Product Stewardship Information Sheet
CR350CL

Contents

Product Manufacturer

This product is manufactured by Phillips 66 Company in Linden, NJ.

Food Contact:

European Union (EU) Food Contact

This product complies with applicable European Union (EU) food-contact legislation, including (EU) No10/2011, as amended, when used in food packaging applications, subject to the following conditions and limitations:

- All monomers and additives used in this product are included in the positive lists of (EU) No10/2011, as amended.
- One additive used in the product is subject to a specific migration limit (SML). Information on the applicable SML will be supplied upon request.

It is the responsibility of the manufacturer of the finished food-contact article to verify compliance of the finished article with applicable EU legislation, including the SML noted above, as well as the overall migration limit. In addition, it is the responsibility of the manufacturer of the finished article to verify that their final article, made according to good manufacturing practices (GMPs), does not modify the organoleptic properties of the food.

Provided that the above limitations are met in the finished article, the product complies with applicable EU law, including Article 3 of the Framework Regulation 1935/2004/EC, and (EU) No 10/2011, as amended.

2008/282/EC –the product is manufactured from propylene and ethylene and does not contain recycled materials and is suitable for food contact applications as defined herein.

2006/2023/EC Good Manufacturing Practices – The manufacturing process for the product is compliant with the good manufacturing practices set out in this regulation and its amendments.

US Food and Drug Administration (FDA)

The base resin in this product complies with 21 CFR 177.1520(a) (3) (i) and (c) 3.1a and (c) 3.2a. In addition, all other ingredients used in this product meet the requirements of their respective FDA regulations and 21 CFR 177.1520(b), subject to limitations on temperature or food type contacted. Accordingly, this product can be used in contact with all food types listed in 21 CFR 176.170(c), Table 1, under Conditions of use A through H, identified in 21 CFR 176.170(c), Table 2.

Canada Health Protection and Food Branch (HPFB)

A letter of "no objection" for food contact use of this product has not been obtained from HPFB.

Tallow

Tallow derived additives are not used in the manufacturing of this product.

Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)/"Mad Cow"

This product does not contain additives derived from animal sources.

Drug Master File (DMF)

Information on this product is listed in DMF 19969 (Polypropylene Grades)

US Pharmacopeia (USP)

This meets the requirements for USP <661.1>.

USP 39 / NF 34 Supplement 2

Plastic Materials of Construction—PP
Identification, Physicochemical Tests, Extractable metals

Plastic Materials of Construction—Plastic Additives
(Phenolic Antioxidants – Test B, and Nonphenolic Antioxidants, Amides and Stearates – Test A)

<87> Biological Reactivity Tests, In Vitro—Elutriation Test: meets

<88> Biological Reactivity Tests, In Vivo

European Pharmacopeia (EP)

This product has been tested for EP 3.1.3. This product meets EP 7th edition specifications for the test conducted.

UL

This product is not UL listed.

NSF

This product is not NSF listed.

Phthalates

Phthalates are not used in the manufacture of or the formulation of this product. However, we do not test this product for phthalates.

Metals: May Be Present

The following metals are used in some Copylene™ products and may be present at or below the levels indicated below as determined by mass balance calculation:

- Al Aluminum < 0.1 ppm
- Ca Calcium < 50 ppm
- Mg Magnesium < 10 ppm
- Na Sodium < 0.1 ppm
- Zn Zinc < 0.1 ppm

REACH (Regulation (EC) No. 1907/2006)

Substances of Very High Concern (SVHC)

This product does not contain any of the candidate chemical substances proposed to be Substances of Very High Concern (including the most recent list dated 1/15/2018) above the 0.1% threshold as stated in REACH (Article 57, Regulation No. 1907/2006) determined either through (i) non-use of the substance, (ii) mass balance calculation, or (iii) specific testing.

REACH ANNEX XVII STATEMENT

This product does not contain any of the chemical substances listed in the Annex XVII to REACH as of 22 January 2018 which includes all the restrictions adopted in the framework of REACH and the previous legislation, Directive 76/769/EEC. This was determined either through (i) non-use of the substance, (ii) mass balance calculation, or (iii) specific testing.

California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)

California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)
This product presents ""no significant risk"" for cancer to the people of California. This product contains no substances known to the State of California to cause reproductive toxicity at a level of exposure subject to the requirements of Proposition 65 (including the most recent list dated December 29th, 2017).

Chemical Inventories

All ingredients in this product are in compliance with the following chemical inventories:

- United States: Toxics Substances Control Act Inventory (TSCA)
- Canada: Domestic Substances List
- Europe: EINECS/ELINCS replaced by REACH
- Korea: Korean Existing Chemicals List (KECL)
- Australia Inventory of Chemical Substances (AICS)
- Japan: Japanese Inventory of Existing and new Chemical Substances (ENCS)
- The Philippines: Philippines Inventory of Chemicals and Chemical Substances (PICCS)
- China: Inventory of Existing Chemical Substances Manufactured or Imported in China (IECSC)
- New Zealand: New Zealand inventory of Chemicals (NZIoC)

This product has no special requirements under US TSCA (e.g. consent orders, test rules, 12(b) requirements, etc.).

Cosmetic Act, 76/768/EEC

The product does not contain any of the chemical substances listed in Annex II of the EU Council Directive 76/768/EEC determined through non-use of the substance. However, this product has not been tested for all of these chemical substances.

Metals: Not Present

This product does not contain any of the substances listed below as determined either through (i) non-use of the substance, (ii) mass balance calculation, or (iii) specific testing.

- Ag Silver
- As Arsenic
- Au Gold
- B Boron
- Ba Barium
- Cd Cadmium
- Co Cobalt
- Cr Chromium
- Cu Copper
- Fe Iron
- Hg Mercury
- Ir Iridium
- K Potassium
- Li Lithium
- Mn Manganese
- Mo Molybdenum
- Ni Nickel
- Os Osmium
- Pb Lead
- Pd Palladium
- Pt Platinum
- Rh Rhodium
- Ru Ruthenium
- Sb Antimony
- Se Selenium
- Sn Tin
- Tl Thallium
- V Vanadium
- W Tungsten

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NOTICE REGARDING MEDICAL APPLICATION RESTRICTIONS:

In no event should a Phillips 66 Company COPYLENE™ product be used in any US FDA Class III Medical Device or Health Canada Class IV Medical Device. No Phillips 66 Company COPYLENE™ product should be used in any US FDA Class II Medical Devices or Health Canada Class II or Class III Medical Devices without prior written approval by Phillips 66 Company for each specific product or application.

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