



POLYPROPYLENE ISPLEN® PP064S1F

REGULATORY COMPLIANCE CERTIFICATE

Rev. 3.1
12/06/2014

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.
- **Regulation 10/2011** on plastic materials and articles intended to come into contact with food and amendments (Regulations 321/2011, 1282/2011, 1183/2012 and 202/2014).
- **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. **REPSOL QUÍMICA** does not use recycled plastic in this grade.
- **Regulation 1895/2005** on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food. **REPSOL QUÍMICA** does not include BADGE, BFDGE and NOGE in the composition of this grade.
- **Directive 2011/8**, restriction of use of Bisphenol A (BPA) in plastic infant feeding bottles. **REPSOL QUÍMICA** does not include Bisphenol A in the composition of this product.
- **Regulation 321/2011** amending Regulation 10/2011 on restriction of use of Bisphenol A (BPA) in plastic infant feeding bottles. **REPSOL QUÍMICA** does not include Bisphenol A in the composition of this product.

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

Dual additives: it contains silicon dioxide, which is authorised as food additive in EU legislation.

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).

The product could contain as impurities coming from the catalyst system DNBP/DBP (SML=0,3 mg/kg) and DEHP (SML=1,5 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 (revised as of April 1, 2012): 177.1520 "Olefin Polymers" (a)(1)(i), (b) and (c) 1.1a.

- For use only in polyolefin food-contact films.
- 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.
- 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

3. EUROPEAN PHARMACOPOEIA

REPSOL QUÍMICA does not certify this product for pharmacopoeia uses.



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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 2011/65** on the restriction of the use of certain hazardous substances in electrical and electronic equipment (**RoHS**) amended in Directives 2012/50 and 2012/51, 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 2012/19** on waste electrical and electronic equipment (WEEE). It repeals Directive 2002/96.
- **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**.
- **Regulation 1223/2009** relating to cosmetic products: in the manufacture of our products we do not intentionally incorporate any of the chemicals regulated in 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 88/378** concerning the safety of toys amended in Directives 93/68 and 2008/112 and partially repealed by Directive 2009/48.
- **Directive 2009/48** concerning the safety of toys. This directive repeals partially Directive 88/378 and amendments.
- **Directive 2005/84** relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles). The product does not contain any of the phthalates included in annex at concentrations above the applicable limits.
- **European Norm EN 71-3** relating to safety in toys: Part 3 (migration of certain elements).

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, 207/2011, 252/2011, 253/2011, 366/2011, 494/2011, 109/2012, 125/2012, 412/2012, 835/2012, 836/2012, 847/2012 and 848/2012. 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, **REPSOL QUIMICA** does not intentionally incorporate into its polymers any of those chemicals in quantities above the applicable limits. Although it is



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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). **REPSOL QUÍMICA** does not intentionally incorporate any of these substances in the composition of its products in concentrations exceeding 0,1%, as defined in article 7.2 and 57. To complete this information refer to the general **REACH/SVHC** declaration.
- **Regulation 1272/2008** on classification, labelling and packaging of substances and mixtures (**CLP**), amended in Regulation 790/2009, 286/2011 and 618/2012. 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 **POLYPROPYLENE ISPLEN® PP064S1F** is not a dangerous preparation. To complete this information refer to the Material Safety Data Sheet (MSDS).

8. RECYCLING

This polymer is recyclable, including energy recovery, but it is neither compostable nor biodegradable.

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

Our above mentioned grade of **POLYPROPYLENE ISPLEN® PP064S1F** 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 2001/83, Regulations 999/2011, 1326/2001 and 1069/2009 and Guidance EMA/410/01 rev.3 (2011), so there is not risk of transmitting BSE/TSE.

10. OTHERS REGULATIONS / NORMS

REPSOL QUIMICA does not 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.

- **Directive 98/83** on the quality of water intended for human consumption amended in Regulations 1882/2003 and 596/2009: the polymer does not contain intentionally in its composition acrylamide, epichlorohydrin or vinyl chloride.
- **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, 757/2010 and 519/2012: 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.
- **Regulation 1169/2011** on the provision of food information to consumers: the polymer does not contain intentionally in its composition any of the substances or products causing allergies or intolerances listed in annex II.
- **GMO (Genetically Modified Organisms):** according with the information from our raw materials suppliers, the polymer does not contain intentionally in its composition any GMO.
- **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.



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- **California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986):** list of the California State relating to chemicals known to the state to cause cancer or reproductive toxicity (update February 2012).
- **GADSL (Global Automotive Declarable Substance List 2012 GADSL Version 1.0):** no use of prohibited or declarable substances above applicable limits.
- **OSPAR List of Chemicals for Priority Action**, revised 2011.
- **CHEMICAL INVENTORIES:** we confirm that monomers and additives used in this polymer are listed or are in compliance with the following chemical inventories:
 - AICS (Australia)
 - DSL (Canada)
 - EINECS / ELINCS (Europe), replaced by REACH
 - ENCS (Japan)
 - IECSC (China)
 - KECL (Korea)
 - NZIoC (New Zealand)
 - PICCS (Philippines)
 - TSCA (USA)
 - CSNN (Taiwan)

11. ABSENCE OF SUBSTANCES

REPSOL QUIMICA does not intentionally incorporate in the composition of 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), Bisphenol F (BPF) and Bisphenol S (BPS)
- 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)
- 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



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- Nitrosamines
- Nitrofural / Nitrofurazone
- Nyckel and nyckel compounds
- Nonylphenol, nonylphenol ethoxylate and cement
- Organostannic / Organotin compounds
- Parabenes (esters of p-hydroxybenzoic acid)
- PBT Substances (Persistent, Bioaccumulating and Toxics) and vPvB (very persistents and very bioaccumulating)
- Pentachlorophenol and its salts and esters
- Phenol
- Perfluorooctanoic acid (PFOA) and Perfluorooctane sulfonates (PFOS)
- Polycyclic aromatic hydrocarbons (PHA): anthracene, fluoranthene, naphthalene, pyrene, benzoanthracene, benzofluoranthene...
- Solvents: dichlorometane, dimethylacetamide, dimethylformamide, 2-ethoxy ethanol, nitrobenzene, trichloroethylene, trichlorobenzene, trichloromethane, hexachlorobenzene...
- Styrene and Polystyrene
- Thiuram
- 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.