Formulation Data Propylene Glycol USP

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A Versatile Ingredient in Consumer Products

General

Propylene Glycol USP is an ingredient used to improve the texture and stability of many pharmaceuticals, cosmetics, and health and beauty aides:

- Foundations
- Gentle beauty washes
- Facial creams and alpha hydroxy lotions
- Mascara
- Dental whiteners
- Shampoos

The U.S. Food and Drug Administration also has cleared use of PG USP for specified uses and in specified quantities for certain food applications.

Propylene Glycol, USP has several functions in the products in which it is used. It serves as a:

- Stabilizer
- Emulsifier
- Texturizer
- Antioxidant
- Anti-caking agent
- Humectant (moisture absorber)

Lyondell Chemical Company manufactures Propylene Glycol, USP using monitored processes and following applicable FDA good manufacturing practices and ISO 9000 standards.

FAQs Is Propylene Glycol safe?

The U.S. Food and Drug Administration has given Propylene Glycol the same classification given to common products such as vinegar and table salt: Generally Recognized As Safe (GRAS).

The Cosmetic Ingredient Review (CIR) Panel also has concluded that Propylene Glycol is safe for use up to 50% in cosmetics. The panel is a scientific committee that uses the expertise of dermatologists, toxicologists, oncologists and other health scientists in assessing the safety of cosmetic ingredients.

What kind of testing has been done on propylene glycol?

As part of standard product safety research, Propylene Glycol has been tested on bare skin at a variety of concentrations under a variety of conditions. While full-strength Propylene Glycol that is applied to the skin and prevented from evaporating was found to cause skin irritation, these conditions are more extreme than practical applications of consumer products using Propylene Glycol.

Studies using actual product formulations have shown that Propylene Glycol is safe in cosmetics in concentrations up to 50%. Typically, it is used in concentrations less than 10%.

Propylene Glycol has also been extensively tested for chronic effects, such as cancer and reproductive problems. Long-term studies by independent panels of medical and scientific experts, as well as industry experts, have demonstrated the safety of Propylene Glycol in all cosmetic and personal care applications.

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This product(s) may not be used in:

(i) any U.S. FDA Class I, Health Canada Class I, and/or European Union Class I medical devices, without prior notification to Seller for each specific product and application; or

(ii) the manufacture of any of the following, without prior written approval by Seller for each specific product and application: U.S. FDA Class II Medical Devices; Health Canada Class II or Class II Medical Devices; European Union Class II Medical Devices; film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned medical devices; packaging in direct contact with a pharmaceutical active ingredient and/or dosage form that is intended for inhalation, injection, intravenous, nasal, ophthalmic (eye), digestive, or topical (skin) administration; tobacco related products and applications, electronic cigarettes and similar devices; Health Canada Class IV Medical Devices; European Class III Medical Devices; (ii) applications involving permanent implantation into the body; (iii) life-sustaining medical applications; and (iv) lead, asbestos or MTBE related applications. All references to U.S. FDA, Health Canada, and European Union regulations include another country's equivalent regulatory classification.

Users should review the applicable Safety Data Sheet before handling the product.

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