

## **PRODUCT REGULATORY COMPLIANCE STATEMENT**

### **High Density Polyethylene**

#### **TITANVENE HD5120GB-B**

#### **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
Taiwan	: Chemical Substance Nomination and Notification (CSNN)

All components of this product are not listed on:

EU	: the No-Longer Polymers list (NLP)
Japan	: Industrial Safety and Health Law (ISHL) Inventory

#### **EU Food Contact Material Regulation**

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.

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.

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.

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**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 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.

**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).

**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.

**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.

**Phthalates**

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

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## **REACH (Regulation (EC) No. 1907/2006) and amendments (January 2022)**

### **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 Jan 17th, 2022: 223 substances) 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 (72 valid entries, 14 December 2020).

### **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.

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 March 19<sup>th</sup>, 2021).

### **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)

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.

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### **Animal-derived Materials**

None of raw materials utilized to manufacture this product are animal-derived materials. This product therefore is free from Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE).

### **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 meets the requirements of USP 25 <661> Containers physicochemical test and Polyethylene containers.

### **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)

### **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).

### **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 (January 2020)**

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

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## 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)
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. Nitrosamine
35. N-Ethyl-toluenesulfonamide (ortho/para)
36. Nonyphenol
37. Octyl or Nonyphenols or phenoethoxylates
38. Organic tin compound/Alkyltin compound
39. Phenols
40. Phtahalates
41. Polyaromatic Hydrocarbons (PAHs)
42. Polybrominated biphenyl
43. Polybrominated diphenyl ethers
44. Polychlorinated naphthalenes
45. Polychlorinated biphenyl
46. Polychlorinated terphenyls
47. Radioactive Substances
48. Tris(nonylphenol) phosphite (TNPP) and 4-Nonylphenol (4-NP)
49. Silicone/Siloxane

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50. Softeners
51. Plasticizer: 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with  $\geq 0.3\%$  of dihexyl phthalate.
52. 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
53. Trifluoroacetic acid
54. Hexabromobiphenyl, Hexabromodiphenyl ether and heptabromodiphenyl ether
55. Hexachlorobenzene (HCB), Alpha hexachlorocyclohexane
56. Beta hexachlorocyclohexane, Lindane
57. Mirex, Pentachlorobenzene, Polychlorinated biphenyls (PCB)
58. Technical endosulfan and its related isomers
59. Tetrabromodiphenyl ether and pentabromodiphenyl ether, Toxaphene DDT
60. Perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride
61. Polychlorinated dibenzo-p-dioxins (PCDD)
62. Polychlorinated dibenzofurans (PCDF), Hexachlorobenzene (HCB)
63. Pentachlorobenzene, Polychlorinated biphenyls (PCB)
64. Butyl benzyl phthalate (BBP)
65. Dibutyl phthalate (DBP)
66. Bis(2-ethylhexyl) phthalate (DEHP)
67. Diisobutyl phthalate (DIBP)
68. 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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