

## TECHNICAL DATA SHEET

Effective date: 01.2020  
Rev.0

## Aurora Airless bottle, 30 ml

## REGULATORY COMPLIANCE CERTIFICATE

## 1. EUROPEAN UNION FOOD CONTACT

We hereby certify that all the monomers and additives used in the manufacture of our above cited grade of polymer are authorised in current documents relating to:

**Regulation 1935/2004** on materials and articles intended to come into contact with food, developed for plastics in specific.

**Regulation 10/2011** on plastic materials and articles intended to come into contact with food. These directives correspond in the Spanish Legislation to **Real Decreto 866/2008** amended in **RD 103/2009** and **Orden PRE/628/2011**.

**Regulation 10/2011** replaces **Directive 2002/72** with effect from 1 May 2011.

**Regulation 2023/2006** on good manufacturing practice (GMP) for materials and articles intended to come into contact with food amended by **Regulation 282/2008**.

**Regulation 282/2008** on recycled plastic materials and articles intended to come into contact with foods amending Regulation 2023/2006: does not use recycled plastics in its processes.

**Regulation 1895/2005** on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food and in the Spanish Legislation **RD 293/2003** amended in **RD 12/2005**.

**Directive 2011/8**, restriction of use of bisphenol A in plastic infant feeding bottles: we do not include bisphenol A in the composition of this product. In Spanish Legislation correspond to **Orden PRE/628/2011**.

**Regulation 321/2011** amending **Regulation 10/2011** on restriction of use of bisphenol A in plastic infant feeding bottles: we do not include bisphenol A in the composition of this product.

**Substances subject to restrictions (SML/QM/DUAL):**

**Dual additives:** it does not contain any food additive.

**Monomers:** no monomers subject to restriction are used.

**Additives:** this product contains the following additive/s authorised by Regulation 10/2011 but regulated with specific migration limit:

-N,N-bis(2-hydroxyethyl) alkyl (C8-C18)-amine (SML = 1,2 mg/Kg).

-bis(4-propylbenzylidene) propylsorbitol (SML = 5 mg/Kg)

According with **Regulation 10/2011**, the verification of compliance with the overall migration limit (OML) and when necessary with the specific migration limit (SML) should be assessed by the converter or packer **in the finished product state at the real conditions of use** (time, temperature and foodstuff or appropriate food simulants). Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in **Directives 82/711/EEC** (amended in **Directives 93/8** and **97/48**) and **85/572/EEC** (amended in **Directive 2007/19**). It is also necessary the testing of the mutual compatibility between the finished products and the food substances, in particular the non modification of their organoleptic properties.

## 2. UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA)

**Code of Federal Regulation (CFR)**, Title 21 (4-1-09 Edition): 177.1520 "Olefin Polymers" (a)(3)(i)(c)(1), (b) and (c) 3.1a.

o For use only in polyolefin food-contact films.

o Polypropylene containers that contact food only of the types identified in Sec.176.170(c), Table 1, under types I, VI-B, VII-B, and VIII, under the conditions of use E through G described in Sec.176.170(c), Table 2, provided such foods have a pH above 5.0

o Molded or extruded polypropylene homopolymers and copolymers that contact food only of the types identified in Sec.176.170(c), Table 1, under Types II, III, IV, V, VII-A, and IX, under the conditions of use C through G described in Sec.176.170(c), Table 2

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We do not certify this product for pharmacopoeia uses.

**4. HEAVY METALS**

The composition of this grade meets the relevant requirements of the following documents:

**Directive 94/62** on packaging and packaging waste (PPW) amended in Directives 2004/12 and 2005/20 and Regulations 1882/2003 and 219/2009, on respect to the limit set (100 ppm) for heavy metals defined as lead, cadmium, mercury and chromium (VI).

**Directive 2000/53** on end-of life vehicles (ELV) amended in Commission Decisions 2002/525, 2005/63, 2005/438, 2005/673, 2008/689 and 2010/115 and Directives 2008/33, 2008/112 and 2011/37 which establishes a maximum concentration value up to 0.1 % by weight for lead, mercury and chromium (VI) and up to 0.01 % for cadmium.

**Directive 2002/95** on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) amended in Commission Decisions 2005/618, 2005/717, 2005/747, 2006/310, 2006/690, 2006/691, 2006/692, 2008/385, 2009/428, 2009/443, 2010/122 and 2010/571 and Directive 2008/35 which establishes a maximum concentration value up to 0.1 % by weight for lead, mercury and chromium (VI), polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE) and up to 0.01 % for cadmium.

**Directive 2002/96** on waste electrical and electronic equipment (WEEE) amended in Directives 2003/108, 2008/34 and 2008/112.

**CONEG (Coalition of Northeastern Governors - USA):** the total content of lead, mercury, chromium (VI) and cadmium is less than 100 ppm.

**5. COSMETICS**

**Directive 76/768** and amendments relating to cosmetic products, partially repealed by **Regulation 1223/2009**: in the manufacture of our products we do not use or intentionally incorporate any of the chemicals regulated in this document (Annex II and Annex III, part 1) in quantities above the applicable limits. Thus, it is not foreseeable their presence in the final product. However, most of these chemicals have not been specifically analysed to assure their absence.

**6. TOYS**

**Directive 2009/48** concerning the safety of toys.

**Directive 88/378** concerning the safety of toys amended in Directive 93/68 and 2008/112 and partially repealed by Directive 2009/48.

**Directive 2005/84** relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles). See note about phthalates.

**European Norms EN 71-3 and EN 71-9** relating to safety in toys: Part 3 (migration of certain elements) and Part 9 (organic chemical compounds).

**7. REACH and CLP**

**Regulation 1907/2006** concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (**REACH**) and amendments Regulations 1354/2007, 987/2008, 1272/2008, 134/2009, 552/2009, 276/2010, 453/2010, 143/2011 and 207/2011. According with article 2 (9), polymers are exempted from registration and evaluation under REACH. However, raw materials (monomers, additives, catalysts...) must be registered.

**REPSOL QUÍMICA** has registered the monomers used in the manufacture of its grades of Polyethylene (PE), Polypropylene (PP), Ethylene-Vinyl Acetate Copolymer (EVA) and Ethylene-Butyl Acrylate Copolymer (EBA). Regarding the chemical substances included in **annex XVII** of **Regulation 1907/2006**, **MANUFACTURER** does not use or

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intentionally incorporate into its polymers any of those chemicals in quantities above the applicable limits. Although it is not foreseeable their presence in the final product, specific analyses to assure the absence of most of these chemicals have not been performed.

**Substances of Very High Concern (SVHC):** in the framework of the authorisation process, the European Commission decides on including substances that have been identified as **SVHC** and placed on the candidate list in Annex XIV of REACH (list of substances subject to authorization). Does not use any of these substances in its polyolefins' manufacturing process in concentrations exceeding 0,1%, as defined in article 7.2 and 57. To complete this information refer to the general **SVHC** declaration.

**Regulation 1272/2008** on classification, labelling and packaging of substances and mixtures, amended in Regulation 790/2009 and 286/2011. **CLP** implements the Globally Harmonised System (GHS). CLP will stepwise replace **Directive 67/548/EEC** (substances) and **Directive 1999/45/EC** (preparations). According with this regulation **POLIPROPILENO ISPLEN® PR280P1M** is not a dangerous preparation. To complete this information refer to the Material Safety Data Sheet (MSDS).

**8. RECYCLING**

This polymer is recyclable but it is neither compostable nor biodegradable.

**9. BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) / TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE)**

Our above mentioned grade of **POLIPROPILENO ISPLEN® PR280P1M** could contain additives of animal origin, but according with the information from our suppliers, the processing and transformation conditions are more severe than those included in the Commission Decision 2001/2, Directives 2000/6 and 1999/82 and Regulation 1774/2002, 1326/2001 and 999/2001, so there is not risk of transmitting BSE/TSE.

**10. OTHERS REGULATIONS / NORMS**

**MANUFACTURER** does not use or intentionally incorporate in the composition of its polymers any of the chemicals regulated in the following documents. The presence of these substances is then not foreseeable in the final product; however, specific analyses to assure the absence of most of these chemicals have not been performed.

**GMO (Genetically Modified Organisms):** according with the information from our raw materials suppliers, the polymer does not contain intentionally in its composition any GMO.

**Allergens - Directive 2000/13** relating to the labelling, presentation and advertising of foodstuffs, amended in Directives 2001/101, 2003/89, 2006/107, 2006/142 and 2007/68 and Regulations 1332/2008, 1334/2008 and 596/2009. The polymer does not contain intentionally in its composition any of the substances listed as allergens in annex IIIa.

**Directive 2000/60** on Water Policy amended in Commission Decision 2455/2001 and Directives 2008/32, 2008/105 and 2009/31. The polymer does not contain intentionally in its composition any of the priority substances listed on annex X.

**Directive 850/2004** on persistent organic pollutants, amended in Regulations 1195/2006, 172/2007, 323/2007, 219/2009, 304/2009, 756/2010 and 757/2010. The polymer does not contain intentionally in its composition any of the substances included in annex I, II, III and IV.

**Regulation 465/2008** on substances that may be persistent, bioaccumulating and toxic (PBT). The polymer does not contain intentionally in its composition any of the substances included in annex I

**Regulation 1005/2009** on Ozone Layer Depleting Substances amended in Regulation 744/2010. The polymer does not contain intentionally in its composition any of the substances included in annex I & II. This Regulation repeal 2037/2000.

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**US Clean Air Act, title VI (Stratospheric Ozone Protection):** the polymer does not contain intentionally in its composition any of the substances class I and class II.

**California Proposition 65:** list of the California State relating to chemicals known to the state to cause cancer or reproductive toxicity (update March 2011).

**GADSL (Global Automotive Declarable Substance List):** no use of prohibited or declarable substances above applicable limits (2011 GADSL Version 1.0).

**ÖKO Tex Standard 100:** list of substances on annex 4 (product class I, II, III and IV).

**OSPAR List of Chemicals for Priority Action,** update 2007.

**IKEA IOS-MAT-0010** (rev. 2009) / **IKEA IOS-MAT-0054** (rev. 2011).

**CHEMICAL INVENTORIES:** we confirm that monomers and additives used in this polymer are listed or are in compliance with the following chemical inventories:

- o EINECS / ELINCS (Europe)
- o TSCA (USA)
- o DSL (Canada)
- o AICS (Australia)
- o KECL (Korea)
- o ENCS (Japan)
- o PICCS (Philippines)

**11. ABSENCE OF SUBSTANCES**

MANUFACTURER does not use or intentionally incorporate into its polymers any of the following chemicals. Although it is not foreseeable their presence in the final product, specific analyses to assure the absence of most of these chemicals have not been performed. This is a non-exhaustive list of substances.

- Acrylamide
- Alkylphenol ethoxylates (APEO)
- Aromatic amines
- Arsenic and arsenic compounds
- Asbestos
- Azoic colorants
- Benzene
- Benzophenone, hydroxybenzophenone and 4-methylbenzophenone
- Biocides
- Bisphenol A (BPA) and Bisphenol F (BPF)
- Boron and boron compounds
- Butylated hydroxytoluene (BHT) / Butylated hydroxyanisole (BHA)
- Cadmium and cadmium compounds
- CFC (chlorofluorocarbons) y HCFC (hydrochlorofluorocarbons)
- CMR substances class 1A and 1B (Carcinogens, Mutagens and Reprotoxics) according with Regulation CLP (1272/2008)
- Diethylhexyl adipate (DEHA)
- Dimethyl fumarate (DMF)
- Dioxines
- Epichlorhydrin
- N-Ethyl o-Toluensulfonamide and N-Ethyl p-Toluensulfonamide (NETSA)

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Flame retardants: organic brominated compounds (pentabromodiphenyl ether, octabromodiphenyl ether...), antimony compounds, chlorinated paraffins, triaryl phosphates...

Formaldehyde

Formamide

Halogens and halogenated compounds

Hexavalent Chromium and hexavalent chromium compounds

Isopropylthioxantone (ITX)

Latex

Lead and lead compounds

Lindane

Melamine

Mercury and mercury compounds

Nitrosamines

Nyckel and nyckel compounds

Nonylphenol, nonylphenol ethoxylate and cement

Organostannic / Organotin compounds

PBT Substances (Persistent, Bioaccumulating and Toxics) and vPvB (very persistents and very bioaccumulating

Pentachlorophenol and its salts and esters

Phenol

Perfluorooctane sulfonates (PFOS)

Polycyclic aromatic hydrocarbons (PHA): anthracene, fluoranthene, naphthalene, pyrene, benzoanthracene, benzofluoranthene

Solvents: dichlorometane, dimethylacetamide, dimethylformamide, 2-ethoxy ethanol, nitrobenzene, trichloroethylene trichlorobenzene, hexachlorobenzene...

Styrene

Toluene

Triclosan

Vinyl chloride monomer (VCM) and its polymers (PVC...)

**12. PHTHALATES**

This product could contain less than 20 ppm of DIBP, DNBP/DBP and DEP coming from the catalytic system.

This information is only regarded to the above cited product supplied in original packaging and does not cover any subsequent modification of its composition or any usage which might produce a denaturalized material.

**DECLARATION OF FITNESS FOR CONTACT WITH FOOD****ERACLENE MP 90 U -HDPE PISTON**

Our product mentioned, as supplied by us in original packaging, complies with composition with current regulations on plastic materials intended for contact with foods in the following countries:

- Italy: Ministerial Decree 21.03.73 "Hygienic discipline of packaging, containers, tools intended to come into contact with food and personal use substances "and following amendments.
- Germany: Bedarfsgegenständeverordnung von 30.11.2006 and following amendments.
- Austria: Kunststoffverordnung 2003, BGBl. Teil II 476/2003 and following amendments.

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- France: Applicable regulations published in the Brochure N ° 1227. Arrêté of 02.01.2003 "Matériaux et objets en matière plastique mis ou destinés à être mis au contact des denrées, produits et boissons alimentaires "and following amendments.
  - Netherlands The Netherlands: Verpakkingen en Gebruikaartikelen Besluit (Warenwet) 08/21/1991 and following amendments.
  - Belgium: Arrêté Royal 11 Mai 1992 "Materiaux et object destines a entrer en contact avec les denrées alimentaires and following amendments. Arrêté Royal 3 juillet 2005 and following amendments.
  - United Kingdom: Statutory Instrument 2002, No. 2364 "The Plastic Materials and Articles in Contact with Food, Regulations 2002 "and following amendments. Statutory Instrument 2009, No. 2938 (England).
  - Spain: Real Decree 118/2003 of 31.01.2003 and following amendments. Real Decree 103/2009 of 06.02.2009.
  - Switzerland: RS 817.023.21 "Ordinance of the Federal Department of the Interior on materials and plastic objects dated 23.11.2005.
  - USA: Code of Federal Regulations, 2010 Food and Drug Administration (FDA) Title 21 §177.1520 (Olefin polymers) - paragraph (c) point 3.1.a.
  - ☑ Union European Union: Commission Regulation (EU) No 10/2011 "Plastic materials and articles intended to come into contact with food "and following amendments.

The product does not contain monomers or additives with migration limit and does not contain substances also authorized as flavorings or as food additives with restriction by European directives applicable.

We confirm that our product mentioned is made in application of the best practices of manufacture as per Regulation (EC) no. 2023/2006 and that our management system of the quality guarantees the traceability required by Regulation (EC) 1935/2004.

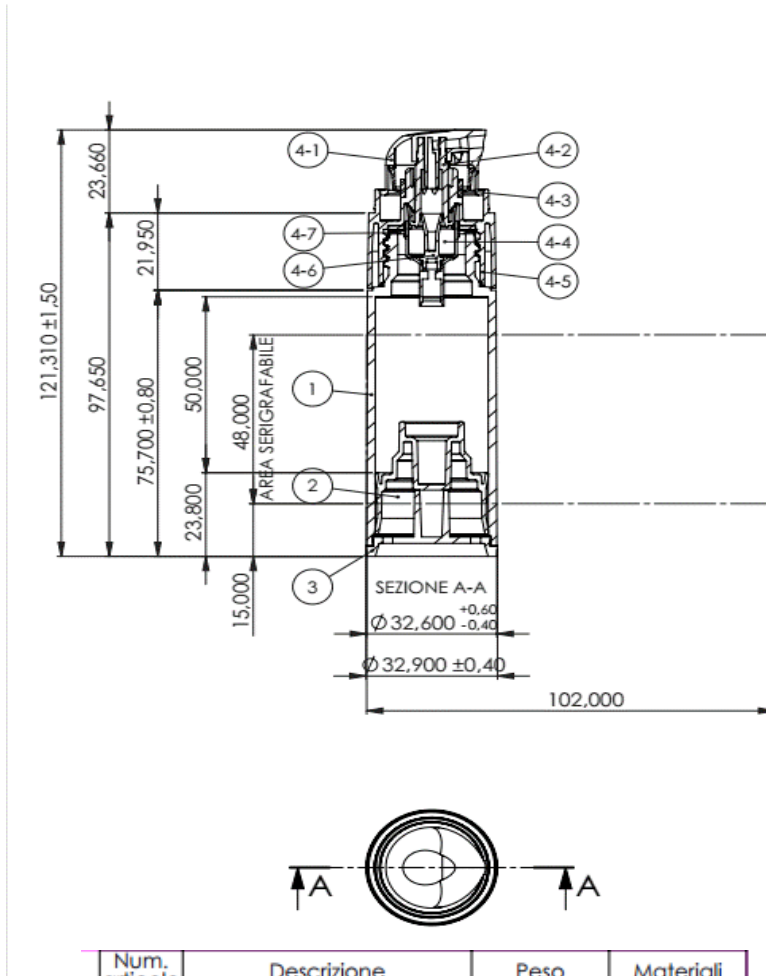
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**TECHNICAL DRAWINGS**

**Bottle, 30cc 24/410, 31.6gr±2, 34ml±3**



Num. articolo	Descrizione	Peso	Materiali
1	AIRLESS NINA 50cc	15,70gr	PP
2	PISTONE	3,50gr	PE
3	BASE	2,20gr	PP
4	POMPA NINA 24/410	10,20gr	VARI
4-1	EROGATORE		PP
4-2	STELO		PE
4-3	MOLLA		TPE
4-4	CORPO		PBT
4-5	GHIERA		PP
4-6	MEMBRANA		② TPV
4-7	GUARNIZIONE		PE

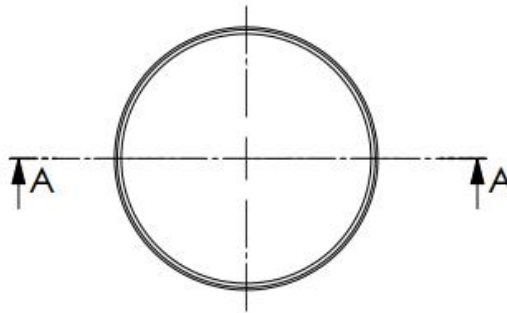
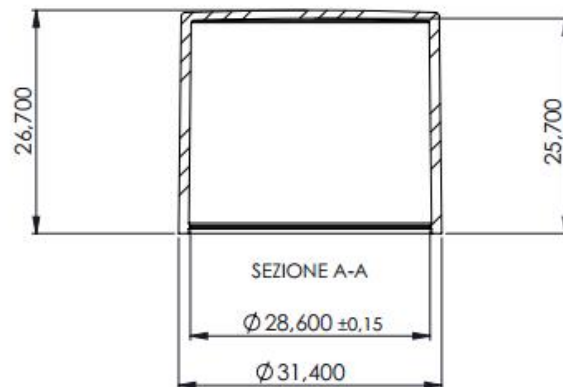
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**Cap, PP, 18/415, 3,4gr±0,5**



**Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications.**