



Phillips Sumika

Polypropylene Company

BOX 792 • PHONE: (713) 475-3666

PASADENA, TEXAS 77501-0792

Pasadena Plastics Complex

PRODUCT REGULATORY OVERVIEW (PRO)

Marlex® HLN-120-01 Polypropylene

Product Manufacturer

This product is manufactured by Phillips Sumika Polypropylene Company.

Chemical Inventories

All the components of this product are listed in the following inventories.

AUSTRALIA: Australian Inventory of Chemical Substances (AICS)

CANADA: Domestic Substances List (DSL)

PEOPLE'S REPUBLIC OF CHINA: Inventory of Existing Chemical Substances (IECSC)

JAPAN: Existing & New Chemical Substances (ENCS) inventory

KOREA: Existing Chemicals List (ECL)

NEW ZEALAND: Inventory of Chemical Substances (NZIoCS)

PHILIPPINES: Philippine Inventory of Chemicals and Chemical Substances (PICCS)

UNITED STATES: Toxic Substances Control Act (TSCA) Chemical Inventory

Food Contact

U.S. FDA Food Contact

This product meets the requirements for polyolefin resins intended for food packaging applications as described in the FDA olefin polymer regulations 21 CFR 177.1520(c)1.1. The resin may be used in contact with all types of foods as defined in Table 1, 21 CFR 176.170(c) and at use conditions B-H as defined in Table 2, 21 CFR 176.170(c).

This product is produced in accordance with good manufacturing practices (GMP) as outlined in 21 CFR 174.5.

European Union (EU) Food Contact

All constituents of this resin are listed in Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. For full compliance an overall migration limit of 10mg/dm² and specific migration limit (SML) apply to the final article intended to come in contact with food.

This product meets the requirements of Framework Regulation (EC) No. 1935/2004 on materials and articles intended to come in contact with food.

This product is produced in accordance with good manufacturing practice (GMP) as outlined in GMP Regulation (EC) No 2023/2006.



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Canada Food Contact

A “No Objection” letter for this product has been approved by Health Canada. This product may be used for films and molded articles having direct contact with all types of food provided the temperature does not exceed 212°F (100°C) and it is technically suitable for intended end uses.

It is the responsibility of the converter to verify that the finished article meets both the technical and regulatory requirements of the intended application, and in particular does not modify the organoleptic properties of the food.

U.S. Pharmacopeia (USP)

This product meets the requirements of USP 23 <661> Containers Physicochemical Tests.

European Pharmacopoeia

This product meets the requirements of European Pharmacopoeia 3.1.3. the 5th edition “Polyolefines” materials used for the manufacture of containers.

Drug Master File (DMF)

This product is listed in United States FDA Type III Drug Master File 10562.
This product is listed in the Canadian Drug Master File 2002-007.

Animal-derived Materials / Kosher status

This product contains a substance used as a post-polymerization acid neutralizer of the base polymer. This acid-neutralizer contains a trace amount of tallow based ingredient. According to the best information of the supplier, the tallow used in the acid-neutralizer is sourced from the United States, Canada or South America, and has undergone the 200°C/20 min. process treatment called for in Directive 2004/C 24/03. Typical further treatment include approximately: 1) polymerization reaction temperatures from 75° C - 100° C for about 2 hour residence time, 2) finishing to produce pellets from about 200° C for less than 5 minutes, and subsequent 3) converting steps, estimated at around 200° C at less than 5 min. residence time.

The manufacturer does not certify its resins to be Kosher or in compliance with Kosher requirements.

California’s Safe Drinking Water and Toxic Enforcement Act (Proposition 65)

This product, as shipped by Phillips Sumika Polypropylene Company, is not known to contain any carcinogens or reproductive toxins presently known by the State of California to cause cancer or reproductive toxicity at a level of exposure subject to the requirements of California Proposition 65.



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Clean Air Act

This product is in compliance with the federal Clean Air Act, as amended in 1990.

Heavy metals, RoHS, WEEE, Waste packaging, CONEG

No heavy metals (i.e., antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, or silver) are purposely added to this product in quantities that would violate governmental guidelines. The summation of lead, cadmium, mercury, and hexavalent chromium in this product is less than 20 ppm. No polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), and Deca Brominated Diphenyl Ethers (Deca BDE) are intentionally added to this product. This product therefore meets the relevant requirements of the following Directives or Regulations:

- 2002/95/EC (RoHS)
- 2002/96/EC (WEEE)
- 2000/53/EC (ELV)
- 94/62/EC (Packaging Waste Directive)
- USA CONEG Regulation

Toys

This product meets the requirements of ASTM F963 and EN-71 concerning its use in toy manufacturing. Arsenic, antimony, barium, selenium, silver, lead, mercury, cadmium, and hexavalent chromium are not intentionally used in the process nor are they expected to be part of the raw materials to manufacture this product.

Phthalates

Phillips Sumika Polypropylene Company can state that we do not intentionally use or add phthalates as polymer additives when we produce this product. However, based on the levels of phthalic esters used in the synthesis of the catalyst, there is a theoretical possibility that less than 5 ppm phthalic esters remain in the product.

Absence of Substances and Chemicals

None of the following substances are used in the process nor are they expected to be part of the raw materials to manufacture this product:

- Acrylamide
- Alkylphenol Ethoxylates, including nonylphenol ethoxylate and octylphenol ethoxylate
- Allergens, such as peanuts, tree nuts, milk, eggs, wheat gluten, soy, fish, and shellfish
- Aromatic amines
- Asbestos
- Azo compounds



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- Bisphenol A
- Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)
- Dioxins
- Epoxy derivatives listed in EU Directive 2002/16/EC
- Hazardous Air Pollutants (HAP)
- Melamine
- Methyl Bromide
- Natural rubber latex and dry natural rubber
- Nonyl phenol
- Ozone-depleting chemicals
- Polychlorinated and Polybrominated Biphenyls (PCBs and PBBs)
- Polychlorinated and Polybrominated Terphenyls (PCTs and PBTs)
- Polybrominated Diphenyl Ethers (PBDEs)
- Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonates (PFOS)
- Polyaromatic Hydrocarbons
- Radioactive Substances
- Organo-Tin Compounds
- Tris-Nonylphenol Phosphite
- Vinyl Chloride Monomer (VCM) and Polyvinyl Chloride (PVC)
- Volatile Organic Compounds (VOC)

It is the responsibility of the customer to check compliance of the final articles with the relevant legislative and applicable regulatory requirements including their restrictions.

Disclaimer: *Before using this product, the user is advised and cautioned to make its own determination and assessment of the safety and suitability of the product for the specific use in question and is further advised against relying on the information contained herein as it may relate to any specific use or application. It is the ultimate responsibility of the user to ensure that the product is suited and the information is applicable to the user's specific application. Phillips Sumika Polypropylene Company does not make, and expressly disclaims, all warranties, including warranties of merchantability or fitness for a particular purpose, regardless of whether oral or written, express or implied, or allegedly arising from any usage of any trade or from any course of dealing in connection with the use of the information contained herein or the product itself. The user expressly assumes all risk and liability, whether based in contract, tort or otherwise, in connection with the use of the information contained herein or the product itself. Further, information contained herein is given without reference to any intellectual property issues, as well as federal, state or local laws which may be encountered in the use thereof. Such questions should be investigated by the user.*

Additional information on the health and safety aspects of our product is listed in the MSDS of the product.