

U.S. Food Safety Declaration MIGS® / Polyfuze® Polymer Fusion Label Technology

DISCLAIMER

Polymer Fusion Labeling Technology is supplied as a raw material and becomes an integral part of the finished polyolefin thermoplastic product through the fusion process. Once fused, the label cannot be mechanically separated into different materials, eliminating the potential for material migration through damage or removal. Consequently, the entire product should be considered a homogeneous material for compliance purposes.

FDA Compliance

Polymer Fusion Labeling can be formulated to meet FDA compliance standards and may be safely used in applications governed by 21 CFR 174.5. This includes compliance with:

- **FDA 21 CFR 177.1520** – Olefin polymers approved for food contact applications.
- **FDA 21 CFR 178.3297** – Use of FDA-approved pigments in polymers for indirect food contact.
- **FDA Food Safety Modernization Act (FSMA)** – Ensuring materials used in food-related industries meet safety standards.

Unlike traditional surface coatings, adhesives, or print-on labels, Polymer Fusion Labels are composed of pigmented polymer material. During the fusion process, the label melts and fully integrates into the base plastic, just like the pigmentation within polyolefin thermoplastics. Once fused, the label takes on the same characteristics as the product itself, eliminating the risk of surface migration, peeling, or contamination.

Testing and Compliance Responsibilities:

- **Testing on Raw Material Labels** – Per the Mutual Non-Disclosure Agreement (MNDA), third-party testing or analysis of Polymer Fusion Labeling as a raw material is not permitted. Compliance testing should be conducted only after the label has been fully fused into the finished molded product.
- We ensure that materials identified as prohibited on the Restricted Substances Specifications are neither used in the manufacture nor intentionally added during the formulation of Polymer Fusion Labeling Technology. Therefore, their presence in the finished product is not anticipated.
- **Customer Responsibility for Compliance Testing** – Customers are responsible for ensuring that the final product meets applicable regulatory requirements by conducting necessary testing on the finished product.
- **Third-Party Testing Requests** – Any requests for third-party testing of Polymer Fusion Labeling prior to application must be reviewed on a case-by-case basis and are subject to MNDA restrictions with Mold In Graphic Systems® / Polyfuze® Graphics Corporation.

Migration & Safety Statement

- **Migration Testing** – Polymer Fusion Labels have not been subject to specific migration testing. However, the raw materials used meet FDA compliance for indirect food contact.
- **FDA-Approved Pigments** – For labels requiring FDA approval, only FDA-compliant pigments are used in the formulation of Polymer Fusion Labeling Technology.
- **No Expected Leaching or Contamination** – Based on material selection and the fusion process, migration of restricted substances is not anticipated.
- **Non-Shedding & Integrated Labeling** – Once applied, the label becomes part of the molded product, meaning there is no risk of flaking, peeling, or chemical transfer under normal conditions.



Mold In Graphic Systems® /
Polyfuze® Graphics Corporation
999 W. State Route 89A
Clarkdale, AZ. 86324
Tel: 928.634.8888

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- **Hygienic & Easy to Sanitize** – When applied to FDA-approved polyolefin thermoplastics, Polymer Fusion Labels take on the same hygienic properties as the base material. Unlike traditional label methods with adhesives and layered constructions that can trap bacteria and degrade over time, the homogeneous nature of Polymer Fusion Labeling ensures a seamless, non-porous surface that is easy to clean and maintain in food-safe environments.

Allergen & Contaminant-Free Statement

Polyfuze Graphics Corporation ensures that Polymer Fusion Labeling Technology:

- Does not contain BPA, Phthalates, or PFAS
- Does not contain latex, gluten, or other known allergens
- Is GMO-free and does not use animal-derived ingredients

Quality Management System & Manufacturing Practices

Polyfuze Graphics Corporation operates a LEAN Six Sigma-based Quality Management System (QMS) to ensure process efficiency, continuous improvement, and customer satisfaction. Our QMS integrates:

- Total Quality Management (TQM) principles
- Center of Excellence (COE) leadership initiatives
- LEAN Six Sigma Blackbelt & Greenbelt-led process optimizations
- Good Manufacturing Practices (GMP) – Adhered to during production to ensure product integrity.
- Batch Traceability – Each batch of labels is fully traceable through our production process.

Our Quality Management System documentation is available upon request, as is our methodology for employing LEAN initiatives.

Supporting Documentation Available Upon Request

Polyfuze Graphics Corporation can provide the following documents upon request:

- Material Safety Data Sheets (MSDS)
- FDA Ingredient Compliance Documentation

Conclusion

Based on the compliance measures outlined above, Polymer Fusion Labels are safe for use in applications where food safety is a concern. Customers are responsible for verifying compliance requirements for their specific application and conducting any required final product testing.

For further information or compliance inquiries, please contact:

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999 W. State Route 89A
Clarkdale, AZ 86324
Tel: (928) 634-8888



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