

Code	PRO_PRS_01	PRO	
Rev.:	0	PRODUCT REGULATORY	
Page:	1	STATEMENT	
Date:	06/21/222	PRS	

FC 10130, FC 10175, FC 10570

SECTION 1: IDENTIFICATION

FOOD CONTACT: ANVISA

ERT hereby declares for the proper purposes that the products were manufactured in accordance with Good Manufacturing Practices, and that it meets the requirements set out in Resolution RDC No. 91/2001 – ANVISA, published on 11 May 2001, as well as that all its components are UNRESTRICTED in the Positive Lists described in Part I – list of monomers and other initiators authorized in ANVISA RDC No. 56/2012 published on 21 November 2012, in ANVISA RDC No. 326/2019 published on 3 November 2019, in ANVISA RDC No. 589/21 published on 20 December 2021 and in ANVISA Resolution No. 17/2008 of 17 March 2008 – Positive List of additives for plastic materials intended for the preparation of packaging and equipment for food contact. In addition, ERT hereby also declares that the products mentioned above meets the requirements set out in Resolution RDC No. 589/21 – ANVISA published on 20 December 2021.

We emphasize that considering the substances present in the composition of the resin, there is no restriction for its application in relation to any type of food, or temperature and contact time in the processing or storage. To ensure compliance with all applicable legal requirements, the primary plastic packaging manufactured from this material should be analyzed in relation to total migration as set forth in Resolution RDC No. 51/2010 – ANVISA published on 10 November 2010.

FOOD CONTACT: EUROPE

ERT hereby declares that this product has been evaluated and were found to be suitable for use in food contact applications in the European Union. The evaluation was in line with the requirements of Regulation (EC) No 1935/2004 of 27 October 2004 and Regulation (EC) No 10/2011, as amended by 321/2011, 1282/2011, 71183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/988, 2019/1338 and 2020/1245, applying to all EU member states, and the Commodity Act Packaging and Food Utensils Regulations of the Netherlands and its amendments [Hereinafter called 'Regulations'].

The product is produced using ingredients listed in Table 1 of Annex 1 of the Plastics Regulation. There are no specific migration limits (SML) or total specific migration limits (SML(T)) listed under Table 1 of Annex 1 for these ingredients.

Code	PRO_PRS_01	PRO	
Rev.:	0	PRODUCT REGULATORY	
Page:	2	STATEMENT	
Date:	06/21/222	PRS	

SECTION 2: GLOBAL REGULATORY INFORMATION

ANIMAL-DERIVED SUBSTANCES

ERT hereby declares that animal-derived substances are not intentionally added in this product. During the process, the products does not come in contact with animal origin material. Our products are declared to be free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE). Our products are declared to be free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE).


GMO – Genetically Modified Organisms

ERT hereby declares that substances derived from Genetically Modified Organism (GMO) are not intentionally added in this product.

REACH

ERT hereby declares that the product mentioned above is compliant with EU Regulation (EC) 1907/2006 of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation). The processing aids substances contained in this product meets the conditions detailed in Annex V - Paragraph 7 and Paragraph 9 - of REACH Regulation, respectively, and that the initial monomers already have a REACH EU registration. We also inform that this product is not intentionally manufactured or formulated with any substance listed on the following REACH sections:

- Restrictions on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Mixtures and Articles of Regulation (EC) No 1907/2006 – ANNEX XVII - of the European Parliament.
- List of Substances Subject to Authorization of Regulation (EC) No 1907/2006 - ANNEX XIV - of the European Parliament.

Code	PRO_PRS_01	PRO	
Rev.:	0	PRODUCT REGULATORY STATEMENT	
Page:	3		
Date:	06/21/222	PRS	

SVHC– Substances Very High Concern

ERT hereby declares that this product is not intentionally formulated to contain the substances listed as Substances of Very High Concern (SVHC) on the latest version of the Candidate List of 17 January 2022.

RoHS – Restriction of Hazardous Substances


ERT hereby declares that this product complies with the standards established by Directive 2002/95/EC (RoHS 1), Directive 2011/65/EU (RoHS 2) as amended by Directive 2017/2102/EU and Directive 2019/1846/EU and Directive 2015/863/EU (RoHS 3). We inform that this product does not contain/contains less than the maximum levels of the following restricted substances:

- Cadmium (Cd): < 100 ppm
- Mercury (Hg): < 100 ppm
- Benzyl butyl phthalate (BBP): < 1000 ppm
- Bis(2-Ethylhexyl) phthalate (DEHP): < 1000 ppm
- Dibutyl phthalate (DBP): < 1000 ppm
- Diisobutyl phthalate (DIBP): < 1000 ppm
- Hexavalent Chromium: (Cr VI) < 1000 ppm
- Lead (Pb): < 1000 ppm
- Polybrominated Biphenyls (PBB): < 1000 ppm
- Polybrominated Diphenyl Ethers (PBDE): < 1000 ppm

METALS

ERT hereby declares that during the manufacture of this product does not intentionally add any of the following metals (#CAS number):

- | | |
|-------------------------|------------------------------------|
| • Antimony (7440-36-0) | • Hexavalent chromium (18540-29-9) |
| • Barium (7440-39-3) | • Mercury (7439-97-6) |
| • Beryllium (7440-41-7) | • Molybdenum (7439-98-7) |
| • Cadmium 7440-43-9 | • Nickel (7440-02-0) |
| • Chromium (7440-47-3) | • Palladium 7440-05-3 |
| • Cobalt (7440-48-4) | • Silver (7440-22-4) |
| • Gold (7440-57-5) | |

Code	PRO_PRS_01	PRO	
Rev.:	0	PRODUCT REGULATORY	
Page:	4	STATEMENT	
Date:	06/21/222	PRS	

- Tantalum (7440-25-7)
- Thallium (7440-28-0)
- Tin (7440-31-5)
- Vanadium (7440-62-2)

ERT does not test for these metals in our products as these metals are not intentionally added.

ALLERGENS


ERT hereby declares that the allergens listed on Annex II of Regulation (EU) No 1169/2011 and below are not intentionally added in our products:

- Celery and products thereof;
- Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof;
- Crustaceans and products thereof;
- Eggs and products thereof;
- Fish and products thereof;
- Lupin and products thereof;
- Milk and products thereof (including lactose);
- Mollusks and products thereof;
- Mustard and products thereof;
- Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof;
- Peanuts and products thereof;
- Sesame seeds and products thereof;
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/L;

We inform that this product may contains soy.

CONEG – Coalition of Northeastern Governors

ERT hereby inform that this product does not contain incidental levels lead, mercury, cadmium or hexavalent chromium greater than 100 parts per million (ppm) in compliance with CONEG Model Legislation.

Code	PRO_PRS_01	PRO PRODUCT REGULATORY STATEMENT PRS	
Rev.:	0		
Page:	5		
Date:	06/21/222		

CMR SUBSTANCES

ERT hereby declares that that according to the specifications of our raw materials and to our current knowledge, the product does not contain intentionally added CMR substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1A or 1B or 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008. The presence of CMR traces cannot be completely excluded as technically unavoidable in raw materials.

BISPHENOLS

ERT hereby declares that this product is not manufactured or formulated with the following bisphenol compounds (#CAS number):

- Bisphenol A, BPA (80-05-7)
- Bisphenol B, BPB (77-40-7)
- Bisphenol F, BPF (620-92-8)
- Bisphenol S, BPS (80-09-1)
- Bisphenol-A-diglycidyl ether, BADGE (1675-54-3)
- Bisphenol-F-diglycidyl ether, BFDGE (2095-03-6)
- Tetrabromobisphenol-A (79-94-7)

NANOMATERIALS

ERT hereby declares that this product does not contain any nanomaterials as identified in the Cosmetic Regulation 1223/2009/EC.

LATEX

ERT hereby declares that Natural Rubber latex (NRL), Dry Natural Rubber (DRL), synthetic latex or rubber that contains natural rubber are not intentionally added to the process or to this product.

OTHER SUBSTANCES

ERT hereby declares that this product does not intentionally add or use any of the following compounds during the manufacturing of this product (#CAS number):

Code	PRO_PRS_01	PRO PRODUCT REGULATORY STATEMENT PRS	
Rev.:	0		
Page:	6		
Date:	06/21/222		

- Asbestos (1332-21-4)
- Silicon (7440-21-3)
- Radioactive Substances (N/A)

SECTION 3: COMPANY INFORMATION

This statement does not cover convertors and/or final product manufacturers in case of:

- modification of our product by any addition of any other product to it.
- modification of the product resulting from processing of the product.
- inadequate use and / or storage of the material and of the finished article.

Scheyla E. C. Zeck
 Technical Manager
 CRQ 09201194