
European Union Food Contact Compliance 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 due to damage, wear, or removal. As a result, the finished product, including the fused label, should be considered a single homogeneous material for regulatory and compliance purposes.

Mold In Graphic® Systems / Polyfuze® Graphics Corporation does not perform analytical testing on raw materials. Compliance determinations are based on supplier-provided Certificates of Analysis (CofA) and Safety Data Sheets (SDS). It is the responsibility of the manufacturer of the final product to ensure that all applicable regulatory requirements are met for the intended use, including any required testing of the finished article.

Any third-party testing or analysis of Polymer Fusion Labeling Technology in its raw material form requires a signed Mutual Non-Disclosure Agreement (MNDA) with Mold In Graphic® Systems / Polyfuze® Graphics Corporation. Once the label has been applied and fused into a substrate in accordance with standard processing conditions, it is no longer considered a separate material and is not subject to MNDA restrictions.

European Union (EU) Compliance

Polymer Fusion Labeling Technology can be formulated to support compliance with applicable European Union regulatory requirements for materials used in polyolefin thermoplastic products. Due to its unique construction, where the label becomes fully integrated into the base polymer during the fusion process, the finished product is considered a single homogeneous material for the purposes of regulatory evaluation.

REACH (Regulation (EC) No 1907/2006):

Polymer Fusion Labeling Technology is manufactured without the intentional use of substances listed on the REACH Candidate List of Substances of Very High Concern (SVHC). Based on supplier-provided documentation, such substances are not expected to be present above applicable threshold limits in the finished homogeneous material. As the label becomes part of the base polymer, there are no separate layers, adhesives, or coatings that would introduce additional chemical exposure or migration pathways.

RoHS (Directive 2011/65/EU and amendments):

Polymer Fusion Labeling Technology may be formulated to meet the substance restrictions defined under RoHS, including Directive (EU) 2015/863 and subsequent amendments. Restricted substances such as lead, mercury, hexavalent chromium, PBBs, and PBDEs are not intentionally added, and any threshold-based compliance is evaluated at the level of the final homogeneous material, consistent with EU regulatory guidance.

Material Integrity & Compliance Advantage:

Unlike traditional labeling systems that rely on adhesives, inks, or multi-layer constructions, Polymer Fusion Labeling Technology eliminates the risk of delamination, material incompatibility, and surface degradation. This reduces the likelihood of compliance failures associated with label loss, contamination, or exposure of underlying materials during the product lifecycle.

Because the label is not a separate component but a fused extension of the base polymer, regulatory considerations such as substance restrictions and material safety are evaluated as part of the finished product rather than as an applied label. The mono-material construction supports recyclability by eliminating non-compatible label components typically associated with multi-material labeling systems.



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Testing and Compliance Responsibilities

Compliance with applicable European Union regulations is the responsibility of the manufacturer of the finished product. All necessary testing and validation should be conducted on the final article, including the polyolefin substrate with the fused Polymer Fusion Label, to ensure suitability for the intended use and regulatory requirements.

Polymer Fusion Labeling Technology is supplied as a raw material and is not evaluated independently as a separate component once fused. Regulatory assessments, including substance restrictions and safety evaluations, must be performed on the finished homogeneous material.

Any third-party testing or analysis of Polymer Fusion Labeling Technology in its raw material form requires a signed Mutual Non-Disclosure Agreement (MNDA) with Mold In Graphic® Systems / Polyfuze® Graphics Corporation.

Mold In Graphic® Systems / Polyfuze® Graphics Corporation relies on supplier-provided Certificates of Analysis (CofA) and Safety Data Sheets (SDS) for raw material compliance. It is the responsibility of the customer to determine final product compliance based on their specific application and use conditions.

Chemical Safety and Migration Statement

Polymer Fusion Labeling Technology is composed of pigmented polymer material that is fully integrated into the base polyolefin during the fusion process. Once fused, the label becomes part of the finished product and does not exist as a separate layer, coating, or surface-applied component.

Because the label is not applied using adhesives, inks, or multi-layer constructions, there are no interfaces or pathways that would facilitate material separation, degradation, or unintended chemical migration under normal use conditions.

Substances identified as restricted under applicable European Union regulations, including REACH and RoHS, are not intentionally added during the formulation of Polymer Fusion Labeling Technology. Based on supplier documentation, their presence in the finished homogeneous material is not expected above applicable regulatory thresholds.

Any migration or extractables evaluation, if required for a specific application, should be conducted on the finished product under actual use conditions. It is the responsibility of the manufacturer of the final article to determine suitability for the intended application and to ensure compliance with all applicable EU regulatory requirements.

EU Food Contact Compliance (OPTIONAL APPLICATIONS)

When required for food-contact or related applications, Polymer Fusion Labeling Technology can be formulated to support compliance with:

- Regulation (EC) No 1935/2004 (Framework Regulation for materials and articles intended to come into contact with food)
- Commission Regulation (EU) No 10/2011 (Plastic materials and articles intended for food contact)

Polymer Fusion Labeling Technology is composed of pigmented polyolefin-based material that becomes fully integrated into the base polymer during the fusion process. Once fused, the label is no longer a separate component but part of the finished plastic article, eliminating the use of adhesives, inks, or coatings that could introduce additional substances or migration pathways.

Because the label and substrate form a single homogeneous material, any migration or extractables evaluation must be performed on the finished product under intended use conditions. Compliance with applicable migration limits and food contact requirements is the responsibility of the manufacturer of the final article.



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Declaration

Mold In Graphic® Systems / Polyfuze® Graphics Corporation declares that Polymer Fusion Labeling Technology, when formulated as specified and applied in accordance with standard processing conditions, can support compliance with applicable European Union regulatory requirements for polyolefin thermoplastic products.

This declaration is based on supplier-provided Certificates of Analysis (CofA), Safety Data Sheets (SDS), and internal knowledge of material composition. No independent analytical testing has been conducted on the raw material by Mold In Graphic® Systems / Polyfuze® Graphics Corporation.

This statement applies solely to Polymer Fusion Labeling Technology as supplied. It is the responsibility of the manufacturer of the finished product to ensure that the final article complies with all applicable European Union regulations, directives, and requirements for its intended use

For further information or compliance inquiries, please contact:

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