



# **DECLARATION OF COMPLIANCE**

This information sheet is intended for informational purposes only. Determination of the suitability or fitness of this product for any particular application is the sole responsibility of the purchaser.

**COUNTRY OF ORIGIN:** All of Mold-Rite Plastics, LLC products are manufactured in the United States of America at our facility located at; 1 Plant Street Plattsburgh NY, 12901

#### US REGULATORY INFORMATION:

## FDA FOOD CONTACT STATUS:

21 CFR 177.1520(c)(3.1) Olefin Polymers. This regulation describes polymers that may be safely used in articles for food contact except for articles used for packing or holding food during cooking, subject to any use restrictions stated below. The user should determine that the physical properties of the resin are compatible with the desired conditions of use. Also, product may contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. These substances may include substances permitted for such use in 21 CFR 170 through 189, substances generally recognized as safe in food or food packaging, and substances used in accordance with a prior sanction or approval.

**ALLERGEN STATEMENT:** Major food allergens (Milk, Eggs, Fish, Crustacean Shellfish, Tree Nuts, Wheat, Peanuts, Soybeans) are not used in the formulation or manufacture of Mold-Rite Plastics, LLC products.

ANIMAL BASED: Mold-Rite Plastics does not add animal derived product during the manufacture of our products.

**CALIFORNIA PROPOSITION 65:** Proposition 65 requires manufactures or distributors of consumer products into the State of California to provide a warning statement if the product contains ingredients for which the State has found to cause cancer, birth defects or other reproductive harm. Mold-Rite Plastics, LLC's product, do not contain any ingredients listed in Proposition 65, with some exceptions.

**CONEG - Coalition of Northeastern Governors (Heavy Metals)** This product complies with the CONEG Model Legislation regarding heavy metals content. The sum of the concentrations of lead, mercury, cadmium and hexavalent chromium is less than 100 ppm by weight.

**COLORS:** Our white and black colorant suppliers have certified that all white and black colorants supplied to MoldRite meet FDA regulations for food and drug contact as well as USP regulation and are latex and heavy metal free. FDA status and other certifications of our colors are the responsibility of our customer and can be identified upon request.

**DRUG MASTER FILE (DMF) STATUS:** Our products are listed in the Mold-Rite TYPE III Drug Master File, No. 16574. Letters of Authorization can be requested exclusively through or by Mold-Rite direct sales customers.

The Toxics in Packaging Prevention Act, California Health & Safety Code § 25214.11 This product complies with The Toxics in Packaging Prevention Act, California Health & Safety Code § 25214.11 regarding heavy metals content. The sum of the concentrations of lead, mercury, cadmium and hexavalent chromium is less than 100 ppm by weight.

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UL: Mold-Rite Products have not been evaluated for UL clearance.

#### **EUROPEAN REGULATORY INFORMATION:**

**EUROPEAN FOOD CONTACT STATUS:** Mold-Rite Plastics, LLC has collected information from vendors of raw materials and, to the best of our knowledge, all stock raw materials listed below comply with 10/2011/EC (2002/72/EC).

PACKAGING AND PACKAGING WASTE: Mold-Rite Plastics, LLC's FDA compliant products meet European Directive 94/62/EC (2004/12/EC), Packaging Waste - This directive requires that the product comply Article 11 regarding concentration levels of heavy metals in packaging. The sum of the concentrations of lead, mercury, cadmium and hexavalent chromium is less than 100 ppm by weight. No direct testing has been completed. However, none of the raw materials used to produce Mold-Rite's FDA compliant products contain the above heavy metals.

**REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)** In accordance with the European Chemical Agency "Guidance for Monomers and Polymers, plastic finished articles are considered exempt under REACH. "The producer or importer of an article containing a polymeric substance is under no circumstances required to register the polymer, as polymers are exempt from registration". This statement is made under the understanding and interpretation of the REACH obligation by Mold-Rite Plastics, LLC. However, users are reminded that the REACH regulation may be interpreted differently and the end user is responsible for ensuring ultimate REACH obligations.

**RESTRICTION OF HAZARDOUS SUBSTANCES (RoHS):** Mold-Rite Plastics, LLC does not intentionally use lead, cadmium, chromium, mercury, or any compounds of these metals as listed in the RoHS regulation 2002/95/EC and its amendments in the manufacture or formulation of our products.

# **COMPONENT-SPECIFIC REGULATORY:**

**COLORANT** Black and white colorant complies with EU 10/2011, for other colors desired please contact the Quality Assurance Department.

LINER (Sancap) HS02 VENT/20FOAM, HS035 HEAT SEAL, HS035 LITE, FOIL GLASSINE, PRESSURE SEAL, PS304, PULPBOARD, HS035 PS FOAM R SFYP

**LINER (Selig)** ESTERFOIL 50, FS M-1, FS M-4, FS 1 -7, FS 4-6, FS 5-4, FS 5-9, FS 1 -13, FS 1 -15, FS 1 -16, FS 1 -17, FS 3-19, FS 3-25, LIFT N PEEL U5, WHITE LINED PULP, FS 5-9, FSLEM, C25FSLE5, C25FSLE1

# LINER (SeligCanada)

ISPE, ISPE/PP-U, PSF1, SAFE-GARD 75M, SAFE-GARD 90, SAFE-GARD 100, SAFE-GARD 518,

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SAFE-GARD 529, TT-562, LIFT N PEEL (LP-E) LIFE N PEEL (LPP), TOP TAB 518

LINER (Tech-Seal) HSL-1, HSS-5.6/20, HSL-5.6/20, I (HD), PHARMSEAL V, VINYL LINER, ALUMINUM FOIL LINER

LINER (Tekni-plex) ALUMINUM FOIL, FOAMSEAL PS22, HS 123, HS 128, HS 130, HS 205 F

LINER (Tri-Seal) F-217 HY, TRI-GARD II-TS PE, TRI-GARD II-TS PP

LINER (MRP) (A01) MRPLN04 UNIVERSAL HEAT SEAL FOAM LINER Mold-Rite products are considered food articles.

RESIN FPT300F PP, H5618 PE, 2535A (CP-0001), 6535A (CP0001), NA870252 LDPE, H5618 HDPE

## OTHER SUPPORTING INFORMATION:

**ADDITIVES & FILLERS** Mold-Rite Plastics, LLC does not add any types of additives or fillers throughout the manufacturing process with the exception of certain versions of the products listed below.

33mm Smooth CRC 38mm Smooth CRC 38mm Tear Away Cap 38mm Valve Seal

MoldWiz INT-33PA is a processing aid which complies to applicable FDA food contact regulations 21 CFR 175.320, 178.3570, and EU regulation 10/2011. Please contact the Quality Assurance department for any additional part specific information.

**ANIMAL DERIVED MATERIALS:** The Polypropylene and Copolymer resins used by Mold-Rite Plastics, LLC are free of animal derived content. Mold-Rite Plastics, LLC does not add any animal derived content in the manufacture of our products.

**BISPHENOL- A:** Mold-Rite Plastics, LLC does NOT add or use raw materials in the production of finished product that contain BispenolA. Mold-Rite Plastics, LLC utilizes polypropylene and polyethylene plastics in our finished products. Bisphenol-A is more commonly used or found in polycarbonate plastic and epoxy resins. Bisphenol-A is also used as an antioxidant in plasticizers and as a polymerization inhibitor in PVC. Mold-Rite Plastics, LLC does not use these materials in our finished product.

CHILD RESISTANT CLOSURES: Mold-Rite Plastics, LLC's child resistant closures comply with CFR 16, part 1700.

**CHLORINATED ITEMS:** Chlorinated Items are not used directly or indirectly, as additives or processing aids in the manufacturing or converting of any Mold-Rite Plastics, LLC product.

**FUNGICIDES, PESTICIDES, PRESERVATIVES OR FUMIGANTS:** Mold-Rite Plastics, LLC does not add to our products, any type of fungicides, pesticides, preservatives or fumigants.

GENETICALLY MODIFIED ORGANISM (GMO): Mold-Rite Plastics, LLC does not add any GMO's in the manufacture of our products.

LATEX: Latex or natural rubber materials are not intentionally used as plasticizers, additives or raw materials in Mold-Rite products.

MIGRATION/EXTRACTABLES/LEACHABLES Mold-Rite does not perform pharmacopeia testing on its products. Mold-Rite Plastics, LLC certifies its products comply with good manufacturing practices regulations of EC Ng 2023/2006 and is compliant with United States of America's Food and Drug Administration (USFDA) Title 21 CFR Part 110, cGMP. Mold-Rite certifies its product comply with European Pharmacopoeia of Section 3.1.3 "Polyolefines" (Appendix XX B) & section 3.2.2 "Plastic containers and closures" (Appendix XIX C). In accordance with EU directives, migration should be measured using appropriate food stimulants or actual foodstuff at the real time and temperature conditions of use. It is the responsibility of the recipient of our products to ensure that any existing laws and legislation are

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observed.

**PHTHALATES:** Phthalates are not used directly or indirectly, as additives or processing aids in the manufacturing or converting of any Mold-Rite Plastics, LLC product

Sincerely,

Richard Jarrette ISO Coordinator Mold-Rite Plastics, LLC

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