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REGULATORY INFORMATION SHEET[i]

Polypropylene

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SECTION I: FOOD CONTACT REGULATIONS

ESENTTIA declares that the composition of this product, when used unmodified, complies with the following legislations, recommendations or communications as described in:

USA: FDA FCN 1409, 21 CFR (Updated); Numeral 177.1520 (a) (3) (i) (c) (1) (b) and (c) 3.1a olefin polymers.
As specified in FCN 1409, the final blend incorporating on this reference has a minimum number-average molecular weight of 25.000 Daltons and is intended for use in contact with all types of food under conditions of use A through H as described in Tables 1 and 2 of FDA 21CFR 176.170 (c), subject to the requirements of good manufacturing practice from the FDA. Adjuvant substances permitted for use in olefin polymers complying with 21 CFR 177.1520 (c), items 1.1, 3.1, and 3.2 may also be used in this food-contact substance, subject to the prescribed limitations and specifications. This reference is not for use in contact with infant formula and breast milk. Such uses were not included as part of the intended use of the substance in the FCN.
The adjuvants are cleared according to Part 178 (Indirect food additives) or are generally recognized as safe (GRAS - Parts 182, 184 or 186), are prior-sanctioned food ingredients (Part 181) or are cleared on basis of regulations for food additives of before 1958. It is the responsibility of the packer or food converter, controller that the final package meets the requirements and conditions under foreseeable conditions of use.

EU: ▪ Regulation (EC) No 1935/2004, to now applicable to polymeric beads.
▪ Regulation (EC) 2023/2006, this material has been manufactured in accordance with the relevant requirements of good manufacturing practice for materials articles intended to come into contact with foodstuffs.
▪ Regulation (EU) 10/2011 and subsequent amendments up to **(EU) 2020/1245**.

In accordance with Article 12 of Regulation (EU) 10/2011, Materials and plastic articles in contact with food shall not transfer their constituents to food simulants in quantities that exceeding 10 mg of constituent released per square decimeter of surface contact (mg/dm^2). Nevertheless, materials and plastic articles intended to come into contact with food for infants and young children, as defined in Directives 2006/141/EC and 2006/125/EC of the Commission, must not transfer their constituents to food simulants in quantities that exceeding 60 mg of constituent released per kilogram of food simulant.

▪ **Dual Use Additives**: Regarding Article 11, item 3 of Regulations (UE) 10/2011, this product contains one or more additives considered dual-use in accordance with Regulation (EC) No. 1333/2008 and its amendments (EU) No. 1129/2011 and (EU) No. 380 / 2012 "on food additives" Annex II, "List of the Union of food additives approved for use in food, and conditions of use". For further information, please submit a request through the service channels described at the end of the document.

ECUADOR: Ecuadorian Technical Regulation RTE INEN 100 Quality undersecretary of the Ministry of Industry and Productivity Ecuadorian about the overall migration limits to be met plastic materials and articles intended to come into contact with food (Resolution No 13 389/2013 and its resolution amending No 14077/2014).
In accordance with the Item 5 of this regulation, the limits of the overall migration on general provisions for plastic containers and equipment should not exceed 60 mg per kilogram of constituent released food simulants. (mg / kg) or 10 mg per square decimeter constituent released contact surface (mg/dm^2).

COLOMBIA: Technical Regulation 683 / 2012 about the health requirements to be met by materials, objects and equipment intended to come into contact with food for human consumption. Technical Regulations 4143 / 2012 about the health requirements to be met by materials, objects, packaging and equipment and plastic and elastomeric additives, intended to come into contact with food and beverages for human consumption in the Colombian territory.

ANVISA: Resolution No. 105 (1999) and subsequent amendments including RDC Nº 589 (2021); Resolution RDC No. 51; Resolution RDC No. 56 (2012) and its amendment and Resolution RDC No. 326 (2019).

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This resin meets fully the Positive List of Polymers and Resins - Annex II - presented in the Resolution No. 105 of May 19th 1999, the positive list of additives for plastic materials for Packaging Elaboration and Equipment on with food presented on Resolution RDC No. 326 of December 2nd 2019 , the criteria of migration of the materials, packaging and plastic equipment intended to come into contact with food in accordance with Annex to the Resolution RDC No. 51 and 52 of November 26th 2010 and positive list of monomers, other starting substances approved for the production of plastic containers and equipment that will be in contact with food in accordance with the annex to Resolution No. 56 RDS polymers of November 16, 2012 .
On these resolutions, the Sanitary Vigilance National Agency - ANVISA - sets Limits Composition (LC) and / or Specific Migration Limits (SML) for substances in packaging intended for food contact.

MERCOSUR: Technical Regulation on the Positive List of Polymers and Resins Plastic to Packaging and Equipment in Food Contact (MERCOSUR / GMC / RES. No. 002/12 and its amendment GMC/RES. Nº 19/21). Technical Regulation on the Positive List of Additives for the manufacture of Plastics Materials and Polymer Coatings intended to come into contact with Food (MERCOSUR / GMC / RES. No. 039/2019).

This Polypropylene is Including in the list of permitted and resins for the manufacture of packaging equipment and food contact polymers. Polypropylene has no use restrictions neither Composition Limits (LC) or regulated with specific migration limit (SML).

The overall migration limits are set out in the Technical Regulations Colombians and in the ANVISA Resolutions here mentioned, which states that from plastic materials and articles intended to come into food contact should not exceed 50 mg constituent released per kilogram of food simulant (mg / kg), or 8 mg constituent released per square decimeter of surface contact (mg/dm^2) and MERCOSUR Resolutions establish an overall migration limit of 10 mg of constituent released per square decimeter of surface contact (mg / dm2) or 60 mg of constituent released per kilogram of food simulants (mg / kg).

The monomers used are not regulated with specific migration limit (SML).

It is our experience that the migration of additives about based on estimates calculated with a recognized EU migration mathematical model of this reference or a comparable degree standards made with food simulants for 10 days at 40 ° C, at which a specific migration limit (SML) was imposed or has other restriction (s) for any other regulation in Colombia or the EU, under these conditions, migration does not exceed the limits.

Substances used as food additives are not present in the final product in quantities such that migration to the food product may exceed the limits specified in the relevant legislation to the type of food or have a technological function in the final product.

This product contains one or more additives with a Specific Migration Limit (SML) according to the lists of regulated additives for migration purposes EU 10/2011, RDC No. 326/2019 (ANVISA) and GMC/RES. No.039/2019 (MERCOSUR). For further information, please submit a request through the service channels described at the end of the document.

Compliance with these requirements, the overall and specific migration must be measured in the finished articles in contact with food and thus is the responsibility of the converter or packer using real food or appropriate food simulants under time and temperature conditions according to the applicable standards specified in each of the regulations described above.

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SECTION II: REGULATIONS ON HEAVY METALS

ESENTTIA declares that, with respect to the regulations and standards, listed herein, it does not use or intentionally add the followings Heavy Metals during the manufacture of this product in amounts which exceed the applicable limits; therefore, we are confident that, if present at all, the levels of heavy metals comply with the limits in:

USA:
- CONEG "Toxics in Packaging" Model Legislation, rev. February 2021 – the sum of Pb, Cd, Hg and Cr(VI), should not exceed 100 ppm.

UE:
- Directive 94/62/EC and 2004/12/EC on packaging and packaging waste (PPW) - Pb, Cd, Cr(VI) and Hg <100 ppm.
- Directive 2000/53/EC and 2002/525/EC on end-of-life vehicles (ELV)- Cr(VI), Hg y Pb < 0.1 wt%, Cd < 0.01 wt%.
- Directive RoHS 3 (Directive 2015/863/EU to amend Annex II to EU RoHS 2 (Directive 2011/65/EU)) on restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) – Cr(VI), Hg, Pb, PBB, PBDE, DEHP, BBP, DBP, DIBP < 0.1 wt%, Cd < 0.01 wt%.
- Directive 2009/48/EC (safety of toys) and update 2012/7/EC; European Standard EN 71 "Safety of Toys", Part 3 (1994): "Migration of certain elements" (Sb< 60; As<50; Ba<1000; Cd< 75; Cr< 60; Pb< 90; Hg< 60; Se< 500 mg/kg toy material) and Part 9 (2005) "Organic chemical compounds - Requirements" (none of the substances listed in Tables 2 A-I are intentionally added).
- Directive 2012/19/EU (Waste Electrical & Electronic Equipment - WEEE) - Annex VII - No ingredients used which require selective waste treatment (As, Hg, PCB, PCT, CFC, HCFC, HFC, brominated FR).

COLOMBIA:
- Resolution No. 4143/2012 which establishes the technical regulations on the health requirements to be met by materials, objects, packaging and equipment plastics and elastomeric, that the sum of the incidental concentration levels of heavy metals such as Lead (Pb), Cadmium (Cd), Mercury (Hg) and hexavalent chromium (Cr VI), should not exceed 100 ppm by weight.
- Colombian Technical Standard NTC-EN 71-3 "Safety of Toys, Part 3 (1997):" Migration of certain elements (Sb <60; As <25; Ba <1000; Cd <75, Cr <60; Pb <90; Hg <60; Se <500 mg / kg toy material).

SECTION III: CHEMICAL INVENTORIES STATUS

The substances used in the manufacture of polypropylene, and which so far cover the basic polymers, are listed in the following chemical inventories:

TSCA (USA)	**AICS (Australia)**	**DSL/NDSL (Canada)**
EINECS (Europe)	**ENCS (Japan)**	
PICCS (Philippines)	**KECL (Korea)**	

SECTION IV: CHEMICAL COMPONENTS WITH REGULATORY RESTRICTIONS

ESENTTIA declares that in the composition of this resin, it does not use or intentionally add (above the applicable limits) any of the substances listed below. ESENTTIA does not routinely perform any analysis or testing for the identification or quantification of these substances or compounds.

CHEMICAL COMPONENT	ADDITIONAL COMMENTS

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CHEMICAL COMPONENT	ADDITIONAL COMMENTS
Acrylamide	-
Acrylonitrile	-
Allergens	Including: milk products, eggs or egg products, soybean products, peanuts or peanut derivatives, tree nuts or derivatives (including coconut), cereals containing gluten (wheat, rye, barley, oats, spelt, kamut), fish or derivatives, crustacea or derivatives, mollusks or derivatives, sulfites, FD&C colors, tartrazine, monosodium glutamates, glutamic acid, MSG or derivatives, sesame seeds or derivatives, celery or derivatives, mustard or derivatives, lupine or derivatives, carmine / cochineal or derivatives, kiwi, peach, corn, hydrolyzed protein, lecithin, aspartame, sunflower seeds, poppy seeds, malt.
Aluminosilicate Refractory Ceramic Fibers and/or Zirconia Aluminosilicate	-
Aromatic Amines	Restricted in Regulation (EC) No. 1907/2006, Annex XVII
Artificial Musks	Including: Musk Xylene, Musk Ketone
Arylamines	Including: 4-Aminobiphenyl, Benzidine, o-Aminoazotoluene, 2-Amino-4-nitrotoluene, 4-Chloroaniline, 2,4-Diaminoanisole, 3,3'-Dichlorobenzidine, 3,3'-Dimethoxybenzidine, 3,3'-Dimethylbenzidine, 4,4'-Methylenedi-o-toluidine, p-Cresidine (6-Methoxy-m-toluidine), Aniline, 4-Chloro-o-toluidinium chloride, 2,4,5-Trimethylaniline hydrochloride.
Asbestos and their compounds	-
Azimidobenzene	-
Azocolorants	Restricted in Regulation (EC) No. 1907/2006, Annex XVII
Azodicarbonamide	-
Benzene	-
Benzophenone	-
Benzotriazole	-
Biocides	Including: pesticides, herbicides, insecticides, fungicides, bactericides.
Bisphenols and their compounds	Including: Bisphenol A (BPA), Bisphenol B (BPB), Bisphenol F (BPF), Bisphenol S (BPS), Bisphenol-F-diglycidyl ether (BFDGE), Bisphenol-A-diglycidyl ether (BADGE) and Novolac Glycidyl Ether (NOGE).
Butylated hydroxyanisole (BHA)	-
Butylated hydroxytoluene (BHT)	-
Chlorinated Hydrocarbons	-
Chlorinated Paraffins	-
Chlorofluorocarbons	Including: CFC and HCFC.
Cyanuric Acid	-
Diazene-1,2-dicarboxamide	
Dimethylfumarate	-
Dioxins	-
Dyestuffs and pigments	Classified as carcinogenic and allergenic.

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Endocrine Disruptors (EDCs)	-
Ethoxyquin	-
Flame retardants	Including: BB, PBBs, PBDEs, HBCD, HBCDD, BBPP, TBPP, TBBPA, TBP, TCDD, PCDDs, PCBs, PCTs, PCDFs, DiBB, TriBB, TriBDEs, TetraBDEs, PentaBDEs, HexaBDEs, HeptaBDEs, OctaBDEs, NonaBDEs, DecaBDE, TRIS, TCEP, HBCDD, TBBP, BBMP, TDCPP, TDBPP, TEPA Boric acid, Diboron trioxide, Diantimony trioxide, Disodium tetraborate anhydrous, Disodium octaborate, Trixylyl phosphate.
Formaldehydes	-
Furans	-
Genetically Modified Materials (GMO)	-
Glycol ethers	Including: EGME, EGMEA, EGEE, EGEEA.
Halogens	Including: Fluorine (F), Chlorine (Cl), Bromine (Br), Iodine (I); Boron (B) and Phosphorus (P).
Latex	-
Melamine	-
Metals and Metalloids	Including: Antimony (Sb) and its compounds, Arsenic (As) and its compounds, Lead (Pb) and its compounds, Cadmium (Cd) and its compounds, Chromium (Cr) and its compounds, Chromium(VI), Cobalt (Co) and its compounds, Copper (Cu) and its compounds, Nickel (Ni) and its compounds, Mercury (Hg) and its compounds, Barium (Ba) and its compounds, Indium (In) and its compounds, Palladium (Pd) and its compounds, Silver (Ag) and its compounds, Tellurium (Te) and its compounds, Thorium (Th) and its compounds, Beryllium (Be) and its compounds, Bismuth (Bi) and its compounds) Europium (Eu) and its compounds, Gadolinium (Gd) and its compounds, Lanthanum (La) and its compounds, Terbium (Tb) and its compounds.
MOAH - Mineral Oil Aromatic Hydrocarbons	-
MOSH - Mineral Oil Saturated Hydrocarbons	-
Nanomaterials	-
Natural Rubbers	-
N-Nitrosamines	-
N-Nitrosatable substances	-
o-Phenylphenol	-
Organotin compounds	Including: BT, TBTC, DBT, DBTC, DBTO, DOT, DOTC, DOTO, TPT, TPTC, TBTO, TPhT, DPhT, DMT, DPT, MMT, MBT, MOT, MPhT, TeBT, TeEt, TCyHT, TMT, TOT.
Octa-/Pentabromodiphenylether	-
Parabens	-
Pentachlorophenol (PCP)	-
Per- and polyfluorinated compounds	Including: PFT, PFOA, PFBS, PFOSA, PFNA, PFOS, PFOSF, N-Me-FOSA, N-Et-FOSA, N-Me-FOSE, N-Et-FOSE, PFHpA, PFDA, PFUdA, PFHxA, PFHxS, PFHpS, PFDS, 7HPFHpA, 4HPFUnA, FTOHs, FTAHs, FTAs, PFAS, PFHS.
Perchlorates	-

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CHEMICAL COMPONENT	ADDITIONAL COMMENTS
Phenol	-
Phthalates	The composition of this resin does not contain any kind of phthalates derived from catalyst system because the catalyst used is not phthalates-based. Moreover, ESENTTIA does not use or intentionally add any type of phthalates during its manufacturing.
Plasticizers	Including: Adipates and ESBO.
Polycyclic aromatic hydrocarbons (PAH)	Restricted in Regulation (EC) No. 1907/2006, Annex XVII
Polyvinyl chloride (PVC)	-
Polyvinylidene chloride (PVDC)	-
POSH: Polyolefin Oligomeric Saturated Hydrocarbons	-
Quaternary ammonium compounds (QAC)	-
Quinoline	-
Radioactive materials	-
Recycled materials	-
Selenium (Se) and its compounds	-
Silicones	-
Siloxanes	Including: D4, D5, D6
Solvent residues	Including: NMP, DMAc and DMF.
Styrene monomer	-
Substances from Animal Origin	This product is considered safe for use in the manufacture of plastic materials and articles intended to come into contact with food respect to TSE (Transmission Spongiform Encephalopathy) and BSE (Bovine Spongiform Encephalopathy) transmissions.
Substances listed on Proposition 65	Chemicals List of Proposition 65 of the State of California and subsequent amendments, as known to the State of California to cause cancer or reproductive toxicity, according to the last updated on **25th February 2022.**
Substances of Very High Concern (SVHC)	Not used or added intentionally (above 0.1% by weight in accordance with Article 33 of REACH Regulation CE 1907/2006) none of the substances listed in Annex XIV related to the Candidate List of Substances of Very High Concern for Authorization (SVHC), according to the criteria established in Article 57 of the REACH Regulation CE 1907/2006, taking into account its last update of **10th June 2022.**
Sulfur (S) and its compounds	-
Surfactants	Including: Octyl-, Nonyl-, Heptyl- or Pentylphenols, Octyl- or Nonylphenolethoxylates or Alkylphenolethoxylates.
Thiuram	-
Triacetin	-
Tris(2-chloroethyl) phosphate	-
UV Hardeners (ITX)	-

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SECTION V: OTHER REGULATIONS

ESENTTIA declares that with respect to the regulations and norms listed herein, it does not use or intentionally incorporate into the manufacturing of this reference, any chemicals regulated by said regulations and norms and their subsequent amendments, in amounts which exceed the applicable limits. ESENTTIA does not routinely perform any analysis or testing for the identification or quantification of these substances or compounds.

USA:
- Clean Air Act, Title VI, Classes I and II (EPA Final Rule; Federal Register 8136, 11.2.1993) on substances that deplete the ozone layer.

UE:
- Directive CE 1223/2009 relating to cosmetic products.
- Annex XVII of the REACH Regulation 1907/2006/EC (superseding Directive 76/769/EEC) - Restrictions on the manufacturing, marketing and use of certain dangerous substances, mixtures, and articles.
- Regulation (EU) 2019/1021 on persistent organic pollutants (POPs).
- Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer.
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council, substances or products causing allergies or intolerances, as described in Annex II.

Conflict Minerals: Regulation (EU) 2017/821 laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas. ESENTTIA declares that fully supports the SEC (Securities and Exchange Commission) and the recent Dodd–Frank Wall Street Reform and Consumer Protection Act as a method to combat human rights abuses by the Democratic Republic of the Congo (DRC) and for making companies more accountable for buying suspect raw materials that directly aid corrupt militias.

SECTION VI: FLAMMABILITY

UL status: this polypropylene resin is not UL certified, however, according to the studies and flammability tests considered in the UL 94 standard, it is classified as HB. This means that when exposed to the flame, horizontally, it burns at a slower rate than the maximum allowed.

SECTION VII: PHARMACEUTICAL APPLICATIONS[ii]

- USP 42 - NF 37: This reference has been tested as defined in chapter USP <661.1> "Plastic materials of construction" with favorable results. The tests include: Identification, physicochemical tests, extractable metals and plastic additives.[iii]

- This product has not been tested according to the criteria of the EU Pharmacopeia

SECTION VIII: MEDICAL APPLICATIONS[iv]

This product has not been evaluated according to Biocompatibility guidelines.

SECTION IX: SPECIAL APPLICATIONS

This product has not been evaluated according to guidelines for other specific applications.

The above statements refer only to the composition of the above-described product and do not guarantee the compliance of final articles made of them. It is the responsibility of the manufacturer of the article, converter and packer, determine

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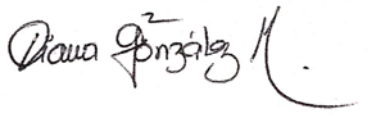
that the product is suitable for its intended use in accordance with the appropriate regulations, and carry out the necessary corresponding tests in accordance with the appropriate regulations, in order to verify that the final product, manufactured according to good manufacturing practice, does not modify the organoleptic properties of the food or product that would contain it, and that it is the appropriate for the food or product that will be in contact with it.

For further information, please make the request through any of the following service channels: our website www.esenttia.co, by clicking on the link Customer Access, with your user's name and password, at the General Technical Information Request button; through our service line (+57)(60)(1) 5960210, or by submitting your request via e-mail at servicioalcliente@esenttia.co.

This statement supersedes all previous related to these topics.

Prepared by ESENTTIA S.A. – Diana Gonzalez



i This document is intended to address compliance standards and commonly requested data. The information contained herein is based on the data available to us and is believed to be correct as the date of publication, however we make no warranty, expressed or implied, regarding the accuracy of these data or the results to be obtained from user thereof. It is the customer's responsibility to inspect and test our products in order to satisfy himself as to the suitability of the products for the customer's particular purpose. Our statement that cited product meets all of the specifications and requirements stipulated in the applicable sections of these regulations in an assurance predicated on the assumption that the chemical composition will not be altered by the addition of non-regulated substances. The customer is also responsible for the appropriate, safe and legal use, processing and handling of our products.
This declaration does not cover:
Any substance subsequently added by the converter.
Poor material or end product due to inexpert manufacture by the converter.
Any negative influence of the finished article on the organoleptic properties of the packaged food hence, we can assume no responsibility for any product incompatibility in these respects.
This declaration applies to the material as it leaves its production facilities and does not cover any additive, pigment, etc., subsequently included by the converter. It is responsibility of the customer to obtain all necessary information relating to the third-party materials and ensure that ESENTTIA's products when used together with these materials are suitable for the customer's purpose. No liability can be accepted in respect of the use of ESENTTIA products in conjunction with other materials.
The absence of chemicals has not been checked by tests. Although the above-mentioned substances are not intentionally added this does not excluded the presence of negligibly traces due to among other things impurities in the components supplied by external parties and used in the production. Analyses for trace impurities in ESENTTIA S.A. products are not conducted as part of routine lot certification procedures.
As the above-mentioned Regulations develop continuously, our declaration will be adapted accordingly, therefore we advise the receiver to ask for a new declaration periodically; ESENTTIA shall not be under a duty to notify you any changes to the regulations.

ii Manufacturers of pharmaceutical products have the responsibility to determine that the ESENTTIA products are safe, legal, and technically suitable for the intended use.

iii Identification tests include: Infrared spectrophotometry and Differential scanning calorimetry. These two tests are carried out in accordance with ESENTTIA's internal methods.

iv ESENTTIA does not endorse or claim the suitability of this product for specific medical applications. Manufacturers of medical devices or pharmaceutical products have the responsibility to determine that the ESENTTIA products are safe, legal, and technically suitable for the intended use and has the responsibility to conduct the appropriate tests to determinate suitability in the application, assuming all risk and liability arising from the use of the information and/or handling of any product in order to ensure compliance of the medical device, including the suitability of all raw materials and components used for its manufacture, and with all applicable laws and regulations. ESENTTIA DOES NOT MAKE ANY GUARANTEE OR WARRANTIES, EXPRESS OR IMPLIED, AS TO THE SUITABILITY OF ANY ESSENTIA'S PRODUCT FOR USE IN MEDICAL APPLICATIONS. For further information please contact us through any of theservice channels.

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