Regulation Compliance Statement

POLIMAXX

1100NK

Polypropylene Homopolymer

Product Manufacturer

This product is manufactured by IRPC Public Company Limited which our product is originally produced in Thailand.

Global Chemical Substances Inventory

This product is listed on the following global chemical substances inventories.

Country	Name of Chemical Substance Inventory
Australia	Australian Inventory of Chemical Substances (AICS)
Canada	Domestic Substance List/Non-Domestic Substance List (DSL/NDSL)
China	Inventory of Existing Chemical Substances Produced or Imported in China (IECSC)
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS) / European List of Notified Chemical Substances (ELINCS)
Japan	Japanese Existing and New Chemical Substances Inventory (ENCS/MITI)
New Zealand	New Zealand Inventory (NZIoC)
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
South Korea	Korean Existing Chemicals List (KECI)
Taiwan	Taiwan Chemical Substance Inventory (TCSI)
U.S.	Toxic Substances Control Act Inventory (TSCA)

Please contact Technical Service & Product Development Division or send an email to polimaxx.technical@irpc.co.th for the status of other country inventories.

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

Under REACH, this product is considered preparation as well as polymer which are generally regarded as representing a low concern due to their high molecular weight, this group of substances is exempted from registration and evaluation; Nonetheless, manufacturers or importers of polymers in supply chain may still be required to register the monomers. IRPC Public Company Limited has registered our monomers used in the production of our resins using an Only Representative (OR), REACHLaw Ltd Along with other requirements, Article 7 requires that any producer or importer of articles to notify the European Chemical Agency when an article contains Substances of Very High Concern (SVHC) in a concentration above 0,1% (w/w). We do not expect this product to be included any of the chemicals as restricted by the following regulations and their subsequent amendments;

- Candidate List of SVHC
  https://echa.europa.eu/candidate-list-table (ECHA information update on Jan 17, 2023)
- List of Substances restricted Annex XVII
  https://echa.europa.eu/substances-restricted-under-reach
- List of substances Annex XIV of REACH ("Authorisation List")
  https://echa.europa.eu/authorisation-list

Food contact

US

This product meets the Food and Drug Administration (FDA) requirements specification according to US. FDA title 21 Code of Federal Regulations part 177.1520 (Olefin Polymers) - Polypropylene homopolymer, paragraphs (a)(1)(i) and (c)1.1a, test report samples of this product met the extractable fraction and soluble fraction requirements according to FDA CFR 21 §177.1520(c).

To access to the test report, please submit a request via https://polimaxx.irpc.co.th/ in the "Contact us" page and select the document type "Test Report: US FDA 21 CFR" under "Request Document". According to company policy, the quality control test will be sent the sample every two years or whenever the standards are revised or amended. This is the current set, and it can be referred to. It should be noted that test report documents have no expiration date.

This product may be used in food contact all types accordance with the FDA criteria CFR 21 §176.170(c) in table 1, under table 2 conditions of use A through H. It is the responsibility of the manufacturer/converter/producer to verify that the finished goods comply the requirements of the intended and foreseeable conditions of use. We cannot assure the applicability or accuracy of this information, or the suitability of our product, because user conditions are beyond our control.

China

This product and the intentionally added additives meets to the requirements of GB4806.6-2016 and/or GB9685-2016 (STANDARD FOR THE USE OF ADDITIVES FOR FOOD CONTACT MATERIALS AND PRODUCTS) and related announcements. Application polymer: Polypropylene Homopolymer. Item number as listed in Appendix A: 74

Additives used for the producing are not regulated with specific migration limits [SML/ SML (T)/ QM].

Japan

The Japanese Ministry of Health, Labour, and Welfare (MHLW) has established food standards, additive standards, and a positive list system for food appliances, containers, and packaging. The monomer and additives are listed in the Japanese Positive List System accordance with APPENDED TABLES 1 & 2 (the Positive List (PL)) as a list of base polymers, list of monomers and list of additives.

EU

Commission Regulation (EC) No. 1935/2004

IRPC Public Company Limited maintains sales and purchase record through all stages of manufacture, processing and distribution in order to meet the requirement of "traceability" in article 17 of the Regulation 1935/2004/EC.

Commission Regulation (EC) No. 2023/2006 (GMP)

This product has been produced in line with GMP requirements as for: Awareness maintained at all levels, Contamination prevention, Effective Management of Change procedures, Measures applied to ensure that the product is consistently suitable for the intended use. However, this product and manufacturer have not been certified GMP.

Commission Regulation (EC) No. 450/2009 and Regulation (EC) No. 282/2008

This product is not intentionally used recycled plastic and this product applicable to these regulations.

Commission Regulation (EC) No. 1895/2005

Bisphenol A diglycidyl ether (BADGE), bisphenol F diglycidyl ether (BFDGE) and novolac glycidyl ethers (NOGE) are not intentionally use in this product formulation.

Commission Regulation (EC) No. 10/2011

This product meets to with Commission Regulation (EU) No 10/2011 and its amendment (Commission Regulation (EU) No 1282/2011, 1183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/831, 2019/37, 2019/1338 and 2020/1245 on plastic materials and articles intended to come into contact with food. This product sample has passed the specific a maximum limit 10 mg/dm2 of heavy metal elements (SM) and overall migration test (OM5), condition of contact is 100 degree Celsius, 2 hours (simulants : 3% acetic acid, 10% & 50% ethanol and olive oil).

To access to the test report, please submit a request via https://polimaxx.irpc.co.th/ in the "Contact us" page and select the document type "Test Report: Commission Regulation (EU) 10/2011" under "Request Document". According to company policy, the quality control test will be sent the sample every two years or whenever the standards are revised or amended. This is the current set, and it can be referred to. It should be noted that test report documents have no expiration date.

The monomers and additives are used to produce this product are in accordance with the requirements of regulation (EU) No 10/2011 as amended and listed in the Union List of Authorized Substances of Regulation. The following substance(s) are subject to restrictions under this legislation:

- Monomer: Monomers used to produce this product are not have the restriction on SML

- Specific Migration Limit (SML): The additives used in the pellet process are not regulated with specific migration limits.

- Dual Use Additives: Calcium stearate is presented as additive in this product, the type of dual use additive reporting as follow; Dual Use Additive (Additives and flavorings regulated by Regulation 1333/2008/EC, Regulation 1334 /2008/EC, Regulation 10/2011/EC Articles 11(3) and paragraph 7 of the Annex IV respectively and amendments): The type of dual use additive reporting the E-Number E470a.

Finished products fabricated with this product must comply with the above restrictions when placed on the market in any of the EU member states or in Non-EU countries which adopted the same legislation.

Thailand

This product meets the Thailand Industrial Standard requirements for general polypropylene resin characteristics TIS 1306-2538.

This product also meets the requirements of TIS 656-2556: Analytical methods for food contact plastics and Thailand's Ministry of Public Health (MOPH) Notification No. 435/2022: Appendix 1 and 2 migration limitation. It is the responsibility of the manufacturer/converter/producer to submit the finished goods plastic food contact packaging or article for testing.

This product may be used under the condition of finished goods plastic in accordance with the TIS 2493 Part 1-2554 (2011) and Part 2-2556 (2013): Plastic food containers for microwave Part 1 for reheating and Part 2 for single reheating. It is the responsibility of the manufacturer/converter/producer to verify that the finished goods comply the requirements of the intended and foreseeable conditions of use. We cannot assure the applicability or accuracy of this information, or the suitability of our product, because user conditions are beyond our control.

The scope of this food contact statement is limited to the regulation details as investigated by our knowledge in this product and does not include the modification, processing, and conversion to produce the finished goods plastic food contact or article. It is the responsibility of the manufacturer/converter/producer to determine and comply the regulatory suitability for food contact compliance when using this product.

The following are the responsibilities of the manufacturer/convertor/producer of any finished goods plastic food contact or article, direct or indirect food additive, or food contact substance or article containing this product:

- **assuring the finished goods plastic food contact compliance with applicable regulations.**
- **assuring the finished goods plastic food contact complies with the requirements of the intended and foreseeable any conditions of use.**
- **the OML and SML determination the finished goods plastic food contact material or article.**
- **processing and manufactured according to GMP (Good Manufacturing Practice).**
- **must verify that finished goods plastic food contact or article does not modify the organoleptic properties of the food.**

Pharmacopoeias

US Pharmacopoeia Class VI

This product has not been tested for USP Class VI .

European Pharmacopoeia

This product has not been certified or tested to European Pharmacopoeia.

Drug Master File

Information on this product is not listed in a DMF.

Kosher

Although no animal fat and no animal derived materials used in this product, we do not certify the resin to be Kosher or in compliance with Kosher requirements.

Hazardous Substances

Thailand Hazardous Substances Act

The chemical substances in List #4 (Prohibitive Substances) of the Thailand Hazardous Substances Act are not used in the formulation of this product. However, this product is not tested for these substances.

California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)

We do NOT intend to use the chemicals listed in California Proposition 65 implemented by The office of Environmental Health Hazard Assessment of California Environmental Protection Agency, in this product recipe. There is no significant risk for cancer to California people from this product.
https://oehha.ca.gov/proposition-65/proposition-65-list

Coalition of Northeastern Governors (CONEG)

We hereby certify that we do NOT intend to use lead, mercury, cadmium and chromium (VI) in this product recipe. Furthermore, this product meets the CONEG requirement of less than 100 ppm for total incidental lead, mercury, cadmium and chromium (VI).

Directive 2011/65/EU (RoHS)

This product complies with the RoHS Directive 2011/65/EU and its subsequent amendments, the restriction of the use of certain hazardous substances in electrical and electronic equipment.

To access to the test report, please submit a request via https://polimaxx.irpc.co.th/ in the "Contact us" page and select the document type "Test Report: RoHS Directive 2011/65/EU" under "Request Document". According to company policy, the quality control test will be sent the sample every two years or whenever the standards are revised or amended. This is the current set, and it can be referred to. It should be noted that test report documents have no expiration date.

Toys

This product complies with the requirements in CEN Standard EN71-3: 2019 + A1: 2021 and not intentionally add the restricted 19 toxic elements in formulation of this product. However, this product has not been tested for these substances.

ELV Directive 2000/53/EC and its following amendments

The quantity of Cd, Pb, Cr(VI) and Hg present in this product are in compliance with 2005/673/EC, amending Annex II of Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles. A maximum concentration value up to 0,1 % by weight and per homogeneous material, for lead, hexavalent chromium and mercury and up to 0,01 % by weight per homogeneous material for cadmium shall be tolerated.

EU Directive 94/62/EC

According to EU Directive 94/62/EC on Concentration Levels of Heavy Metals Article, Lead, Cadmium, Mercury and Hexavalent Chromium, we hereby certify that we do not use these in our product recipe.

Directive 2009/251/EC

According to the requirement of Member States (2009/251/EC) to ensure that products containing the biocide dimethylfumarate (DMF) are not placed or made available on the market. We hereby certify that we do not intend to use DMF in this product recipe and manufacturing process.

CMR substances/Cosmetic Product

We do not intend to use list of substances banned for use in cosmetic products packaging (CMR substances at the URL below) as from 1 December 2010 (updated July 2015).
https://ec.europa.eu/docsroom/documents/11382/attachments/1/translations

Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)/"Mad Cow"

The derived from animal sources are not intentionally used in this product recipe.

Tallow

Tallow derived additives are not intentionally used in the manufacture of or formulation of this product.

Natural rubber Latex

"Natural rubber latex", "dry natural rubber" or "rubber that contains natural rubber" are not used in the manufacture of or the formulation of this product.

Animal Derived Materials

We do not intend to use animal derived material in this product recipe.

Ozone Depleting Substances

Ozone depleting substances listed in Annex I and II in the Regulation (EC) No 1005/2009 OF The European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer are not intentionally use in the product recipe and manufacturing process.
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:286:0001:0030:EN:PDF

GADSL

Substances in "Global Automotive Declarable Substance List (2013)" are not intentionally used in the manufacture of or formulation of this product.
http://www.gadsl.org/

JIG (Joint Industry Guide)

Substances in JIG-201 and JIG-101 are not intentionally used in the manufacture of or formulation of this product.
JIG-201 Ed 1.1 (Material Composition Declaration for Packaging of Electrotechnical Products)
JIG-101 Ed 4.1 (Material Composition Declaration for Electrotechnical Products)
http://www.ce.org/JIG

Moreover, we hereby declare that we do not intend to use the Substances/Chemicals listed below in our product recipe during pellet process,

- Japan CSCL; Class I and Class II Specified Chemical Substances
Japan CSCL; Priority Assessment Chemical Substances (PACs)
Japan CSCL: Monitoring Chemical Substance (MCS)
- Halal
This product was not manufactured from ethanol, pork, or haram ingredients.
The raw materials for producing this product are kept separate from the haram ingredients.
This product's manufacturing equipment is not used to produce any other pork-derived product.
We do not intend to use animal-derived ingredients in product recipe.
To access to the Halal official certification, please submit a request via https://polimaxx.irpc.co.th/ in the "Contact us" page and select the document type "Halal Certificate (Only PP & HDPE Product)" under "Request Document".
- List of substances subject to POPs Regulation https://echa.europa.eu/list-of-substances-subject-to-pops-regulation
- Fluorotelemers, Zonyl fluoroadditives (DuPont trade name), Perfluoroalkyl substances - PFAS (e.g. perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA), perfluorochemicals (PFC)) or other fluorocarbon substances
- Halogenated Flame Retardants and other: Polybrominated Biphenyls (PBBs), Polybrominated diphenyls (PBDE), Penta-BDE (CAS No. 32534-81-9), Octa-BDE (CAS No. 32536-52-0), Deca-BDE (CAS No. 1163-19-5), Polybrominated Diphenyl Ethers (PBDEs), Polychlorinated Biphenyls (PCBs), Polychlorinated Terphenyls (PCTs), Polychlorinated Naphthalenes (PCNs) and Hexabromo cyclododecane (HBCD, CAS No. 3194-55-6; 25637-99-4), Tetrabromobisphenol A (TBBPA, CAS No. 79-94-7), Tris (1,3-dichloro-2-propyl) phosphate

- Phthalates* or Phthalates Group:

Substances	CAS No.	Substances	CAS No.
DEHP (Di-2-ethylhexyl phthalate)	117-81-7	DIDP (Di-isodecyl phthalate)	26761-40-0
BBP (Benzyl butyl phthalate)	85-68-7	DNOP (Di-N-octyl phthalate)	117-84-0
DBP (Di-butyl phthalate)	84-74-2	DMP (Dimethyl phthalate)	131-11-3
DIBP (Di-isobutyl phthalate)	84-69-5	DEP (Diethyl phthalate)	84-66-2
DINP (Di-isononyl phthalate)	28553-12-0		

*may be used in the catalyst system only and we do not intend to use it in product recipe during pellet process, which test result in traces of these phthalates in the product, typically in concentrations below than the RoHS Directive (EU) 2015/863 Limited. Reference of the test report, please submit a request via https://polimaxx.irpc.co.th/ in the "Contact us" page and select the document type "Test Report: RoHS Directive 2011/65/EU" under "Request Document". According to company policy, the quality control test will be sent the sample every two years or whenever the standards are revised or amended. This is the current set, and it can be referred to. It should be noted that test report documents have no expiration date.

- Polycyclic Aromatic Hydrocarbons (PAHs)

Substances	CAS No.	Substances	CAS No.
Benzo(a)pyrene	50-32-8	Cyclopenta(c,d)pyrene	27208-37-3
Acenaphthylene	208-96-8	Dibenzo(a,h)anthracene	53-70-3
1,2-dihydro-acenaphthene	83-32-9	Dibenzo(a,h)pyrene	189-64-0
Anthracene	120-12-7	Dibenzo(a,i)pyrene	189-55-9
Benz(a)anthracene	56-55-3	Dibenzo(a,l)pyrene	191-30-0

Benz(j)aceanthrylene	202-33-5	Fluoranthene	206-44-0
Benzo(b)fluoranthene	205-99-2	9H-Fluorene	86-73-7
Benzo(c)phenanthrene	195-19-7	Indeno(1,2,3,c,d)pyrene	193-39-5
Benzo (e) pyrene	192-97-2	Naphthalene	91-20-3
Benzo(g,h,i)perylene	191-24-2	Phenanthrene	85-01-8
Benzo(j)fluoranthene	205-82-3	Pyrene	129-00-0
Benzo(k)fluoranthrene	207-08-9	5-Methylchrysene	3697-24-3
Chrysene	218-01-9		

- Alkylphenol-tin Compounds [Tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds]
- Alkylphenol, ethoxylates such as Nonylphenol (NP, CAS No. 25154-52-3), Nonylphenol ethoxylates (NPE) and Trinonylphenyl Phosphite (TNPP) or estrogen-mimicking compounds
- Bensophenones (CAS No. 119-61-9), 4-methylbenzophenone (CAS No. 134-84-9) and Hydroxybenzophenone
- Bisphenol A (BPA) / 4,4'-isopropylidenediphenol (CAS No. 80-05-7)
- Benzotriazole (CAS No. 3846-71-7) and 2-Mercaptobenzothiazole (MBT) (CAS No. 149-30-4)
- Butylated Hydroxyanisole (BHA) (CAS No. 121-00-6 and 25013-16-5)
- Butylated Hydroxytoluene (BHT) (CAS No. 128-37-0)
- Semicarbazide
- Dimethylfumarate (DMF)
- Tris (2-chloroethyl) phosphate (TCEP) (CAS No. 115-96-8)
- Refractory ceramic fibers (RCFs)
- Boric Acid (CAS No. 10043-35-3)
- Disodium tetraborate Anhydrous (Borax) (CAS No. 1330-43-4)
- Dimethylfumarate (DMF)
- Tris (2-chloroethyl) phosphate (TCEP) (CAS No. 115-96-8)
- Refractory ceramic fibers (RCFs)
- Boric Acid (CAS No. 10043-35-3)
- Disodium tetraborate Anhydrous (Borax) (CAS No. 1330-43-4)
- Azo Colorants or Azo Pigments
- Triclosan
- Eposidised soyabean oil (ESBO)
- Genetically Modified Organisms (GMO)
- Methyl-4-Methybenzene sulfonate (CAS No. 80-48-8)
- N,N-bis(2-hydroxyethyl)alkyl(C8- C18) amines [Armostat and Atmer163 (CAS No. 70955-14-5)]
- Chlorinated organic compounds
- Bis(2-ethylhexyl)adepate (DEHA)
- Cobalt (II) chloride (CAS no. 7646-79-9)
- Epichlorohydrin (CAS No. 106-89-8)
- Other Heavy metals and its compounds
- Formaldehyde
- Aromatic Amines / Amine Compounds
- Methyl Bromide (CAS No. 74-83-9)
- Natural rubber latex / dry natural rubber
- Polybrominated Terphenyls (PBTs)
- Asbestos and Mica
- Melamine
- Dioxins and Furans

- Acrylamide (CAS No. 79-06-1)
- Recycled Materials
- Perchlorates (CAS No. 14797-73-0)
- PIP (3:1) Phenol, isopropylated, phosphate (3:1) (CAS No. 68937-41-7)
- 2,4,6-Tris(tert-butyl)phenol (CAS No. 732-26-3)
- Hexachlorobutadiene, HCBD (CAS No. 87-68-3)
- Pentachlorothiophenol, PCTP (CAS No. 133-49-3)
- Nitrosamines or Nitrosamine forming agents
- List of substances subject to Certain Hazardous Chemicals and Pesticides - Rotterdam Convention

52 chemicals listed in Annex III, 35 pesticides (including 3 severely hazardous pesticide formulations), 16 industrial chemicals, and 1 chemical in both the pesticide and the industrial chemical categories.
http://www.pic.int/TheConvention/Chemicals/AnnexIIIChemicals/tabid/1132/language/en-US/Default.aspx

- Poly(difluoromethylene), a-fluoro-w-[2-[(1-oxooctadecyl)oxy]ethyl]- (TSCA, NDSL) (CAS No. 65530-65-6)
- Poly(hexadecyl methacrylate/2-hydroxyethyl methacrylate/octadecylmethacrylate)/gamma-omega-perfluoro-C10-C16-alkyl acrylate. (CAS No. 203743-03-7)
- Palm oil (CAS No. 8002-75-3)
- Conflict Minerals: Tin, Tungsten, Tantalum and Gold
- Epoxy derivatives
- Nanomaterials
- Vinyl Chloride(CAS No. 75-01-4)/Polyvinyl Chloride(PVC)
- Food allergens, the following list of allergens are not used in the manufacture of this product:

Peanuts, peanut oil, any peanut products; tree nuts (almonds, Brazil nuts, chestnuts, filberts, hazelnuts, hickory nuts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts); Milk (casein) or milk products, dairy products, dairy derivatives, lactose with protein; Eggs or egg products; Soybeans, soy flour, any soy products; Fish (e.g. cod, salmon) or fish products; Shellfish, crustaceans (e.g. shrimp, crabs, lobsters, oysters, clams, scallops, crayfish); Molluscs (e.g. snails, clams, squid, octopi) or mollusc products; Sulfites; Food colors; Celery or celery products; wheat (gluten) or wheat products; Seeds (e.g. cotton, poppy, sesame, sunflower, mustard) or seed products; Aspartame; Monosodium glutamate (MSG); Caffeine; Hydrogenated vegetable protein (HVP); Grains (e.g. rye, barley, oats); Lupine or lupine products.

- Radioactive Substances
- Mineral oil aromatic hydrocarbons (MOAH) with 1 to 7 aromatic rings, mineral oil saturated hydrocarbons (MOSH) with 16 to 35 carbon atoms

Issued By

Kanjana D.

(Mrs. Kanjana Damduan)
Senior Technical Service Manager
Technical Service and Product Development

Disclaimer:

The data indicated above are the results of IRPC's examinations, knowledge and correspond to the state of the art as of the date of publication and the data refers to the state of the related laws and regulations as of the date of issue. This information will expire after a break in delivery lasting more than 12 (twelve) months or in case of regulatory changes. This "Statement" is provided and subjected to IRPC's terms and conditions and IRPC reserves the right, in its sole discretion, to amend the product specification(s) at any time.

This "Statement" is not intended and shall not be construed as specification, warranty, expressed or implied, or representation of any kind that IRPC would have any legal responsibility or liability. The applicability, accuracy, completeness, reliability, usability, availability, validity with respect to the data or information under this Statement and/or the suitability of IRPC's products cannot be guaranteed for any purpose. IRPC gives no guarantees or makes no warranties of any kind, express or implied, including, but not limited to, any warranties of merchantability, satisfactory quality, non-infringement or fitness for a particular purpose, whether arising by operation of law or otherwise.

In the case that IRPC's products are used in combination with other materials, no liability admitted. When not utilized in combination with any third-party products, the information mentioned above refers only to IRPC's products. It is the customer's responsibility to inspect and test IRPC's products in order to satisfy itself as to the suitability of the products for the customer's particular purpose.

The customer shall be responsible for the appropriate, safe and legal use, processing and handling of IRPC's products. IRPC shall not be liable for any false, inaccurate, inappropriate or incomplete data or information presented on this Statement.

Please do not hesitate to ask IRPC for new information if needed. All terms and conditions regarding the supply of IRPC's products shall be subjected to IRPC's Policy. In the event that any dispute arises, IRPC's decision is final and not subject to appeal.

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