

1, 4-Dioxane

FDA has received questions on the subject of 1,4-dioxane, a contaminant that may occur in trace amounts in certain cosmetics. The following information has been compiled from responses to those questions, from the published scientific literature, and other public sources.

What is 1,4-dioxane?

The compound 1,4-dioxane is a contaminant that may be present in extremely small amounts in some cosmetics. It forms as a byproduct during the manufacturing process of certain cosmetic ingredients. These ingredients include certain detergents, foaming agents, emulsifiers and solvents identifiable by the prefix, word, or syllables "PEG," "Polyethylene," "Polyethylene glycol," "Polyoxyethylene," "-eth-," or "-oxynol-." However, 1,4-dioxane itself is not used as a cosmetic ingredient.

Is 1, 4-dioxane in cosmetic products harmful?

The levels at which a chemical compound would be considered harmful in a cosmetic depend on the conditions of use (FD&C Act, section 601(a)). The 1, 4-dioxane levels we have seen in our monitoring of cosmetics do not present a hazard to consumers.

Concerns initially were raised in the 1970s, when studies at the National Cancer Institute found an association between 1, 4-dioxane and cancer in animals when 1, 4-dioxane was administered in high levels in the animal feed. However, the levels in cosmetic products are far lower than those found to be harmful in feeding studies and, for the most part, the types of products in which it is found are only in contact with the skin for a short time.

As a precaution, FDA followed up with skin absorption studies, which showed that 1,4-dioxane can penetrate animal and human skin when applied in certain preparations, such as lotions. However, further research by FDA determined that 1,4-dioxane evaporates readily, further diminishing the already small amount available for skin absorption, even in products that remain on the skin for hours. (Robert L. Bronaugh, "Percutaneous Absorption of Cosmetic Ingredients," in *Principles of Cosmetics for the Dermatologist*, Philip Frost, M.D., and Steven Horwitz, M.D., Eds. St. Louis: The C.V. Mosby Company, 1982)

What is FDA doing to assure that cosmetics do not contain unsafe levels of 1,4-dioxane?

FDA has been monitoring this issue since the late 1970s. We periodically monitor the levels of 1,4-dioxane in cosmetic products, and have observed that the changes made in the manufacturing process have resulted in a significant decline in the levels of this contaminant. (Roderick E. Black, Fred J. Hurley and Donald C. Havery, "Occurrence of 1,4-Dioxane in Cosmetic Raw Materials and Finished Cosmetic Products," *Journal of AOAC International*, 84 (3), 2001, pp. 666-667)

FDA has not established or recommended a specific limit on the level of 1,4-dioxane in cosmetics. We have provided guidance to manufacturers alerting them to the health concerns and how to minimize 1,4-dioxane by means of a process called "vacuum stripping" at the end of the polymerization process. This information has been posted on our website in the *Cosmetic Handbook for Industry: Cosmetic Product-Related Regulatory Requirements and Health Hazard Issues*. We also provide FDA inspectors with information on this procedure in our *Guide to Inspections of Cosmetic Product Manufacturers* so that when they conduct inspections they will know what to look for and what questions to ask.

If FDA were to determine that a health hazard exists, it would advise the industry and the public, and would consider its legal options for protecting the health and welfare of consumers.

For more on the subject of cosmetic safety and the law, see *FDA Authority Over Cosmetics, Key Legal Concepts: "Interstate Commerce," "Adulterated," and "Misbranded"*, and the cosmetics provisions of the Federal Food, Drug, and Cosmetic Act.
