

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

### **Polypropylene Random Copolymer**

#### **RP 141**

#### **CHEMICAL INVENTORIES**

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

- AUSTRALIA: Australian Inventory of Chemical Substances (AICS)
- NEW ZEALAND: New Zealand Inventory of Chemicals (NZIoC)

#### **BRAZIL FOOD CONTACT**

The Polypropylene Random Copolymer **RP 141**, 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.

Considering the substances present in the composition, there is no restriction regarding the type of food, in cooling, freezing and room temperatures, and hot fill or pasteurization at temperatures below or over 66°C, and not for sterilization with water in ebullition as 100°C, nor sterilization at 121°C. The additives used on the formulation of this product are listed in the positive list of the present resolution and some present specific migration limit.

In order to comply with the requirements of the Resolution mentioned above, products made with this resin must be tested as to the Specific Migration Limits – SML and 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>. For further information on substances containing SML, please contact Braskem S.A.

#### **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.

Considering the substances present in the composition, there is no restriction regarding the type of food, in cooling, freezing and room temperatures, and hot fill or pasteurization at temperatures below or over 66°C, and not for sterilization with water in ebullition as 100°C, nor sterilization at 121°C. The additives used on the formulation of this product are listed in the positive list of the present resolution and some present specific migration limit.

In order to comply with the requirements of the Resolution mentioned above, products made with this resin must be tested as to the Specific Migration Limits – SML and 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>. For further information on substances containing SML, please contact Braskem S.A.

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

This product complies with the FDA (Food and Drugs Administration) Regulations, issued on July 12, 2011, as defined in 21 CFR, section 177.1520 (Olefin polymers) paragraph (c) 3.1a. The additives are covered in the sections 177.1520, 178.2010, 178.3297, 181.29, 184.1324, and as describe in FCN N° 825 and 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 "C" 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 (EC) n° 1935/2004 and 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 and (EU) 174/2015, regarding plastic materials and products 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 additives used on the formulation of this product are listed in the positive list of the present regulation and some present specific migration limit.

In order to comply with the requirements of the Resolution mentioned above, products made with this resin must be tested as to the Specific Migration Limits – SML and the end plastic product must be analyzed by the manufacturer concerning total migration limit and such limit must be less than 10 mg/dm<sup>2</sup>. For further information on substances containing SML, please contact Braskem S.A.

This product is produced in accordance with good manufacturing practice (GMP) as outlined in GMP Regulation (EC) No 2023/2006.

#### **DUAL USE ADDITIVE**

This product contains Calcium Stearate 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), mentioned as E 470a, and considered as "dual use additive".

#### **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 resin complies with the physicochemical requirements (buffering capacity, non-volatile residue and heavy metals (lead)), specified for plastic materials for the purpose to be in contact with pharmaceutical

products, according to the United States Pharmacopeia (USP 33), published in the Chapter <661> Containers – Plastics - Physicochemical Tests and Brazilian Pharmacopeia 5a edition, Chapter 6.2 – Plastics Packaging.

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

This resin complies with the physicochemical requirements (buffering capacity, non-volatile residue and heavy metals (lead)), specified for plastic materials for the purpose to be in contact with pharmaceutical products, according to the United States Pharmacopeia (USP 33), published in the Chapter <661> Containers – Plastics - Physicochemical Tests and Brazilian Pharmacopeia 5a edition, Chapter 6.2 – Plastics Packaging.

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

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

#### **TOYS**

This product was analyzed and meets the maximum migration of elements: antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium complying with NBR NM 300-3: 2011 - Safety of toys - Part 3: Migration of certain elements.

This product was analyzed and meets the maximum migration of certain elements complying with European Standard EN 71-3:2013 - Safety of toys - Part 3.

#### **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).

#### **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**

With regards to the manufacture of this resin the following substances are not intentionally added to the process/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)

However, we inform that diisobutyl phthalate (DIBP) is present as a minor component of the catalytic system used for polymerization of some resins.

In addition, Braskem S.A. has tested several resins, in which the residue amount of Phthalates found was between 0.05 and 0.6 ppm.

## **ORGANO-TIN COMPOUNDS**

With regards to the manufacture of this resin the following tin compounds are not intentionally added to the process/product: tributyl-tin (TBT, CAS# 688-73-3), dibutyl-tin (DBT, CAS# 1002-53-5) and monobutyl-tin (MBT, CAS# 78763-54-9). As these substances are not intentionally added, we inform that they are not tested during our processes.

## **CALIFORNIA PROPOSITION 65**

Although this product has not been tested for each chemical in the Proposition 65 list, based on a review of the manufacturing process of this resin it is not expected that this process contains substances known to the State of California to cause reproductive toxicity.

## **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)**

With regards to the manufacture of this resin the forbidden substances (such as lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)) are neither intentionally added nor are they part of the raw-materials production routes at this product.

Therefore this resin is in compliance with Directive 2011/65/EU (RoHS) as it relates to the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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

With regards to the manufacture of this resin the following substances are not intentionally added to the process/product: cadmium, chromium (VI), lead and mercury. In addition, this product meets the CONEG requirements and Article 11 of Directive 94/62/EC of less than 100 ppm for aggregate levels of cadmium, chromium, lead and mercury.

**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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**application.**



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