Polypropylene **H1500**

# Regulatory Affairs Product Information Data Sheet

## 1. REACH regulation

Polypropylene homopolymer and copolymer, according to the 1907/2006/EC, are not the subject to registration. However, monomers of this product were registered in accordance with REACH. The substances in this product are not also listed in Annex XIV and XVII**.** None of chemical substances included in the most updated Candidate List (See link to Candidate List of 211 Substances of Very High Concern for authorization updated on Jan. 19th, 2021) above the 0.1% threshold are contained in this product. The current list of all SVHCs can be found at the following link to the ECHA website: http://echa.europa.eu/web/guest/candidate-list-table

## 2. Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS)

The EU's Restriction of Hazardous Substances (RoHS) Directive is related to electrical & Electronic equipment and not specifically to plastic raw materials. However, for giving customers information about our product, we inform you that this product complies with the RoHS Directive 2002/95/EC, 2011/65/EU and 2015/863/EC (as amended) regarding the limits of Cadmium, Lead, Mercury, Chromium (VI), Polybrominated biphenyls (PBBs), Polybrominated diphenyl ethers (PBDEs) and the following 4 Phthalates, Bis(2-Ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP).

## 3. Waste of Electrical & Electronic equipment – WEEE, Directive 2012/19/EU

We do not intentionally add substances (As, Hg, PCB, PCT, CFC, HCFC, HFC, Brominated Flame retardants ) restricted by 2012/19/EC.

## 4. Packaging and Packaging Waste (PPW) – Directive 94/62/EC

This product is under the limit set (100ppm) for heavy metals defined as Lead, Cadmium, Mercury and Chromium (VI).

## 5. Organic pollutants - Regulation (EC) No 2019/1021

During the manufacture of this product, we do not intentionally add substances restricted by 2019/1021/EC (persistent organic pollutants, POPs)

## 6. Food Contact Regulations

1) European Union

This product complies with the requirements of Regulation 1935/2004/EC (Framework) and 2023/2006/EC (GMP, Good Manufacturing Practice). The monomers and additives used in this product are also approved according to Regulation (EC) No 10/2011. This product meets the requirements of the LFGB (Lebensmittel-and Futtermittelgesetzbuch.) and Regulation (EC) No 10/2011 and all the amendments up to now (~Regulation (EU) 2020/1245).

- Overall Migration Limit (OML) and Specific Migration Limit (SML)

EU Directive 10/2011/EC includes a limit 10mg/dm$^2$ on the overall migration from finished plastic article into food. . When the representative sample of this resin was tested (Simulant : 3% Acetic acid aqueous solution, 95% Ethanol Aqueous Solution, Olive oil / 40℃ 10days), it did not exceed the limit of 10mg/dm$^2$. The used monomers and additives do not have the restriction on SML. The OML and SML determinations (When applicable) are the responsibility of both the manufacturer of the finished plastic food contact material article and food packer. In addition, the manufacturers of the finished food contact article must make sure that the finished article does not modify the organoleptic properties of the food.

- Dual-Use Additives

This product contains Calcium Stearate (E470a) permitted as food additives in Regulation 1333/2008/EC and 1334/2008/EC. Total concentration of these additives is below 0.1%.

- Regulation (EC) No 450/2009 and Regulation (EC) No 282/2008

This product is not applicable to these regulations.

2) US Food and Drug Administration (FDA)

This product also meets the FDA requirements contained in the Code of Federal Regulations in CFR 21 177.1520 (a)(1)(i) and (c)1.1a (All food types and conditions of A-H). According to our knowledge, all other ingredients used in this product meet the requirements of their respective FDA regulations and 21 CFR 177.1520 (b).

3) China GB Standards

This product complies with the requirements of GB4806.1-2016 and GB31603-2015 (GMP, Good Manufacturing Practice). The additives used in this product are also approved according to GB9685-2016. This grade meets the requirements of GB4806.6-2016 : Appendix A – No. 74 Propylene homopolymer.

## 6. Food Contact Regulations

4) Japan Food Contact - Positive List

- Ministry of Health, Labour and Welfare (MHLW)
  : The monomer and additives of this product meet the requirements of positive list system for food contact materials under Ministry of Health, Labour and Welfare (MHLW).
- Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA)
  : This product is registered on the Positive List of The Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA)

5) Canadian Food and Drug Regulations for Food Packaging Materials and Letters of No Objection

This product is acceptable polymer for use in food packaging applications and substances restricted by Division 23 of the Canadian Food and Drug Regulations are not used during the manufacture of this product. In addition, this grade is in accordance with the requirements of Food contact regulations (USA, EU). Therefore we consider that this product complies with Canadian Food and Drug Regulations for Food Packaging Materials. Letter of No Objection is not available for this product. There is no legal obligation to obtain "Letters of No Objection" from Health Canada's Health Products and Food Branch (HPFB).

## 7. California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposal 65)

None of the substances which are known to the State of California to cause cancer and/or reproductive toxicity above its limit threshold under California Proposition 65 are used as additives or raw materials in the manufacture of this grade.

## 8. Allergen Statements - Regulation (EC) No 1169/2011

The substances listed in Annex II of Regulation 1169/2011/EC, are not used in the manufacture of this product. However, this product has not been tested for these substances.

## 9. Toys Safety Directive 2009/48/EC & CEN Standard EN71.3

This product does not contain restricted chemical substances and heavy metal elements over its limit threshold regulated by 2009/48/EC or CEN standards EN71-3.

## 10. Conflict Minerals

No conflict minerals (Gold, Tantalum, Tungsten, Tin) are used in the manufacture of this product.

## 11. Epoxy derivatives – 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), Novolac glycidyl ether (NOGE) and some of their derivatives.

## 12. Coalition of Northeastern Governors (CONEG)

No heavy metals (Cadmium, Lead, Chromium (Hexavalent) & Mercury) or its compounds are incorporated into the production and formulation of this product, and reasonably results in compliance to CONEG which regulates total incidental Cadmium, Lead, Chromium (VI) and Mercury.

## 13. Perfluorooctanoic acid and Perfluorooctane sulfonate - Directive 2006/122/EC

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

## 14. Cosmetic - Regulation (EC) No 1223/2009

We, hereby, inform you that the prohibited substances in the list of Regulation (EC) No 1223/2009 are not used or added in this product.

## 15. BSE/TSE

Substances causing BSE/TSE are not used during the manufacture of this product, therefore we consider that there is not the risk of BSE/TSE.

## 16. Phthalates

Phthalates are not used as plasticizers when this product is manufactured. This grade may contain trace levels of one phthalate because of catalyst residues and it is expected not more than 10 ppm.

## 17. End of life vehicles (ELV) – Directive 2000/53/EC

We do not use or add the substances restricted by Directive 2000/53/EC (Cr(VI), Hg, Pb and Cd) during manufacturing of this product.

## 18. Other Non-use substances

We, hereby, inform you that the following substances are not added as additive in this resin manufactured by LOTTE Chemical Corporation

- Halogenated Flame Retardants
- PTFE (Polytetrafluoroethylene)
- PVC (Polyvinyl chloride)
- Nanomaterials
- Latex
- Mineral oil (MOAH, MOSH)
- Genetically Modified materials
- Ozone layer-depleting agents as defined by the MONTREAL PROTOCOL
- Asbestos
- Arsenic
- Biocides
- Organotin compounds
- Paraffin
- Styrene
- Cellulose
- Poly aromatic hydrocarbons (PAHs) as defined by 1907/2006/EC and EPA(USA)
- CMR substances of category 1a, 1b or 2 over threshold under Part 3 of Annex Vl to Regulation (EC) No. 1272/2008 and its amendments
- Primary Aromatic Amines
- Nitrites
- Nitrocellulose
- Melamine
- Perchlorate
- Silicone
- N-nitrosamines (Directive 93/11/EEC)
- Tris(nonylphenyl) phosphite (TNPP)
- Parabens
- Radioactive substances

## 18. Other Non-use substances

- Recycled / Reused materials
- Cyanuric acid
- Dimethyl Fumarate (DMF)
- Azo dyes
- Benzophenones
- Vinylidene Chloride Monomer
- Hexabromocyclododecane (HBCD)
- Phenol, isopropylated, phosphate (3:1)
- 2-Ethylhexanoic Acid
- Pentachlorothiophenol
- Hexachlorobutadiene

***DISCLAIMER**
**This statement is based on our current level of knowledge and covers commercial and experimental resins as supplied by LOTTE Chemical Corp. as the date of issue. The information above relates exclusively to our products when not used in conjunction with any other materials. No liability can be accepted in respect of the use and/or storage of our products and of the finished articles. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.**

**Chang-hyoo Choi**
**Division Manager, PO Development Division**
**LOTTE Chemical Corp. / Polymer Group**