

Product Regulatory Information Sheet

DaelimPoly mLLDPE BO1601EN

Product Manufacturer

BO1601EN is manufactured by DL Chemical Co., Ltd., in Korea.

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

Substances of Very High Concern (SVHC)

We hereby confirm that we do not intentionally use any of the candidate chemical substances proposed to be Substances of Very High Concern, SVHC (List as of Jan 19, 2021) as stated in REACH (Article 57, Regulation No. 1907/2006), in the manufacturing of the above-mentioned Product.

Current information for SVHC can be found at the ECHA website,

<https://echa.europa.eu/candidate-list-table>

Chemical Inventories

All the ingredients in the Product *BO1601EN*, are listed on the following chemical inventories:

- United States : TSCA - Toxics Substances Control Act Inventory
- Canada : DSL - Domestic Substances List
- Europe : EINECS/ELINCS replaced by REACH
- Australia : AICS - Australia Inventory of Chemical Substances
- New Zealand : NZIoC - New Zealand inventory of Chemicals
- Korea : KECL - Korean Existing Chemicals List
- Japan : ENCS - Japanese Inventory of Existing and new Chemical Substances
- The Philippines : PICCS - Philippines Inventory of Chemicals and Chemical Substances
- China : IECSC - Inventory of Existing Chemical Substances Manufactured or Imported in China

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Food Contact

European Union (EU) Food Contact

We confirm that the above-mentioned product, *BO1601EN* and all the ingredients, are in compliance with **EU Regulation EC No 10/2011** and amendments up to **Regulation (EU) 2020/1245** relating to plastic materials and articles intended to come into contact with foodstuff.

The product complies with the global and relevant specific migration limit (SML) and Total specific migration limits (SML(T)).

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
FCM Substance No	Ref. No	CAS No	Substance Name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restriction and specifications	Notes on verification of compliance
661	95360	0027676-62-6	1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione	yes	no	yes	5			
671	74240	0031570-04-4	Phosphorous acid, Tris(2,4-di-tert-butylphenyl)ester	yes	no	no				

Dual Use Additives :

We inform you that we do not use the substances defined as 'Dual Use Additives' in producing the above-mentioned Product.

The above-mentioned product meets the requirements of **Framework Regulation (EC) No. 1935/2004** of The European Parliament intended to come into contact with foodstuff and repealing Directives 80/590/EEC and 89/109/EEC.

The above-mentioned product is produced by using our ISO 9001 System, and is reviewed with regard to **Good Manufacturing Practice (GMP)** as outlined in **EU GMP Regulation (EC) No 2023/2006**.

We inform you that the organoleptic properties are influenced by the conditions of use type of processing conditions (e.g. temperature, pressure, etc.), storage conditions and packaged foodstuff. Therefore, the packaging has to be controlled by the user of downstream following the specific end-use conditions.

U.S. FDA Food Contact

The product meets the requirements for polyolefin resins intended for food packaging applications as described in the FDA (Food and Drug Administration) olefin polymer regulations

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21 CFR 177.1520(c).

According to information received from all of our suppliers, all the ingredients used in *BO1601EN* meet the requirements of their respective FDA regulations.

BO1601EN may be used in contact with all types of food as defined in table 1, 21 CFR 176.170 (C). *BO1601EN* meets the FDA criteria for food contact applications listed under conditions of use B through H in 21 CFR 176.170 (c), Table 2.

China Food Contact : GB4806.6-2016, GB9685-2016

The base polymer of above mentioned *BO1601EN*, is listed in **GB4806.6-2016** (National Food Safety Standard – Food Contact Plastic Resins) and complies with **GB9685-2016** (National Food Safety Standard – Standard for the use of additives for Food Contact Materials and Articles) for additives intentionally used in the product.

German Water Hazard Class

We inform you that the above mentioned Product is classified as non-Hazardous substance to water pursuant to number 1.2a (as Index number 766) in Annex I of German Water Hazard Class (WGK).

HALAL /KOSHER

We inform you that we do not have Certification of HALAL/KOSHER Certification or in compliance with Halal/Kosher Requirements for the above-mentioned Product.

European Pharmacopoeia (EP)

The above-mentioned Product has not been tested for EP.

US Pharmacopoeia (USP)

The above-mentioned Product has not been tested for USP.

Biocidal Products Regulation (BPR)

We inform you that we do not use the substances defined as "Biocidal Products", laid down principally in Regulation (EU) No 528/2012, up to amendment of Commission delegated Regulation (EU) No 2017/2100, when producing the above mentioned product.

But we do not have Certification of BPR Certification by the competent authorities.

Packaging and Packaging Waste, RoHS, WEEE, CONEG, etc.

The product complies with the following legislations, recommendations or communications.

- Directive 94/62/EC (Packaging and Packaging Waste Directive) as up to amendment of Directive EU 2015/720

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- Directive 2002/95/EC and 2011/65/EC (RoHS) as up to amendment 2015/863/EC
- Directive 2002/96/EC (WEEE) as up to amendment 2012/19/EC
- USA CONEG Regulation

Persistent Organic Pollutants

We inform you that we do not use the substances defined as "Persistent Organic pollutants", laid down principally in Regulation (EU) No 850/2004, up to amendment of Commission Regulation (EU) No 2016/293, list of substances subject to prohibitions (Annex I) and list of substances subject to release reduction provisions (Annex III), when producing the above mentioned product.

But we do not have Certification by the competent authorities.

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

We inform you that we do not use the substances listed on the Proposition 65, which may cause cancer, birth defects or other reproductive harm, when producing the above mentioned product.

Toy Safety

With Regard to Safety of Toys migration of certain elements, the product complies with the requirements of American Standard ASTM F963-11 and European Standard EN 71 (Part 3) and EN71 (Part 9), Edition 1995, Filing n° S51-214.

Absence of Substances and Chemicals

We hereby confirm that we do not intentionally use the following substances in the manufacture of or formulation of the above-mentioned product. However, we do not test for these chemical substances.

- Acrylamide
- Alkylphenol Ehtoxylates, including nonylphenol ethoxylate and octylphenol ethoxylate
- Allergen substances (i.e., peanuts, tree-nuts, milk, eggs, wheat gluten, soy, fish, and shellfish)
- Antimony Trioxide
- Aromatic amines
- Asbestos
- Azo compounds
- Benzophenone and Benzophenone Derivatives
- Bisphenol Derivatives : Bisphenol-A, Bisphenol-F, Bisphenol-S
- BHT - Butylated Hydroxytoluene, and BHA - Butylated Hydroxyanisole
- Chlorinated Aliphatic Compounds
- Conflict minerals, including Columbite-Tantalite, Cassiterite, Gold and Wolframite
- Dimethylfumarate
- Diisononylphthalate (DINP)
- Dioxins and Difurans
- Epoxy derivatives BADGE, BFDGE, NOGE, listed in EU Regulation 1985/2005/EC
- Ethanol

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- Flame Retardants; Halogenated and Brominated Compounds
- Formaldehyde
- Halogens
- Heavy Metals
- GMOs - Genetically-modified Organisms
- Melamine
- Mineral Oil
- MOSH (Mineral Oil Saturated Hydrocarbons) and MOAH (Mineral Oil Aromatic Hydrocarbons)
- N-Methyl Pyrrolidone (NMP)
- Nano-Materials : EU Commission Recommendation 2011/696/EU
- Natural rubber latex, dry natural rubber and Synthetic Latex
- Nonyl phenol Derivatives and Nonylphenoethoxylates
- Organotin Compounds
- Ozone-depleting substances + Chlorofluorocarbons (CFCs) /HydroChlorofluorocarbons (HCFCs) /Hydrofluorocarbons (HFCs)
- Perfluorooctane (PFOS) and Perfluorooctanoic Acid (PFOA)
- Phthalates
- Polyaromatic Hydrocarbons (PAHs)
- PBDEs - Polybrominated Diphenyl Ethers
- PCBs and PBBs - Polychlorinated and Polybrominated Biphenyls
- PCTs and PBTs - Polychlorinated and Polybrominated Terphenyls
- PFAs - Per- and Polyfluoroalkyl Substances
- PFOA and PFOS - Perfluorooctanoic Acid, and Perfluorooctane Sulfonates
- Radioactive Substances
- Recycled materials
- Silicones and Silicon Compounds
- Substances of Animal Origin : BSE/TSE
- Substances known as toxic for the environment
- Thiuram Mix
- Tris-Nonylphenol Phosphite (TNPP)
- VCM and PVC - Vinyl Chloride Monomer, and Polyvinyl Chloride

This Product Regulatory Information Sheet ("PRIS") is intended for informational purposes only.

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.

The Producer, DL Chemical Co. and/or the Distributor, Daelim PnP make(s) no representations or warranties with respect to the accuracy or completeness of the information contained herein.

Determination of the suitability and fitness of the specific product and/or material for any particular application is the sole responsibility of the purchaser.

Additional Information on the Health and Safety views of Our Product is listed in the SDS of the Product.

Producer : DL Chemical. Co., Ltd., Distributor : Daelim PnP

(Effective Date : Oct. 18th , 2021)

Certified for DL Chemical by :

K. H. Lee 

Team Leader – Quality Assurance Team

Product Stewardship & Regulation affairs: Tel +82-(0)42-869-7405 , e-mail: jhlee5@dlchemical.co.kr

This certificate shall continue in effect for 1 year from its effective date.

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