
Epoxy Resin
Formaldehyde
Isocyanate
Melamine
Natural rubber latex, dry natural rubber, or synthetic latex
Novolac Glycidyl Ethers (NOGE)
Organic phosphates
Parabens
Phthalates / Phthalate esters
Polybrominated Biphenyls (PBB's)
Polybrominated Diphenyl Ethers (PBDEs)
Polybrominated Terphenyls (PBTs)
Polychlorinated Biphenyls (PCBs)
Polycyclic aromatic hydrocarbon (PAH)
Polyvinyl Chloride (PVC)
Polyvinylidene Chloride (PVDC)
Tris-nonylphenol Phosphite (TNPP)

Sterilization Methods

Gamma/e-beam	25-35 kGY – Color Shifts to neutral tint.
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.