



Effective Date: January 11, 2017

REGULATORY INFORMATION PACKET

Flexelene™ MFX 92R

THERMOPLASTIC ELASTOMER

Product Manufacturer

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

Manufacturing Facility Certifications

ISO 9001:2008 and ISO 13485:2003 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 (c).

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.

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.

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. 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, we cannot guarantee this.



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).

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.

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). Resin is not certified to be Kosher or in compliance with Kosher requirements.

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). Resin is certified to be Halal or in compliance with Halal requirements.

REACH 173 Substances (January 12, 2017)

This product is not manufactured or formulated with any of the Substances of Very High Concern (SVHC) as per the candidate list that was current as of the effective date of this regulatory datasheet that would require reporting under this regulation. Monomers and relevant additives used to produce used polymer raw materials has been pre-registered.

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

This product complies with the requirements of Article 4.1 of EU Directive 2011/65/EU (RoHS 2). It 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).

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 as of the effective date of this Regulatory Data Sheet.

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.

- 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
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	Steam to 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.

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.