

RoHS & EU Chemical Threshold Guidance 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.

For a broader compliance overview, including additional regulatory considerations, please refer to the MIGS PGC Regulatory Compliance Declaration document.

Testing and Compliance Responsibilities:

- We recommend that all necessary compliance testing, particularly for the detection of prohibited materials, be conducted on the finished product by the customers. This ensures that the product meets all regulatory requirements for its intended use.
- Any testing of the Polymer Fusion Labeling as a raw material by third parties or external customer facilities requires a signed Mutual Non-Disclosure Agreement (MNDA) with Mold In Graphic® Systems / Polyfuze® Graphic Corporation.
- Once labels are applied to a substrate in accordance with our General Terms & Conditions, they are no longer covered by the MNDA.

Analytical Testing:

Mold In Graphic® Systems / Polyfuze® Graphics Corporation does not perform analytical testing on raw materials. We rely on Certificates of Analysis (CofA) and Safety Data Sheets (SDS) provided by our suppliers. It is the responsibility of end-users to determine specific application and compliance requirements for their products.

Understanding Homogeneous Materials & Compliance Calculations:

Polymer Fusion Labels are distinct from traditional labeling methods because they are fully fused into the plastic substrate, making them a homogeneous material rather than a multi-layer system. As a result, regulatory thresholds for substances such as cadmium, lead chromate, and other restricted elements are calculated based on their proportion within the total composition of the final product.

For additional details on compliance requirements for other regulations, please refer to the MIGS PGC Regulatory Compliance Declaration document.

Meeting RoHS Compliance

If a customer requires ultimate durability while also meeting RoHS and EU Supplier Chemical Declaration limits, we can assess the specific label's composition to ensure compliance. This includes evaluating the label's weight, the amount of any restricted substances within it, and the total weight of the final product to verify that concentrations remain within allowable limits.

- Cadmium (Cd): <100 ppm (0.01% by weight of homogeneous material)
- Lead Chromate (PbCrO₄): <1000 ppm (0.1% by weight of homogeneous material)

See next page for real world example.



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Real-World Compliance Example:

Below is a real-world compliance example from a customer application where a safety label was required for a robust fuel tank system, and cadmium was used in the Polymer Fusion Label for enhanced durability. The provided snippet illustrates how compliance threshold calculations were performed, ensuring the final product met RoHS regulatory limits.

The cadmium used within the formulation of the entire label was calculated and is shown below in gram weight. To determine the PPM threshold of restricted cadmium, as shown in the calculation below, the mass of the restricted substance is divided by the mass of the total homogeneous material (mass of cadmium + product weight) and then multiplied by 1,000,000 to provide the PPM value.

Several different weight variations of the fuel tank system were provided to show the total homogeneous PPM for each. Below is a real-world compliance example from a customer application where a safety label was required for a robust fuel tank system, and cadmium was used in the Polymer Fusion Label for enhanced durability. The provided snippet illustrates how compliance threshold calculations were performed, ensuring the final product met RoHS regulatory limits.

Start/Drive Part Number: XYZ481

The Red Portions of this label contains .0363 grams of Cadmium pigments - Cadmium (Cd).

RoHS Restriction Cadmium (Cd) = **<100 ppm by weight of homogenous material**

*White and Black portions of this label are RoHS Compliant and are thus not calculated in final homogenous material.



PPM Restricted Substance Calculation:

(mass of restricted substance / mass of homogenous material) * 1,000,000 = **PPM total RoHS restricted substance contained in homogenous material.**

.0363 gram Cadmium Pigment / 1 lb. (453.592 gram) Fluorinated Fuel Tank * 1,000,000 = 69.048 ppm

.0363 gram Cadmium Pigment / 3 lb. (1360.78 gram) Fluorinated Fuel Tank * 1,000,000 = 23.016 ppm

.0363 gram Cadmium Pigment / 5 lb. (2267.96 gram) Fluorinated Fuel Tank * 1,000,000 = 13.809 ppm

.0363 gram Cadmium Pigment / 10 lb. (4535.92 gram) Fluorinated Fuel Tank * 1,000,000 = 6.904 ppm

.0363 gram Cadmium Pigment / 15 lb. (6803.89 gram) Fluorinated Fuel Tank * 1,000,000 = 4.603 ppm

.0363 gram Cadmium Pigment / 20 lb. (9071.85 gram) Fluorinated Fuel Tank * 1,000,000 = 3.452 ppm

.0363 gram Cadmium Pigment / 25 lb. (11339.8 gram) Fluorinated Fuel Tank * 1,000,000 = 2.761 ppm

.0363 gram Cadmium Pigment / 30 lb. (13607.8 gram) Fluorinated Fuel Tank * 1,000,000 = 2.301 ppm

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Custom Solutions for Compliance

- **RoHS-Compliant Pigments:** If complete avoidance of threshold calculations is preferred, we can use RoHS-compliant pigments, ensuring full compliance without further adjustments.
- **Durability & Threshold Compliance:** For applications requiring maximum durability in extreme environments, we can work within RoHS-defined limits for restricted substances such as Cadmium and Lead Chromate, maintaining compliance while optimizing performance.

EU Supplier Chemical Declarations

Beyond RoHS, some customers may require Supplier Chemical Declarations under EU Product Safety Regulations. This is especially relevant when evaluating potential migration of substances from materials under specific use conditions. For these declarations, we only utilize Cadmium and Lead Chromate, which are outlined in both RoHS and EU Chemical Regulations. Should a customer require compliance verification, threshold calculations can be performed to ensure regulatory limits are met while maintaining product durability.

Final Considerations

Each application is unique, and we work with customers to determine the best approach based on durability needs and regulatory requirements. Whether selecting fully RoHS-compliant pigments or ensuring compliance through threshold evaluations, we provide solutions tailored to specific product demands.

MIGS/PGC provides compliance calculations and threshold assessments for restricted substances within our Polymer Fusion Labels. Should a customer require a formulation that includes restricted substances for durability or performance reasons, we can determine whether the threshold limits can be met. However, it is the customer's responsibility to ensure that their entire finished product meets all applicable regulatory requirements.