

CID 1030

Propylene glycol

FDA Requirements



Substance added directly to human food affirmed as generally recognized as safe (GRAS).

21 CFR 184.1666 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of February 7, 2010: <http://www.ecfr.gov>

► [Hazardous Substances Data Bank \(HSDB\)](#)

Propylene glycol used as an emulsifying agent in animal drugs, feeds, and related products is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

21 CFR 582.4666 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of November 10, 2003: <http://www.ecfr.gov>

► [Hazardous Substances Data Bank \(HSDB\)](#)

Propylene glycol used as a general purpose food additive in animal drugs, feeds, and related products is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

21 CFR 582.1666 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of February 7, 2010: <http://www.ecfr.gov>

► [Hazardous Substances Data Bank \(HSDB\)](#)

Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses. A number of active ingredients have been present in OTC drug products for various uses, as described below. However, based on evidence currently available, there are inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses: propylene glycol is included in pediculicide drug products.

21 CFR 310.545 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of February 7, 2010: <http://www.ecfr.gov>

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Ophthalmic demulcents. The active ingredients of the product consist of any of the following, within the established concentrations for each ingredient: [Propylene glycol](#), 0.2 to 1 percent.

21 CFR 349.12 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of February 11, 2010: <http://www.ecfr.gov>

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The Food and Drug Administration has determined that propylene glycol in or on cat food is not generally recognized as safe and is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act). The Food and Drug Administration also has determined that this use of propylene glycol is not prior sanctioned.

21 CFR 500.50 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of February 7, 2010: <http://www.ecfr.gov>

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The Food and Drug Administration has determined that propylene glycol in or on cat food has not been shown by adequate scientific data to be safe for use. Use of propylene glycol in or on cat food causes the feed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act (the act), in the absence of a regulation providing for its safe use as a food additive under section 409 of the act, unless it is subject to an effective notice of claimed investigational exemption for a food additive under part

570.17 of this chapter, or unless the substance is intended for use as a new animal drug and is subject to an approved application under section 512 of the act or an effective notice of claimed investigational exemption for a new animal drug under part 511 of this chapter.

21 CFR 589.1001 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of February 7, 2010: <http://www.ecfr.gov>

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