

**KFLEX®**

Effective Date: August 26, 2021

## THERMOPLASTIC POLYURETHANE (TPU) (Outer Layer)

### Product Manufacturer

This product is manufactured by Eldon James, Denver, CO 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 Allergens

Based on the information available to us from our raw material suppliers, the product(s) listed above do not contain additives based on or derived from any known or potential food allergens such as, but not limited to: Fish, Soy, Peanuts, Wheat, Eggs, Milk, Crustacean, Shellfish, Tree Nuts, Sulfites, Glutens, Celery, Sesame and Mustard.

### Animal Derived Components (BSE/TSE)

This product is in compliance with the BSE/TSE requirements. No materials used in the manufacture of this product are of bovine or of any animal origin (either whole or part). In addition, the equipment used to manufacture this product is not used to produce any products of bovine or of any animal origin. Therefore, based upon knowledge of the manufacturing process and the raw materials utilized, the transmission of BSE/TSE via the products listed above is not expected to occur.

### Plant Derived Components

Determination of the presence of GMOs in our products is limited to chemical substances which may have been derived from genetically modified agricultural plants.

### REACH 219 Substances (July 8, 2021)

We or our resin supplier do not intentionally add any of the SVHC substances in the manufacture or formulation of this product and do not believe that any of the chemicals listed on the EU Candidate List of Substances of Very High Concern (SVHC) are present in this product at levels greater than 0.1%. Testing by the resin manufacturer has indicated that this resin may contain trace residues (<10PPB) of 4-nonylphenol, branched CAS # 84852-15-3.

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

EU Directive 2011/65/EC/Restriction on the use of certain Hazardous Substances (RoHS): Based on the information available to us from our raw material suppliers, and our knowledge of the products' compositions, the BASF products listed above do not contain any intentionally added cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs), Decabromo diphenyl ethers (Deca-BDEs), Di (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP). BASF does not routinely analyze these products or the raw materials for the presence of these substances. However, based upon knowledge of the manufacturing process and the raw materials utilized, these substances are not expected

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to be present in the final products in levels exceeding the limitations of EU Directive 2011/65/EC listed below:

<b>Substance</b>	<b>Limitation (wt%)</b>
Cadmium	0.01
Hexavalent Chromium	0.1
Lead	0.1
Mercury	0.1
Polybrominated biphenyls (PBBs)	0.1
Polybrominated diphenyl ethers (PBDEs)	0.1
Decabromo diphenyl ethers (Deca-BDEs)	0.1
Di (2-ethylhexyl) phthalate (DEHP)	0.1
Butyl benzyl phthalate (BBP)	0.1
Dibutyl phthalate (DBP)	0.1
Diisobutyl phthalate (DIBP)	0.1

**Heavy Metals (ELV Directive 2000/53/EC)  
Coalition of Northeastern Governors (CONEG)**

Please be advised that based on the information available to us from our raw material suppliers, this product does not contain as intentional additives, Cadmium and its compounds, Mercury and its compounds, Lead and its compounds and Hexavalent Chromium compounds at a total concentration of 100 ppm or higher. To the best of our knowledge, none of these materials are generated during production. We do not specifically run any analysis on our raw materials or end product to measure for these materials.

**Ozone Depleting Chemicals (ODCs)**

The products offered above do not contain any ozone depleting substances as referenced under the EPA Clean Air Act Section 602 and the Montreal Protocol on substances that deplete the Ozone Layer.

**Phthalates**

Please be advised that based on the information available to us from our raw material suppliers, the current product listed above does not contain any of the below listed phthalates. To the best of our knowledge, none of these materials are generated during production. Because we do not expect these materials to be present above the levels specified, we do not specifically run any analysis on our raw materials or end product to measure for these materials.

**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)

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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 Terphenyls (PBTs)  
Polychlorinated Biphenyls (PCBs)  
Polyvinyl Chloride (PVC)  
Polyvinylidene Chloride (PVDC)  
Tris-nonylphenol Phosphite (TNPP)

**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.