

## Regulatory Information Sheet (RIS)

### Low Density Polyethylene

LDF0034

#### CHEMICAL INVENTORIES

All ingredients in this product are in compliance with the following chemical inventories:

- AUSTRALIA: Australian Inventory of Chemical Substances (AICS)
- CANADA: Domestic Substances List (DSL)
- CHINA: Inventory of Existing Chemical Substances (IECSC)
- JAPAN: Japanese Inventory of existing and New Chemical Substances (ENCS)
- KOREA: Korean Existing Chemicals List (KECL)
- NEW ZEALAND: New Zealand Inventory of Chemicals (NZIoC)
- THE PHILIPPINES: Philippines inventory of Chemicals and Chemical Substances (PICCS)
- TAIWAN: Taiwan Chemical Substance Inventory (TCSI)
- UNITED STATES: Toxics Substances Control Act Inventory (TSCA)
- EUROPE UNION: European Inventory of Existing Commercial Chemical Substances (EINECS)

#### MERCOSUR FOOD CONTACT

This product complies with the requirements defined in Resolution GMC. n. 3/92 of MERCOSUR, published in 1992, which “establishes the general criteria and classification of materials for packaging and equipment in contact with food”, as well as their components are comprised in the Positive Lists described in Resolution GMC n. 02/2012 - Positive List of Resins and Polymers for plastic packaging and equipment in contact with food, published in 2012, and in Resolution GMC n. 32/07, Positive List of additives for plastic materials for the purpose of packaging and equipment manufacturing for contact with food published in 2007.

Taking into consideration substances present in the resin composition, there is no restriction regarding the type of food and/or temperature and time of contact during processing and/or storage.

The monomer and additives used on the formulation of this product are listed in the positive list of the present resolution and some present specific migration limit. The total migration limit must be less than 50 mg/kg or 8

mg/dm<sup>2</sup>. In order to comply with the requirements of the Resolution mentioned above, products made with this resin must be tested as to the total and specific migration limits (SML). For further information on substances containing SML, please contact Braskem Idesa at [Product.Safety@braskem.com](mailto:Product.Safety@braskem.com)

#### **BRAZIL FOOD CONTACT**

This product complies with the requirements defined in Resolution RDC n. 91/2001 of ANVISA (National Agency of Sanitary Control), published in 2001, which “establishes the general criteria and classification of materials for packaging and equipment in contact with food”, as well as their components are comprised in the Positive Lists described in Part I – Positive List of Monomers and other starting substances authorized in the Resolution RDC n. 56/2012 of ANVISA, published in 2012 and in Resolution RDC n. 17/2008 of ANVISA, published in 2008 – Positive List of additives for plastic materials for the purpose of packaging and equipment manufacturing for contact with food.

Taking into consideration substances present in the resin composition, there is no restriction regarding the type of food and/or temperature and time of contact during processing and/or storage.

The monomer and additives used on the formulation of this product are listed in the positive list of the present resolution and some present specific migration limit. The total migration limit must be less than 50 mg/kg or 8 mg/dm<sup>2</sup>. In order to comply with the requirements of the Resolution mentioned above, products made with this resin must be tested as to the total and specific migration limits (SML). For further information on substances containing SML, please contact Braskem Idesa at [Product.Safety@braskem.com](mailto:Product.Safety@braskem.com)

#### **UNITED STATES FOOD CONTACT**

This product complies with the FDA (Food and Drug administration) Regulations, edition 2011, as defined in 21 CFR, section 177.1520 paragraph (c) 2.2. According to our information, all other ingredients used in this product meet the requirements of their respective FDA regulations and 21 CFR 177.1520(b). This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2 and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

#### **EUROPE FOOD CONTACT**

This product complies with the relevant requirements of Regulation 10/2011/EC and all its amendments including Regulation (EU) 2017/752, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes). In addition, the product complies with Article 3 of Regulation (EC) No 1935/2004 concerning the generic product safety requirements of materials and articles intended to come in contact with foodstuffs.

The monomers and additives used to produce the resin are listed in the Union List of Authorized Substances of Resolution EU 10/2011, updated in 2017. Dual use additives subject to restrictions in food as defined in Regulation 10/2011/EC are not intentionally used in the manufacture or formulation of this product.

Braskem Idesa strives for producing all products by following the key elements of good manufacturing practice as outlined in Commission Regulation (EC) No 2023/2006 of 22 December 2006 according to our best knowledge.

The raw materials used for the manufacturing of this resin are of a suitable purity for articles intended for use in contact with foodstuffs.

EU Regulation 10/2011/EC specifies 10 mg/dm<sup>2</sup> as the maximum overall migration (OML) from the finished plastic food contact material or article. The OML and SMLs (when applicable) should be determined according to the requirements specified in EU Regulation 10/2011/EC. The OML and SML determinations are the responsibility of the manufacturer of the finished plastic food contact material or article. In addition, we remind you that the manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food. There are SMLs specified by EU Regulation 10/2011/EC for some chemical substances in this resin. For further information, please contact Braskem Idesa at [Product.Safety@braskem.com](mailto:Product.Safety@braskem.com)

It remains the responsibility of the manufacturer of the finished food contact article and the industrial food packer to make sure that the requirements of Regulation (EC) No 1935/2004, Article 3 pertaining to the final articles are met.

Based on the considerations above as well as on our own safety assessments of all raw materials used in the manufacturing of this resin providing good manufacturing practice applied during processing of this resin, we can confirm that this resin as supplied complies with Article 3 of Regulation (EC) No 1935/2004. Further, systems and procedures have been implemented in the manufacture of this resin in order to fulfill the requirements of Article 17 of Regulation (EC) No 1935/2004 regarding traceability. Article 17 applies as of 27 October 2006.

#### **SUBSTANCES OF VERY HIGH CONCERN (SVHC)**

This product do not contain any of the Annex XIV Candidate List of Substances of Very High Concern for authorization, as updated on 12 January 2017, above the 0.1% threshold as stated in REACH (Article 57, Regulation No. 1907/2006), determined either through (i) non-use of the substances, (ii) nor are they part of the raw-materials' production routes, (iii) mass balance calculation, or (iv) specific testing.

#### **RESTRICTION OF HAZARDOUS SUBSTANCES (RoHS)**

With respect to EU Parliament and Council Directive 2011/65/EU of 8 June 2011 and the amendment 2015/863 of 31 March 2015. The above mentioned product, to the best of our knowledge, does not contain substances as listed in Annex II of EU-Directive 2011/65/EU (RoHS) above the limit of 0.1%wt. Therefore, the product listed above is in compliance with the requirements of Article 4.1 of EU-Directive 2011/65/EU. However, please be advised that we do not analyze for these substances on a routine basis. EU-Directive 2002/95/EC, as amended, is repealed with effect from 3 January 2013.

#### **HEAVY METALS / CONEG / EU DIRECTIVE 94/62/EC**

The regulated metals – lead, mercury, cadmium, and chromium – are not intentionally added during the manufacturing process. Testing for heavy metals on similar resins to this product has shown the following metals are not present at the quantifiable limit listed in parenthesis: arsenic (0.5 ppm), barium (0.5 ppm), chromium (0.5 ppm), cadmium (0.5 ppm), selenium (0.5 ppm), silver (0.5 ppm), lead (0.5 ppm), and mercury (0.0005 ppm). These levels are less than compared to the CONEG requirement of < 100 ppm.

#### **TOYS EN 71-3 / EN71-9**

Based on the information given by our suppliers and knowledge of our process, this product is not formulated with antimony, arsenic, barium, boron, cadmium, cobalt, copper, mercury, lead, nickel, selenium, strontium or tin. To the best of our knowledge it is not expected any of the substances listed in EN 71-3 to be present in the final resin beyond the migration limits sets in this legislation. However it remains to the final manufacturer of the finished toy article to ensure that the limitations described in the legislation are met.

This resin is not manufactured or formulated intentionally with the chemical substances listed in EN71-9, Tables 2D, 2E and 2I, regarding to organic chemical compounds in toys. As these substances are not intentionally added, we inform that they are not tested during our processes.

#### **CALIFORNIA PROPOSITION 65**

According to California Proposition 65, updated on 27 January 2017, this product presents “no significant risk” of cancer for human beings. This product contains no substances known to the State of California (listing according to proposition 65) to cause reproductive toxicity.

#### **ALLERGENS**

With regards to the manufacture of this resin the following allergens or products thereof are not intentionally added to the process/product: cereal containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery,

mustard, sesame seeds, sulphur dioxide and sulphites. As these substances are not intentionally added, we inform that they are not tested during our processes.

#### **TNPP & DNPP**

With regards to the manufacture of this resin tris(nonylphenyl)phosphite (TNPP, CAS number 26523-78-4) and Di(nonylphenyl)phenylphosphite (CAS 25417-08-7) are not intentionally added to the process/product. As these substances are not intentionally added, we inform that they are not tested during our processes.

#### **BISPHENOL A & BISPHENOL F**

This product is not manufactured or formulated with Bisphenol A (BPA, CAS number 80-05-7) and Bisphenol F (BPF, CAS number 620-92-8).

#### **PHTHALATES**

With regards to the manufacture of this resin phthalate additives or plasticizers such as but not limited to the following list, are not intentionally added in the manufacture of this product.

- Bis(2-methoxyethyl) phthalate (CAS# 117-82-8)
- Butyl Benzyl Phthalate (BBP, CAS# 85-68-7)
- Dibutyl phthalate (DBP, CAS# 84-74-2)
- Di (2-ethylhexyl)phthalate (DEHP, CAS# 117-81-7)
- Diisobutyl phthalate (DIBP, CAS# 84-69-5)
- Diisodecyl phthalate (DIDP, CAS# 26761-40-0)
- Di-isononyl phthalate (DINP, CAS# 28553-12-0)
- Diisopentylphthalate (DIPP, CAS# 605-50-5)
- Di-n-hexyl phthalate (DnHP, CAS# 84-75-3)
- Di-n-octylphthalate (DnOP, CAS# 117-84-0)
- N-pentyl-isopentylphthalate (CAS# 776297-69-9)

As these substances are not intentionally added, we inform that they are not tested during our processes.

#### **ABSENCE DECLARATIONS**

With regards to the manufacture of this resin the following substances are not intentionally added to the process/product. As these substances are not intentionally added, we inform that they are not tested during our processes.

1. Latex, Natural rubber latex, dry natural rubber, synthetic latex and/or rubber that contains natural rubber.
2. Epoxy Derivatives such as BADGE, BFDGE, NOGE referenced in 1895/2005/EC
3. Substances listed in REACH Annex XVII – Restriction on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Preparations and Articles.
4. Substances of concern to our customers:
  - Octyl- and Nonylphenols
  - Alkyl Phenol Ethoxylates – Octyl and Nonyl
  - Melamine
  - Mineral Oil
  - Epoxidised Soy Bean Oil (ESBO)
  - Styrene
  - Organo-tin Compounds
  - Perfluoroalkylated Substances (PFA's)
  - PVC & PVDC
  - Cellulose Acetate
  - Animal derived Ingredients
  - CMR Compounds
  - Engineered Nanomaterials
  - Genetically Modified Organisms

Additional information on the health and safety aspects of our product is listed in the MSDS of the product.

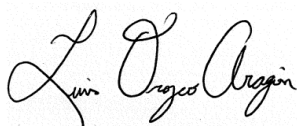
This Regulatory Information Sheet herein relates only to the specific product designated and may not be valid for such product used in combination with any other product or in any process, unless otherwise specified. This information provided is of the date hereof and Braskem IDESA may update, revise or amend such Regulatory Information Sheet or the information contained herein whenever possible.

The user hereby acknowledges and accepts its responsibility to determine and ensure that all conditions, specifications, laws and regulatory requirements are met and the products fabricated from the specific product designated are acceptable for use in the intended application.

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