

## **Regulatory Information Sheet (RIS)**

### **Polypropylene Homopolymer**

#### **H 103**

#### **CHEMICAL INVENTORIES**

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

- ASIA-PACIFIC
- AUSTRALIA: Australian Inventory of Chemical Substances (AICS)
- KOREA: Korean Existing Chemicals List (KECL)
- UNITED STATES: Toxics Substances Control Act Inventory (TSCA)

#### **BRAZIL FOOD CONTACT**

The Polypropylene Homopolymer resin **H 103**, manufactured by Braskem S.A. Brazil, complies with the requirements defined in Resolution RDC n. 91/2001 of the National Agency of Sanitary Control – ANVISA –, published on May 11, 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 on November 16, 2012 and in Resolution RDC n. 17/2008 of ANVISA, published on March 17, 2008 – Positive List of additives for plastic materials for the purpose of packaging and equipment manufacturing for contact with food.

Taking into consideration the components 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 Positive List of the present Resolution. The monomers and additives used on the formulation of this product are listed in the Union List of Authorized Substances of the present Regulation.

This product does not contain monomers and/or additives with specific migration limit (SML) and/or a total specific migration limit (SML(T)) and/or a QMA (residual content per food contact surface area).

In order to guarantee the compliance with the Resolution mentioned above, the packaging and/or the end plastic product must be analyzed by the manufacturer concerning total migration limit and such limit must be less than 50 mg/kg or 8 mg/dm<sup>2</sup>.

### **MERCOSUR FOOD CONTACT**

This product complies with the requirements defined in Resolution GMC n. 3/92 of MERCOSUR, published on April 1, 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 on April 19, 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 on December 11, 2007.

Taking into consideration the components 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 Positive List of the present Resolution. The monomers and additives used on the formulation of this product are listed in the Union List of Authorized Substances of the present Regulation.

This product does not contain monomers and/or additives with specific migration limit (SML) and/or a total specific migration limit (SML(T)) and/or a QMA (residual content per food contact surface area).

In order to guarantee the compliance with the Resolution mentioned above, the packaging and/or the end plastic product must be analyzed by the manufacturer concerning total migration limit and such limit must be less than 50 mg/kg or 8 mg/dm<sup>2</sup>.

### **UNITED STATES FOOD CONTACT**

This product complies with the FDA (Food and Drugs Administration) Regulations, Edition 2015, as defined in 21 CFR, section 177.1520 (Olefin polymers) paragraph (c) 1.1a. The additives are covered in the sections 177.1520, 178.2010, 181.29 and as described in FCN No. 67.

This product can also be used in contact with all types of food from “I to IX” as described in Table 1 of Section 176.170(c) of this chapter, and under conditions of use from “A” to “H” described in Table 2 of Section 176.170(c) of this chapter.

### **EUROPE FOOD CONTACT**

This product complies with the requirements defined in Regulation EU 10/2011 and its amendments (includes Regulations (EU) No 321/2011, (EU) No 1282/2011, (EU) No 1183/2012, (EU) No 202/2014, (EU) 174/2015 and (EU) No 1416/2016) on regarding plastic materials and products for contact with food.

Taking into consideration the components 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 monomers and additives used on the formulation of this product are listed in the Union List of Authorized Substances of the present Regulation.

This product contains monomers and/or additives and/or product production aids (PPAs) with specific migration limit (SML) and/or a total specific migration limit (SML(T)) and/or a QMA (residual content per food contact surface area) as defined in Tables 1-3 of Annex I of EC 10/2011.

In order to guarantee the compliance with the Regulation mentioned above, the packaging and/or the end plastic product must be analyzed by the manufacturer concerning specific migration limit and the total migration limit must be less than 10 mg/dm<sup>2</sup>. For further information on substances containing SML and/or SML(T) and/or QMA please contact your regular commercial or technical service contact at Braskem.

Braskem declares that specific measures are adopted for resin **H 103**, complying with article 5th of Regulation (EC) n° 1935/2004.

#### **DUAL USE ADDITIVE**

This product contains one or more additives approved as authorized food additive in the Annex II of Regulation (EC) No 1333/2008, as amended by Commission Regulation (EU) No 1129/2011 (11.11.2011) and Commission Regulation (EU) No 380/2012 (03.05.2012), and considered as "dual use additive". For further information on dual use additives, please contact your regular commercial or technical service contact at Braskem.

#### **CANADA FOOD CONTACT**

This product has not been assessed by Health Canada.

#### **ODOR & TASTE**

This product complies with the FDA requirements for use in contact with food, as described above. Aspects such as processing, storage period, storage conditions, type of food intended to be in contact with the resin, or other likely conditions may affect the smell or the taste of the food.

#### **ANIMAL ORIGIN**

Additives from animal origin may be used in the manufacture of this product. According to information provided by suppliers, these raw-materials are free from Bovine spongiform encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).

#### **ALLERGENS**

With regards to the manufacture of this resin the following food 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.

#### **GENETICALLY MODIFIED ORGANISM (GMO)**

With regards to the manufacture of this resin genetically modified organisms (GMOs) 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.

#### **BRAZILIAN PHARMACOPEIA**

This product has not been tested and assessed according to the criteria for approval of the Brazilian Pharmacopeia.

#### **UNITED STATES PHARMACOPEIA (USP)**

This product has not been tested and assessed according to the criteria for approval of the US Pharmacopeia (USP).

#### **EUROPEAN PHARMACOPEIA (EP)**

This product has not been tested and assessed according to the criteria for approval of the European Pharmacopeia.

#### **TOYS**

This product has not been tested and assessed according to the criteria for approval of the NBR NM 300-3: 2011 - Safety of toys - Part 3: Migration of certain elements.

This product has not been tested and assessed according to the criteria for approval of the European Standard EN 71-3:2013 + A1:2014 - Safety of toys.

#### **BISPHENOL A, BISPHENOL F & BISPHENOL S**

This product is not manufactured or formulated with Bisphenol A (BPA, CAS number 80-05-7), Bisphenol F (BPF, CAS number 620-92-8) and Bisphenol S (BPS, CAS# 80-09-1).

## **LATEX**

With regards to the manufacture of this resin, "natural rubber latex", "dry natural rubber", "synthetic latex or "rubber that contains natural rubber" 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.

## **DYES OR PIGMENTS**

This product is not manufactured or formulated with dyes or pigments.

## **PHTHALATES**

Braskem S.A. does not intentionally add phthalate additives or plasticizers in the manufacture of its polypropylene grades; however, this product may contain trace levels of phthalates from the polymerization. Any trace levels of phthalates in the product would be below regulatory and advisory standards. For more specific information, please contact your Technical Assistance.

## **ORGANO-TIN COMPOUNDS**

With regards to the manufacture of this resin the following tin compounds are not intentionally added to the process/product: dibutyltin (DBT, CAS# 1002-53-5), diphenyltin (DPhT, cas# 1011-95-6), dioctyltin (DOT, CAS# 15231-44-4), monobutyltin (MBT, CAS# 78763-54-9), monooctyltin (MOT, CAS# 15231-57-9), tetrabutyltin (TTBT/TEBT, CAS# 1461-25-2), tributyltin (TBT, CAS# 688-73-3), tricyclohexyltin (TCyT, CAS# 3047-10-7) and thiophenyltin (TPhT, CAS# 892-20-6).

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

## **CALIFORNIA PROPOSITION 65**

This product may contain one or more chemical substances as set forth in California Proposition 65 chemicals list dated August 5, 2016. For further information on substances, please contact your regular commercial or technical service contact at Braskem.

Every company that sells its products in the territory of California shall be responsible for informing the status of its own products under Prop 65 and developing its own regulatory plan. Braskem makes no representation or Regulatory Information Sheet of its clients' products regarding the Proposition 65.

## **NSF INTERNATIONAL**

At this time Braskem holds no NSF certifications for this product.

## **UL CERTIFICATION**

At this time Braskem holds no UL certifications for this product.

## **DIRECTIVE RoHS (Restriction of Hazardous Substances) (2011/65/EU)**

RoHS Regulation refers to electrical and electronic equipment and not specifically to plastic raw materials. However, based on the available documentation from raw materials suppliers and /or specific analyzes, this resin is in compliance with Directive 2011/65/EU (RoHS) as it relates to the restriction of the use of certain hazardous substances (such as lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Butyl Benzyl Phthalate (BBP), Dibutyl phthalate (DBP), Di (2-ethylhexyl) phthalate (DEHP) and Diisobutyl phthalate (DIBP).

## **COALITION OF NORTHEASTERN GOVERNORS (CONEG) and EUROPEAN DIRECTIVE 94/62/EC**

Based on the available documentation provided by our raw material suppliers and /or specific analyzes, this product complies with the CONEG Model Legislation for requirements regarding the defined limit for the sum of heavy metals (lead, mercury, cadmium and hexavalent chromium).

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

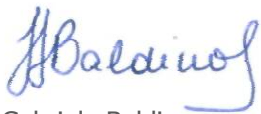
**Further information about SVHC please visit our web site:**

**<http://www.braskem.com.br/site.aspx/Quality-REACH>**

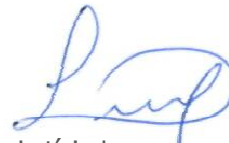
**This Regulatory Information Sheet herein relates only to the specific product designated and may not be valid for such product used in combination with any other product or in any process, unless otherwise specified. This information provided is of the date hereof and Braskem may update, revise or 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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A handwritten signature in blue ink, appearing to read 'Gabriela Baldino'.

Gabriela Baldino  
Regulatory Affairs  
Braskem S.A.

A handwritten signature in blue ink, appearing to read 'Letícia Lopes'.

Letícia Lopes  
Regulatory Affairs  
Braskem S.A.