Product Stewardship Information Sheet
CR350CL

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

Food Contact:
US Food and Drug Administration (FDA)
The base resin in this product complies with 21 CFR 177.1520(c) 3.1a. In addition, all other ingredients used in this product meet the requirements of their respective FDA regulations and 21 CFR 178.2010, subject to limitations on temperature or food type contacted.

It is the responsibility of the manufacturer to determine that the articles fabricated from the product meet both the technical and regulatory requirements for use in their intended applications.

Canada Health Protection and Food Branch (HPFB)
A letter of "no objection" for food contact use of this product has been obtained from HPFB. If a “no objection” letter is needed, contact your P66 sales representative.

European Union (EU) Food Contact
This product complies with applicable European Union (EU) food-contact legislation, including the EU regulation 10/2011, 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 the EU 10/2011.
- At least 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 European Framework Regulation 1935/2004/EC, and the EU regulation 10/2011.

Drug Master File (DMF)
Components in this product are listed in DMF 19969.

US Pharmacopeia (USP)
- This product meets the requirements for USP 39 / NF 34 Supplement 2 <661.1>.
    - 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)
- This product meets the requirements for a USP Class VI plastic.

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.

Notice Regarding Medical Application Restrictions
In no event shall a Phillips 66 Company COPYLENE™ product be used in any connection with the following applications:

- US FDA Class III Medical Device, Health Canada Class IV Medical Device, or European Union Class III Medical Device.
- The manufacture of implanted medical or surgical devices.
- Life-sustaining medical applications.

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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