

PRODUCT REGULATORY COMPLIANCE STATEMENT

SM398

Issuance Date: 28 February 2024

POLYPROPYLENE RANDOM COPOLYMER

Product Manufacturer

This product is manufactured by Lotte Chemical Titan (M) Sdn Bhd.

REACH (Regulation (EC) No. 1907/2006) and amendments (December 2023)

Substances of Very High Concern (SVHC)

This product does not contain any of the Annex XIV candidate substances (240 substances, 23 January 2024) proposed to be Substances of Very High Concern above the 0.1% threshold as stated in REACH (Article 57, Regulation (EC) No. 1907/2006).

This product also does not contain any substances on the REACH Annex XVII Restriction Substances list (73 valid entries, 12 December 2023).

REACH registration

Polymers are generally exempted from the provisions on registration of Title II of REACH (Article 2(9)). However the ethylene and propylene monomers have to be registered. For further enquiries, please contact our Technical Service Department.

Food Contact

US Food and Drug Administration (FDA)

This product, as manufactured, is in compliance with Title 21 (Edition 2021), Code of Federal Regulations (CFR) Parts 177.1520 (a) (3) (i) and (c) 3.1a as promulgated by the US Food and Drug Administration (FDA) for all food types listed in Table 1 and under conditions of use C through H as described in Table 2 of CFR 21 176.170 (C).

European Union (EU) Food Contact – Regulation 1935/2004/EC and (EU) No. 10/2011 and amendments, most recent amendment No. 2023/1627 (August 2023)

This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation), applicable to plastic raw material.

This product complies with the relevant requirements of Regulation 2023/2006/EC (Good Manufacturing Practice), applicable to plastic raw material. Lotte Chemical Titan maintains an ISO 9001 system that corresponds to the requirements of EC No 2023/2006 and adopts good manufacturing practice.

The monomers and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EC.

This product contains one or more substances with Specific Migration Limits (SMLs). As the fabrication process can affect the migration behavior, the fabricator of the articles is responsible to test and determine the migration limit of the final articles intended to come into contact with foodstuffs.

This product contains Calcium Stearate (E470a) and Glycerol Monostearate (E471) as dual use additives, which are permitted as food additives or flavourings in Regulation 1333/2008/EC or Regulation 1334/2008/EC.

To obtain information on restricted substances identity, please contact our Technical Service Department.

China National Standard of Food Safety – GB4806.1-2016, GB4806.6-2016 and GB9685-2016 (Dec 2019)

This product complies with the relevant requirements of GB4806.1-2016: General Safety Requirements for Food-Contact Materials and Articles and GB4806.6-2016 Food-contact Plastic Resins, listed in Table A1 with unrestricted requirements.

The monomers and additives used to produce this product are listed in GB9685-2016: Standard for The Use of Additives for Food Contact Materials and Articles and control well below the maximum allowable limit.

This product contains one or more substances with Specific Migration Limits (SMLs). As the fabrication process can affect the migration behavior, the fabricator of the articles is responsible to test and determine the migration limit of the final articles intended to come into contact with foodstuffs.

Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA)

This product is currently registered under the Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA) for use in food contact packaging applications.

Japan Food Sanitation Law (Law number: Act No. 233 of 1947)

This product is listed in the Positive List of Polymer of Japan Food Sanitation Act (May 2020). The monomers and additives used to produce this product are listed and control below Use Level listed in Positive List of Monomers (May 2020) and Additives (April 2020) of Japan Food Sanitation Act.

Malaysia Food Regulation 1985

The manufacture of this product complies with the relevant requirements of Malaysia Food Regulation 1985 Part VI Packages For Food, applicable to packages raw material.

As the fabrication process can affect the migration behavior, the fabricator of the articles is responsible to test and determine the migration limit of the final articles intended to come into contact with foodstuffs.

Indonesia Food Contact (BPOM)

This product is in compliance with the Badan Pengawas Obat dan Makanan (BPOM) Regulation 20/2019 on Food Packaging (Appendix I: Food contact substances prohibited for use in food packaging and Appendix II: Food contact substances permitted for use in food packaging with migration limit).

This product does not contain any food contact substances in food packaging with Specific Migration Limits (SMLs).

Heavy Metals

No heavy metals (i.e. antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium) are purposely added to this product in quantities that would violate government guidelines. The summation of Lead, Mercury, Cadmium and hexavalent chromium in this product is less than 20ppm. Polybrominated biphenyls (PBB), Polybrominated diphenyl ether (PBDE), Hexabromocyclododecane are not intentionally added to this product. This product therefore meets the relevant requirements of the following Directives or Regulations:

- Restriction of Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) – EU Directive 2011/65/EC and amendments (September 2023)
- Coalition of Northeastern Governors (CONEG) Model Toxics in Packaging
- Packaging and Packaging Waste 94/62/EC and amendment (May 2018)
- Waste Electrical and Electronic Equipment (WEEE) – EU Directive 2002/96/EC and 2012/19/EU
- End of Life Vehicles (ELV) – EU Directive 2000/53/EC

Regulation (EC) NO.1895/2005

The manufacture of this product does not involve addition of Bisphenol A (BPA), diglycidyl-ether (BADGE), Bisphenol F diglycidyl ether (BFDGE) and Novolac glycidyl ethers (NOGE).

California Proposition 65 (1986)

The manufacture of this product does not involve addition of any of the substances listed in California's Proposition 65 chemicals listing (29 December 2023) except Phthalates.

Halogenated Flame Retardants

This product is not intentionally manufactured with halogenated or phosphorous based flame retardants.

Ozone Depleting Chemicals (ODCs)

This product is not intentionally manufactured with Class I and Class II ODCs listed in the US Clean Air Act Amendments of 1990.

Animal Derived Material/BSE/TSE

This product is not intentionally manufactured with animal fats, oils, milk products or other animal- or tallow-derived products.

Carcinogenic/Mutagenic/Reprotoxic Substances

This product is not intentionally manufactured with carcinogenic 1A/1B, mutagenic 1A/1B or reprotoxic 1A/1B (CMR) substances, in accordance with the classification rules of Regulation (EC) No 1272/2008 (CLP) Annex VI.

Global Automotive Declaration Substance List (February 2023)

This product does not contain any prohibited substances or declarable substances above the threshold limit of 0.1%.

Toys

EN71-3:2019+A1:2021, EU Directive 2009/48/EC

The manufacture of this product does not involve addition of allergenic fragrances, aluminium, antimony, arsenic, barium, boron, cadmium, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin and zinc. However, aluminium is a functional component of the co-catalyst system, triethyl aluminium.

EN71-9:2005

The manufacture of this product does not involve addition of chemicals listed in Tables 2D, 2E and 2I

Standard Consumer Safety Specification for Toy Safety ASTM F963

The manufacture of this product does not involve addition of nitrosamines, lead, antimony, arsenic, barium, cadmium, chromium, mercury, selenium.

Phthalates

This product is not intentionally added with any Phthalates as listed in:

REACH

Substance of very high concern (SVHC) list
Annex XIV, SVHC authorization list
Annex XVII, restricted substances list, item 51 & 52 phthalate

California Proposition 65

American CPSIA (Consumer Product Safety Improvement Act)

Washington Children's Safe Product Act (WAC 173-334) – Chemicals of High Concern to Children (85 CHCC, September 29, 2017)

ASTM F963 Standard Consumer Safety Specification for Toy Safety

However, Isobutyl phthalate (DIBP) is present as a minor component of the catalytic system used for polymerization. The total Phthalates residual/impurities in product is expected not more than 25 ppm (0.0025%) and this is far below the 0.1% restriction by weight.

Food Allergens

The manufacture of this product does not involve addition of food allergens as listed in:

- US Allergen Labelling and Consumer Protection Act of 2004. 21 note – FALCPA and
- EU Regulation No 1169/2011 (25 October 2011) Annex II.

Conflict Minerals

The manufacture of this product does not involve addition of tin, tantalum, tungsten, gold and minerals associated with these metals (Columbite-Tantalite, Cassiterite, Gold, Wolframite)

Nanomaterial

This product is not a nanomaterial.

Persistent Organic Pollutants

This product is not intentionally manufactured with chemical substances as listed in Regulation (EU) 2019/1021 and amendments.

Global Chemical Inventory Compliance

All ingredients of this product are listed in the following chemical inventory lists or exempt:

Country	Inventory	Y/N	Country	Inventory	Y/N
United States	TSCA	Yes	Japan	ENCS	Yes
Euro	EINECS	Yes	Korea	KECL	Yes
Canada	DSL	Yes	New Zealand	NZIoC	Yes
Australia	AICS	Yes	Philippines	PICCS	Yes
China	IECSC	Yes	Taiwan	TCSI	Yes

Other Chemical Substances

The following chemical substances are not intentionally added in the manufacture of or formulation of this product.

No.	Substance name	No.	Substance name
1.	Adipates	29.	Nano Materials
2.	Aromatic Amines	30.	Nitrosamines
3.	Azo compounds	31.	Nitrosatable Substance
4.	Biocide/Pesticide	32.	N-Ethy-toluenesulfonamide (ortho/para)
5.	Blowing agent	33.	Nonylphenol
6.	Brominated & Chlorinated substances	34.	Octyl- or Nonylphenols or -phenoethoxylates;
7.	Chlorophenols	35.	Organic tin compounds/Alkyltin compounds
8.	Chlorinated aromatic hydrocarbons	36.	O-alkyl (C<=10,Incl. Cycloalkyl) (Me,Et,n-Pr or I-Pr)-phosphonofluoridates
9.	Chlorinated plastic, Polyvinyl chloride (PVC) & its blends, Polyvinylidene chloride & its blends	37.	O-alkyl (C<=10,incl. Cyclically)N,N-dialkyl (Me,Et,n-Pr or I-Pr) phosphoramidocyanidates
10.	Dioxins	38.	O-alkyl (C<=10,incl. Cycloalkyl) S-2-dialkyl (Me,Et,n-Pr or I-Pr) -aminoethyl alkyl (Me,Et,n-Pr,IPr) phosphonothiolate and its alkylated or protonated salts
11.	Ditertbutyl peroxide	39.	S-2-dialkyl (Me,Et, n-Pr or I-Pr)-aminoethyl= hydrogen= alkyl(Me,Et,n-Pr,I-Pr) phosphonothiolate and its alkylated or protonated salts
12.	Enamel	40.	O-alkyl (C<=10 ,incl. cycloalkyl) O-2-dialkyl (Me, Et, n-Pr or i-Pr) -aminoethyl alkyl (Me, Et, n-Pr or I-Pr) phosphonites and its alkylated or protonated salts
13.	Epoxy derivatives	41.	O-2-dialkylethyl (Me, Et, n-Pr or i-Pr) = hydrogen = alkyl (Me, Et, n- Pr or i-Pr) phosphonites and its alkylated or protonated salts
14.	Ethylene Glycol Ethers	42.	Perfluorinated Chemicals
15.	Flame retardant	43.	Phenols
16.	Fragrances	44.	Polybrominated Biphenyls
17.	Genetic Modified Organism	45.	Polybrominated Diphenyl Ethers
18.	Isocyanates	46.	Polychlorinated Naphthalenes
19.	Halogen (Cl, Br, F)	47.	Polychlorinated and polybrominated Biphenyls
20.	Halogenated Phenols	48.	Polychlorinated and polybrominated Terphenyls
21.	Hydrofluorocarbon, Perfluorocarbon	49.	Polycyclic aromatic hydrocarbons
22.	Long-chained chlorinated paraffins	50.	Quartz
23.	Medium-chained chlorinated paraffins	51.	Radioactive substances
24.	Melamine and derivatives	52.	Recycled materials
25.	Microbial	53.	Silicone / Siloxane
26.	Mineral Oil Aromatic Hydrocarbons	54.	Shortchain Chlorinated Paraffins
27.	Mineral Oil Saturated Hydrocarbons	55.	Softeners
28.	Natural rubber or latex		

Additional information on the health and safety aspects of our product is listed in the SDS of the product. Please contact our Technical Service Department for any other technical enquiry and clarification.

The information supplied here is valid for 1 year from the date of issuance or will be updated when appropriate or changes made in any of the regulatory. User is advised to revisit to check for any update.

Disclaimer

The above information supplied is to the best of our knowledge and available data. However, since the actual conditions of use and the specific uses of our products are beyond our control, the user necessarily assumes all risks of their uses. As such, all users must make their own determination that the uses of our products are safe, lawful, and technically suitable in its intended applications. This information in no way modifies amends, enlarges, or creates any specification or warranty. This information sheet is neither a quality assurance certificate nor an approval permit and shall not be used for legal litigation purposes.