	<b>LOW DENSITY POLYETHYLENE REPSOL HEALTHCARE HLD02G</b>	
	<b>REGULATORY COMPLIANCE CERTIFICATE</b>	Rev. 8.1
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## 1. PHARMACOPOEIA

This product complies with EP 3.1.3, EP 3.1.5 and USP 661. It complies with USP 88 class VI Biocompatibility, USP 87 Cytotoxicity (Elution Test) and ISO 10993-4, ISO 10993-5, ISO 10993-10 and ISO 10993-11. The use of this product in any Medical Device must comply with the following criteria:

- Class I Medical Devices (European Union and/or U.S. FDA): the product may only be used for this purpose with prior notification to Repsol of each specific final application.
- Class II Medical Devices (European Union and/or U.S. FDA): the product may only be used for this purpose with Repsol's prior written approval.

This product **may not be used** for implantable devices and for Class III Medical Devices (European Union and/or U.S. FDA).

- Repsol makes no warranties, express or implied, which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.
- Before using a product sold by Repsol, users should make their own independent determination that the product is safe, lawful and technically suitable for the intended use
- Repsol accepts no liability from the use of Repsol materials in conjunction with other materials

Before using a product sold by Repsol, users should make their own independent determination that the product is safe, lawful and technically suitable for the intended use. **DRUG MASTER FILE**

This material has been assigned the FDA Drug Master File number(s): DMF 032480

## 2. EUROPEAN UNION FOOD CONTACT

We confirm that all the monomers and additives used in the manufacture of our above cited grade of polymer are authorised for use in materials in contact with food and it complies with the relevant requirements for intermediate materials (plastic granules) 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, 202/2014, 865/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/988, 2019/1338 and 2020/1245).
- **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 amended by Regulation 2015/1906. **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.
- **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.

### **Information on substances subject to restriction**

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

**Dual use additives:** it contains talc, which is authorised as food additive in EU legislation.

**Additives / other substances:** it does not contain any additive with specific migration limit.

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**Compliance verification:** 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 Regulation 10/2011. 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.

### 3. UNITED STATES FOOD CONTACT (FDA – Food and Drugs Administration)

The composition of this product meets the relevant requirements of Code of Federal Regulation (CFR Title 21 revised as of April 2018):177.1520 “Olefin Polymers” (a)(2)(i), (b) and (c) 2.1. Polyethylene for use in articles that contact food except for articles used for packing or holding food during cooking.

The components of this product have not any limitation of Food type and Conditions of use according to table 1 and 2 of CFR §176.170.

### 4. HEAVY METALS


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

- **Directive 94/62** and amendments, on packaging and packaging waste (PPW), on respect to the limit set (100 ppm) for heavy metals defined as lead, cadmium, mercury and chromium (VI).
- **Directive 2000/53** and amendments, on end-of life vehicles (ELV) 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** and amendments, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) which establishes a maximum concentration value up to:
  - Lead (0,1 %)
  - Mercury (0,1 %)
  - Cadmium (0,01 %)
  - Hexavalent chromium (0,1 %)
  - Polybrominated biphenyls (PBB) (0,1 %)
  - Polybrominated diphenyl ethers (PBDE) (0,1 %)
  - Bis(2-ethylhexyl) phthalate (DEHP) (0,1 %)
  - Butyl benzyl phthalate (BBP) (0,1 %)
  - Dibutyl phthalate (DBP) (0,1 %)
  - Diisobutyl phthalate (DIBP) (0,1 %).
- **Directiva 2012/19** on waste electrical and electronic equipment (WEEE).
- **CONEG** (Coalition of Northeastern Governors - USA): the total content of lead, mercury, chromium (VI) and cadmium is less than 100 ppm.

### 5. COSMETICS

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

- **Regulation 1223/2009** and amendments, relating to cosmetic products: in the manufacture of our products we do not intentionally use as additive any of the chemicals regulated in annex II and annex III, 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.

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## 6. TOYS

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

- **Directive 2009/48** concerning the safety of toys and amendments (Directives 2012/7, 2014/79, 2014/81, 2014/84, 2015/2115, 2015/2116, 2015/2117, 2017/738, 2017/774 and 2017/898 and Regulation 681/2013): in the manufacture of our products we do not intentionally incorporate as additive any of the chemicals regulated in annex II, 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 analyzed to assure their absence.
- **Directive 2005/84** relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles), now included in annex XVII of REACH Regulation. The product does not contain any of the phthalates included in mentioned annex at concentrations above the applicable limits.
- **European Norm EN 71** relating to safety in toys: Part 3 (migration of certain elements) and Part 9 (organic chemical compounds). In the manufacture of this product we do not intentionally incorporate any of the chemicals regulated in these norms 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 analyzed to assure their absence.

## 7. REACH AND CLP REGULATIONS

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

- **Regulation 1907/2006** (REACH) and amendments, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. 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** or its suppliers have 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 QUÍMICA** does not 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.


- **SVHC** (Substances of Very High Concern): 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 this product 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** and amendments, on classification, labelling and packaging of substances and mixtures. CLP implements the Globally Harmonised System (GHS). According with this regulation this polymer 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)

This product does not contain any additive of animal origin, so there is not risk of transmitting BSE/TSE.

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## 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** and amendments, on the quality of water intended for human consumption: the polymer does not contain intentionally in its composition acrylamide, epichlorohydrin or vinyl chloride.
- **Directive 2000/60** and amendments, on Water Policy: the polymer does not contain intentionally in its composition any of the priority substances listed on annex X.
- **Regulation 1021/2019** and amendments, on persistent organic pollutants: 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** and amendments, on Ozone Layer Depleting Substances: the polymer does not contain intentionally in its composition any of the substances included in annex I and 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.
- **Nanoparticles: REPSOL QUIMICA** does not incorporate in this product any additive in nanoparticle form.
- **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** (Safe Drinking Water and Toxic Enforcement Act): list of the California State relating to chemicals known to the state to cause cancer or reproductive toxicity: this product does not intentionally incorporate any of the chemicals regulated in quantities above the applicable limits.
- **GADSL** (Global Automotive Declarable Substance List): this product does not intentionally incorporate any of the chemicals regulated in quantities above the applicable limits.
- **OSPAR** List of Chemicals for Priority Action.
- **Conflict Minerals (US Dodd-Frank Wall Street and Consumer Protection Act)**: the product does not intentionally incorporate in its composition any of the metals Tantalum, Tin, Gold and Tungsten.

## 11. CHEMICAL INVENTORIES

Monomers and additives used in the manufacture of this polymer are listed or are in compliance with the following chemical inventories:


- AICS (Australia)
- DSL (Canada)
- EINECS / ELINCS (REACH)
- ENCS (Japan)
- IECSC (China)
- KECL (Korea)
- NZIoC (New Zealand)
- PICCS (Philippines)
- TSCA (USA)

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## 12. ABSENCE OF SUBSTANCES

**REPSOL QUIMICA** does not intentionally incorporate in the composition of its polymers as additive 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
- Allergens (annex II Regulation 1169/2011)
- Alkylphenol ethoxylates (APEO)
- Aromatic amines
- Arsenic and arsenic compounds
- Asbestos
- Azoic colorants
- Benzene
- Benzophenone, hydroxybenzophenone and 4-methylbenzophenone
- Biocides
- Bisphenol A (BPA), Bisphenol B (BPB), Bisphenol F (BPF) and Bisphenol S (BPS)
- Boron and boron compounds
- 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
- Nitrosamines
- Nitrofural / Nitrofurazone
- Nickel and nickel 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...
- Silicones
- Styrene and Polystyrene
- Thiuram
- Toluene
- Triclosan
- Vinyl chloride monomer (VCM) and its polymers (PVC...)

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### 13. PHTHALATES

This product does not contain intentionally in its composition any phthalate.

### 14. ICH HARMONIZED GUIDELINE Q3D (Elemental Impurities)

**REPSOL QUIMICA** does not intentionally incorporate into this product any elemental impurity of Class 1, 2 or 3, listed in the ICH Harmonized Guideline Q3D of 28 March 2019. However this product has not been tested for these substances.

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. The information provided herein is based on our best knowledge and experience. We cannot accept any responsibility for the interpretation or improper use made of this document. Because it is impossible to know in advance all the conditions under which our products are used, we cannot relieve users of our products the responsibility to conduct their own tests to determine the safety and suitability of each product or combination thereof to their own purposes.