

**Flexelene™ MFX 92R**

Effective Date: November 6<sup>th</sup>, 2019

**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).

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### 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.

### 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, 6<sup>th</sup> 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 (7<sup>th</sup> 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). We do not certify this resin 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). We do not certify this resin to be Halal or in compliance with Halal requirements.

### 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.





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### **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.