



FDA News

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FDA Advises Consumers to Avoid Toothpaste From China Containing Harmful Chemical

FDA Detains One Contaminated Shipment, Issues Import Alert

The U.S. Food and Drug Administration (FDA) today warned consumers to avoid using tubes of toothpaste labeled as made in China, and issued an [import alert](#) to prevent toothpaste containing the poisonous chemical diethylene glycol (DEG) from entering the United States.

DEG is used in antifreeze and as a solvent.

Consumers should examine toothpaste products for labeling that says the product is made in China. Out of an abundance of caution, FDA suggests that consumers throw away toothpaste with that labeling. FDA is concerned that these products may contain "diethylene glycol," also known as "diglycol" or "diglycol stearate."

FDA is not aware of any U.S. reports of poisonings from toothpaste containing DEG. However, the agency is concerned about potential risks from chronic exposure to DEG and exposure to DEG in certain populations, such as children and individuals with kidney or liver disease. DEG in toothpaste has a low but meaningful risk of toxicity and injury to these populations. Toothpaste is not intended to be swallowed, but FDA is concerned about unintentional swallowing or ingestion of toothpaste containing DEG.

FDA has identified the following brands of toothpaste from China that contain DEG and are included in the import alert: Cooldent Fluoride; Cooldent Spearmint; Cooldent ICE; Dr. Cool, Everfresh Toothpaste; Superdent Toothpaste; Clean Rite Toothpaste; Oralmax Extreme; Oral Bright Fresh Spearmint Flavor; Bright Max Peppermint Flavor; ShiR Fresh Mint Fluoride Paste; DentaPro; DentaKleen; and DentaKleen Junior. Manufacturers of these products are: Goldcredit International Enterprises Limited; Goldcredit International Trading Company Limited; and Suzhou City Jinmao Daily Chemicals Company Limited. The products typically are sold at low-cost, "bargain" retail outlets.

Based on reports of contaminated toothpaste from China found in several countries, including Panama,

FDA increased its scrutiny and began sampling toothpaste and other dental products manufactured in China that were imported into the United States.

FDA inspectors identified and detained one shipment of toothpaste at the U.S. border, containing about 3 percent DEG by weight. In addition, FDA inspectors found and tested toothpaste products from China located at a distribution center and a retail store. The highest level found was between 3-4 percent by weight. The product at the retail store was not labeled as containing DEG but was found to contain the substance.

DEG poisoning is an important public safety issue. The agency is aware of reports of patient deaths and injuries in other countries over the past several years from ingesting DEG-contaminated pharmaceutical preparations, such as cough syrups and acetaminophen syrup. FDA recently issued a [guidance document](#) to urge U.S. pharmaceutical manufacturers to be vigilant in assuring that glycerin, a sweetener commonly used worldwide in liquid over-the-counter and prescription drug products, is not contaminated with DEG.

FDA continues to investigate this problem. If FDA identifies other brands of toothpaste products containing DEG, FDA will take appropriate actions, including adding products and their manufacturers to the import alert to prevent them from entering the United States.

Consumers can report adverse reactions or quality problems experienced with the use of these products to FDA's MedWatch Adverse Event Reporting program:

www.fda.gov/medwatch/report.htm

(800) 332-1088

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