

PRODUCT REGULATORY COMPLIANCE STATEMENT

High Density Polyethylene

TITANVENE HD6070EA

Product Manufacturer

PT LOTTE CHEMICAL TITAN NUSANTARA

Chemical Inventory Listing

All components of this product are listed on:

USA	: Toxic Substances Control Act (TSCA) Chemical Inventory
Canada	: Domestic Substances List (DSL)
EU	: European Inventory of Existing Commercial Chemical Substances (EINECS)
Australia	: Australian Inventory of Chemical Substances (AICS)
New Zealand	: New Zealand Inventory of Chemical Substances (NZIoCS)
China	: Inventory of Existing Chemical Substances (IECS)
Korea	: Korea Existing Chemicals Inventory (KECI)
Philippines	: Philippines Inventory of Chemicals and Chemical Substances (PICCS)
Japan	: Existing and New Chemical Substances (ENCS) Inventory, Industrial Safety and Health Law (ISHL) Inventory
Taiwan	: Chemical Substance Nomination and Notification (CSNN)

All components of this product are not listed on:

EU	: the No-Longer Polymers list (NLP)
Germany	: Polycyclic Aromatic Hydrocarbon

EU Food Contact Material Regulation

This product, as manufactured, is in compliance with Title 21 (Edition 2021), Code of Federal Regulations (CFR) Parts 177.1520 (a) (3) (i) (a) (1) and (c) 3.1a & 3.2a as promulgated by the US Food and Drug Administration (FDA) for all food types listed in Table 1 and under conditions of use B through G as described in table 2 of CFR 21 176.170 (C).

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

According to Table 1 of Annex I to Commission Regulation No 10/2011, no monomers and additives used for manufacturing of this grade are under restriction or specification. And this product complies with Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

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 dual use additive as defined in Regulation 10/2011/EC.

This product contains Calcium Stearate (E470a) as dual use additive, which is permitted as food additives or flavourings in Regulation 1333/2008/EC or Regulation 1334/2008/EC.

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This product does not contain any substance with Specific Migration Limits (SMLs). However aluminium (CAS No. 7429-90-5), may exist as a functional component of the co-catalyst system, triethyl aluminium (CAS No. 97-93-8). The total Al content is expected to be below the SML limit (1mg/kg).

Provided that appropriate manufacturing process is carried out, this product is suitable for use as food contact materials or articles according to articles 3 of Regulation (EC) 1935/2004. Compliance with the provision of regulation (EC) 1935/2004 especially the suitability of the articles for the given application, the smell and taste of the food, and observance of any given limitations must be ensured by the final articles fabricator.

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.

This Product complies with Regulation (EU) 2023/1442 of 11 July 2023 amending Annex I to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as regards changes to substance authorisations and addition of new substances.

This Product complies with Regulation (EU) 2023/1627 of 10 August 2023 amending Annex I to Regulation (EU) No 10/2011 as regards the authorisation of the substance bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate (FCM No 1079).

However, the overall and specific migration test shall be made from the final articles intended to come into contact with foodstuff. It is the responsibility of the converter or food packer to verify that the final articles are in compliance with requirements as set out by the applicable legislation.

US Food and Drug Administration (FDA)

This product is in compliance with Food and Drug Administration – Code of Federal Regulation Title 21 Part 177 Subpart B – Substances for Use as basic Components of Single and Repeated Use Food Contact Surfaces – 177.1520 Olefin polymers (a)(2)(i), (c)2.1 and (c)2.2 and (c) 3.1a & 3.2a as promulgated by the US Food and Drug Administration (FDA) for all food types listed in Table 1 and under conditions of use B through G as described in the table 2 of CFR 21 176.170 (C).

Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA)

This product is not 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 and comply in the Positive List of Polymer of Japan Food Sanitation Act (November 2023). The monomers and additives used to produce this product are listed and control below Use Level listed in Positive List of Monomers and Additives of Japan Food Sanitation Act.

Japan Positive List

This product is listed and comply in Japan Positive List (Updated draft lists of base materials and additives based on revised at 30th November 2023). Enforcement of the Positive List is scheduled to commence on 1 June 2025. This follows the MHLW's earlier publication in April 2020 of the first draft positive list of substances assessed for safety in contact with utensils, containers, and packaging. The amendments to Article 18(3) of the Food Sanitation Act came into effect on 1 June 2020.

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Indonesia Food Contact (BPOM)

This product is in compliance with Peraturan Kepala Badan Pengawas Obat dan Makanan (BPOM) Republik Indonesia Nomor 20 Tahun 2019 tentang Kemasan Pangan (Lampiran 1: Zat Kontak Pangan yang Dilarang Digunakan sebagai Kemasan Pangan dan Lampiran II: Zat Kontak Pangan yang Diizinkan sebagai Kemasan Pangan dengan Persyaratan Batas Migrasi).

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

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 behaviour, the fabricator of the articles is responsible to test and determine the migration limit of the final articles intended to come contact with foodstuffs.

China National Standard of Food Safety

This product is in compliance with relevant requirement of GB4806.1-2016: General Safety Requirement for Food Contact Materials and Articles, and GB4806.7-2023: Plastic Material and Product for Food Contact, listed in Table A1 with unrestricted requirement.

This product is in compliance with requirement of GB 31603-2015 National Food Safety Standard -- General Health Code for Production of Food-contacted Materials and Products. GB 9685-2016 National Food Safety Standard: Standard for the Use of Additives in Food Contact Materials and Articles.

This product is in compliance with requirement of GB 31604.30-2016 National Food Safety Standard - Food Contact Materials and Articles - Determination of the Content and Migration of Phthalate Esters.

European Commission

EC 1272/2008

The manufacture of this product does not involved addition of substances listed in CLP EC 1272/2008 as CMR category 1A /1B/2 and CLP EC 1272/2008 as Skin Sensitizers (H317).

EC 1223/2009

The manufacture of this product does not involved addition of substances listed in annexes II & III substances.

Toys

EN71-3:2019, 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.

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.

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Phthalates

Phthalates are not intentionally utilized as raw materials in manufacturing this product. Hence, this product is expected to be proclaimed as phthalate-free.

REACH (Regulation (EC) No. 1907/2006) and amendments (November 2024)

SVHC / REACH

None of raw materials utilized in manufacturing of this product are classified as Substances Very High Concern released by European Chemical Agency (Last updated on January 21st, 2025 : 247 substances) as stated in REACH (article 59(10), regulation (EC) no.1907/2006).

This product also does not contain any substances on the REACH Annex XVII Restriction Substances list (74 valid entries, November 12th, 2024)

This product is included in Authorisation List Annex XIV of REACH Regulation (**Entry No.:59**).

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 contactour Technical Service Department.

Heavy Metals: RoHS, WEEE, Packaging Waste, CONEG

This product meets heavy metal requirements as described in following regulations:

- CONEG (Coalition of Northeastern Governors) - US.
- Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on Packaging and Packaging Waste.
- Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles
- DIRECTIVE 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (recasting of Directive 2002/95/EC) . Directive 2015/863 was published in 2015 by the EU.
- End of Life Vehicles (ELV) – EU Directive 2000/53/EC.

Substances and their compounds of Cadmium, Lead, Mercury and Hexavalent chromium, flame retardants PBB (Polybrominated biphenyls) and PBDE (Polybrominated diphenyl ether), Bis(2Ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) are neither used or intentionally involved during the whole process.

California Proposition 65 (1986)

Manufacturing of this product does not involve addition of substances listed on "Chemicals Known to the State to Cause Cancer or Reproductive Toxicity" of California Proposition 65: Safe Drinking Water and Toxic Enforcement Act of 1986 released by Office of Environmental Health Hazard Assessment - Environmental Protection Agency – State of California – USA (Last updated on January 03rd, 2025).

Ozone Depleting Substances

The following substances are absence from this product:

- Class I Ozone-depleting Substances (55 substances)
- Class II Ozone-depleting Substances (34 substances)

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Hence, this product is in compliance with the following regulations:

- US – Environment Protection Agency – Code of Federal Regulation Title 40 –Protection of Environment Part 82 – Protection of Stratospheric Ozone.
- Regulation (EC) No 2037/2000 of the Parliament and of the Council of 29 June 2000 on Substance that deplete the ozone layer.

Animal-derived Materials

This product is not intentionally manufactured with animal fats, oils, milk products or other animal- or tallow-derived products. This product therefore is free from Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE).

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.

Genetically Modified Organism (GMO)

To the best of our knowledge, none of raw materials used to produce this product are genetically modified. Beside it can be stated that no DNA or proteins from given organism (genetically modified or not) can resist to high temperature and pressure during manufacturing process.

Nanomaterial / Nanotechnology

Substances categorized as nanomaterial accordingly with Point 2 of EU Commission Recommendation of 18 October 2011 on the definition of nanomaterial are not involved as raw material during production of this product.

U.S. Pharmacopeia (USP)

This product has not been tested under any U.S. Pharmacopeia guidelines.

European Pharmacopoeia (EUP)

This product has not been tested under any European Pharmacopoeia guidelines.

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

Packaging and Packaging Waste 94/62/EC

The manufacture of this product does not involve addition of Cadmium, Chromium (VI), Lead and Mercury.

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).

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EU Directive 2006/122/EC

The manufacture of this product does not involve addition of perfluorooctanoic acid (PFOA), perfluoro-alkyl sulphonates (PFAS) and perfluorooctane sulfonate (PFOS).

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).

Persistent Organic Pollutants

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

Global Automotive Declaration Substance List (February 2022)

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

Chemical High Concern

The manufacture of this product does not involve addition of Chemical of High Concern as listed in Maine Chemicals of High Concern Triennial Update Documentation 2015.

EU Regulation (EU) 2019/1148

The manufacture of this product does not involve addition of restricted explosive precursor as listed in both Annex I and Annex II.

The German Product Safety Commission

The manufacture of this product does not involve addition of Polycyclic Aromatic Hydrocarbon (PAH) as listed in **AFPS GS 2019:01**.

Absence of Substances

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

1. Allergens (as defined in Directive 2000/13/EC, as amended)
2. Aromatic amines
3. Asbestos
4. Azodicarbonamide or semi-carbazide compounds
5. Adipates
6. Benzophenone, hydroxybenzophenone, and 4-methyl benzophenone
7. Biocides
8. Bisphenol A (BPA) and Bisphenol F (BPF)
9. Brominated flame retardants
10. Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)
11. Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC)
12. Chlorophenols
13. Chlorinated plastics, Polyvinyl Chloride (PVC) & its blend, Polyvinylidene chloride & its blend
14. Colorants / pigments
15. Conflict Material (gold, tin, tantalum, tungsten, wolframite, cassiterite, Columbite-tantalite)

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16. Decabromodiphenylether (decaBDE)
17. 2-ethylhexanoic acid (2-EHA)
18. Di(ethylhexyl)adipate (DEHA) & di(ethylhexyl)maleate (DEHM)
19. Dimethyl fumarate (DMF)
20. Dioxins and furans
21. Endocrine Disruptors
22. Epoxy derivatives:
 - a. BADGE [2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl)ether]
 - b. BFDGE [bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ether]
23. Ethylene Glycol Ethers
24. Flame retardant
25. Fragrances
26. Genetic modified organism
27. Halogens (Cl, Br, F)
28. Halogenated Phenols
29. Hydrofluorocarbon, Perfluorocarbon
30. Long chain chlorinated paraffins
31. Medium chain chlorinated paraffins
32. Melamine derivative
33. Natural rubber or latex
34. Nitrites
35. Nitrosamine
36. N-Ethyl-toluenesulfonamide (ortho/para)
37. Nonyphenol
38. Octyl or Nonyphenols or phenoethoxylates
39. Organic tin compaound/Alkyltin compound
40. Phenols
41. Phtahalates
42. Polyaromatic Hydrocarbons (PAHs)
43. Polybrominated biphenyl
44. Polybrominated diphenyl ethers
45. Polychlorinated naphthalenes
46. Polychlorinated biphenyl
47. Polychlorinated terphenyls
48. Radioactive Substances
49. Tris(nonylphenol) phosphite (TNPP) and 4-Nonylphenol (4-NP)
50. Silicone/Siloxane
51. Softeners
52. Plasticizer: 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with $\geq 0.3\%$ of dihexyl phthalate.
53. Fragrance: 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane and 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane
54. Trifluoroacetic acid
55. Hexabromobiphenyl, Hexabromodiphenyl ether and heptabromodiphenyl ether
56. Hexachlorobenzene (HCB), Alpha hexachlorocyclohexane
57. Beta hexachlorocyclohexane, Lindane
58. Mirex, Pentachlorobenzene, Polychlorinated biphenyls (PCB)
59. Technical endosulfan and its related isomers
60. Tetrabromodiphenyl ether and pentabromodiphenyl ether, Toxaphene DDT
61. Perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride
62. Polychlorinated dibenzo-p-dioxins (PCDD)
63. Polychlorinated dibenzofurans (PCDF), Hexachlorobenzene (HCB)
64. Pentachlorobenzene, Polychlorinated biphenyls (PCB)
65. Butyl benzyl phthalate (BBP)
66. Dibutyl phthalate (DBP)

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- 67. Bis(2-ethylhexyl) phthalate (DEHP)
- 68. Diisobutyl phthalate (DIBP)
- 69. Carcinogenic/Mutagenic/Reprotoxic Substances

Since conditions and methods of use of our products are beyond our control, it is the responsibility of the users to verify that the final articles are in compliance with requirements as set out by the applicable regulations.

Disclaimer: The information and statements herein are based on our current knowledge and has been prepared with reasonable care. This information is provided for general guidance purpose only and is not to be construed as guarantees or warranties in respect of this information. We have no responsibility or liability for any use by any third party of this information. Users should make sufficient verification and testing to determine that the uses of our products are safe, lawful and technically suitable in their intended application.

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