

Flexelene™ MFX 82M

Effective Date: August 19, 2021

THERMOPLASTIC ELASTOMER**Product Manufacturer**

This product is manufactured by Eldon James in Denver, Colorado U.S.A.

Manufacturing Facility Certifications

ISO 9001 and ISO 13485 Quality Standards, ISO Class 7 Cleanroom.

Chemical Inventories

Please see SDS for chemical inventory listings.

Food Contact Status**US Food and Drug Administration (FDA):**

When used unmodified and processed in accordance with Good Manufacturing Practices (GMP) for food contact applications, this product will comply with the U.S. Food and Drug Administration's food additive regulation at 21 CFR 177.1810 (b) (3) and 177.2600.

This product complies with the requirements of FDA regulation 21CFR 178.2010 (Antioxidants and/or stabilizers for polymers) or applicable Food Contact Notifications (FCN) for additives used, (FCN No. 385).

European Commission Regulation (EU) No 10/2011 (Food Contact):

The composition of this product complies with the requirements for use in contact with non-fatty foodstuffs under European Commission Regulation (EU) No 10/2011, including any subsequent amendments that are in force, Regulation 1935/2004/EC (Framework Regulation), Regulation 2023/2006/EC (GMP) as amended and Regulation 10/2011/EC (PIM) as amended.

Food Allergens

To the best of our knowledge, there are no raw materials, including additives, that have their origin in peanuts, soybeans, milk, eggs, fish, shellfish (mollusks), crustaceans, tree nuts, mustard, celery, sesame, lupine, animal or vegetable proteins, caffeine, monosodium glutamate (MSG), colorants (including carmine and cochineal), corn, wheat, barley, rye, triticale, gluten, mushrooms, yams, and/or phenylalanine and its derivatives. No sulfates or sulfites are used in the manufacturing of this material.

Food Allergen - European Regulation 1169/2011 The food ingredients listed in Annex II of Regulation (EU) No 1169/2011, are not used in the manufacture of or formulation of this product. This evaluation is based on information provided by our raw material and additive suppliers for the presence of the allergen-stimulating substances shown above. Therefore, although we believe this product to be free of the specified known allergy stimulating food substances. However, this product has not been tested for these substances.

US Pharmacopeia (USP)**USP <661> Containers, "Physiochemical Tests – Plastics"**

This product meets the requirements of USP <661> Containers, "Physiochemical Tests - Plastics" (including non-volatile residues, residue on ignition, heavy metals, buffering capacity).

USP <88> USP Biological Test for Plastics, class VI

This material meets the requirements of USP class VI (USP<88> Biological Test for Plastics, Class VI-70°C).

Flexelene™ MFX 82M

ISO 10993-4 Hemolysis Test, Biological Evaluation of Medical Devices

The product is non-hemolytic and meet the requirements of the Hemolysis Test, ISO 10993-4 Biological Evaluation of Medical Devices Part 4; Tests for Hemolysis (Rabbit Blood Direct and Indirect Contact (complete ASTM Method)).

ISO 10993-5 Elution Test, Biological Evaluation of Medical Devices

The product is non-cytotoxic and meet the requirements of the Elution Test, ISO 10993-5 Biological Evaluation of Medical Devices Part 5; Tests for In Vitro Cytotoxicity.

ICH Harmonized Guideline Q3D (Elemental Impurities)

To the best of our knowledge and based on information from our raw material suppliers, the elemental impurities of Class 1, 2, 3 listed in the ICH Harmonized Guideline Q3D of 16 December 2014 are not intentionally used in the manufacture or formulation of this product. However, this product has not been tested for these substances.

European Pharmacopoeia (EPHC)

Only raw materials used to contain additives that are listed in European Pharmacopoeia, 6th edition, monograph 3.1.3 and 3.1.6. This product is also in compliance with the formulation requirements of the European Pharmacopoeia, monograph 3.1.3 (7th edition) and contains only additives listed in monograph 3.1.3.

Animal Derived Components (BSE/TSE)

To the best of our knowledge and based on information from our raw material suppliers, product does NOT intentionally contain any ingredients of animal origin (including additives in used raw materials). We therefore state that this product is to be considered safe with respect to BSE and TSE transmissions.

Plant Derived Components

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

Kosher

To the best of our knowledge and based on information from our raw material suppliers, product does NOT intentionally contain any ingredients of animal origin (including additives in used raw materials).

Halal

To the best of our knowledge and based on information from our raw suppliers, product does NOT intentionally contain any ingredients of animal origin (including additives in used raw material).

REACH 219 Substances (July 8, 2021)

The REACH Regulation 1907/2006/EC adopted by the European institutions. This product does not contain and is not manufactured or formulated any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern (SVHC) above the 0.1% threshold as stated in REACH (Article 57, Regulation No. 1907/2006) as per the candidate list that would require reporting under this regulation.

EU Directive 2011/65/EU Restriction of Hazardous Substances (RoHS 3)

This product complies with the requirements of Article 4.1 of EU Directive 2011/65/EU (RoHS2) and Annex II as per 2015/863/EU, as amended and is not intentionally manufactured or formulated with cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), or Diisobutyl phthalate (DIBP).

Flexelene™ MFX 82M

Heavy Metals, EU 94/62/EC Packaging and Packaging Waste Coalition of Northeastern Governors (CONEG)

This product conforms to the European Directive 94/62/EC, as amended, on Packaging and Packaging Waste, Article 11. Any incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

EU Directive 2002/96/EC Waste Electrical & Electronic Equipment (WEEE), latest amended by EU Directive 2008/34/EC

EU Directive 2002/96/EC on WEEE: Selective treatment of the waste (Article 6.1 and Annex II). None of the substances listed in Annex II are intentionally added or used in the formulation of this product.

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

All monomers and raw materials used in the manufacture conform to EC directive 2002/72/EC (amended by 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC and Regulation (EC) 975/2009, Regulation (EC) 1895/2005 – BADGE, NOGE and BFDGE are not used for the production of this product.

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

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels which would require a warning under the statute.

Conflict Materials (Dodd-Frank Wall Street Reform and Consumer

This product is not intentionally manufactured or formulated with the listed conflict minerals as per Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act; however, we do not analyze for these specific substances or compounds.

- 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 suppliers, we believe this information to be accurate and reliable.

Ozone Depleting Chemicals (ODCs)

This product is not manufactured or formulated with Class I or II substances as defined under 40 CFR part 82 of the Clean Air Act of 1990, as amended (58 FR 8136).

Phthalates

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

Materials from Genetically Modified Organisms

To the best of our knowledge, there are no raw materials, including additives, that have been derived from genetically modified organisms (GMO). This is based on information from our raw material suppliers. Therefore, although we believe this product to be GMO free, we cannot guarantee it at this time.

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.

Flexelene™ MFX 82M

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 or synthetic latex
Nitroso compounds
Nitrosamines
Novolac Glycidyl Ethers (NOGE)
Organic phosphates
Parabens
Perfluorooctanoic Acid (PFOA)
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

E-beam/Gamma	< 40 C/kg (4Mrad) / Up to 25 kGy.
EtO	No Issues. Can safely be used.
Autoclave	Sterilize by Steam at 121 °C.

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.

Flexelene™ MFX 82M

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.