



Frequently Asked Questions on What You Need to Know About Diethylene glycol, Ethylene glycol.

1. What are diethylene glycol and ethylene glycol?

Diethylene glycol is an organic compound that is colourless, practically odourless liquid which can absorb water from the environment and has a sweetish taste. It is a solvent for dyes, oils and other organic compounds. It is used to maintain moisture in tobacco, cork, printing ink and glue. It is also a component in brake fluid, lubricants, wallpaper strippers, artificial fog and haze solutions, and heating/cooking fuel.

Ethylene glycol is a synthetic liquid substance that absorbs water. It is odourless but has a sweet taste. It is used to make antifreeze and de-icing solutions for cars, airplanes and boats. It is also used in hydraulic brake fluids and inks used in stamp pads, ballpoint pens and print shops.

2. How might I be exposed to diethylene glycol and ethylene glycol?

- The general public can be exposed to diethylene and ethylene glycol through skin contact when using antifreeze solution.
- Accidental or intentional ingestion can occur because antifreeze is a sweet tasting, brightly coloured liquid.
- People who work in industries that use diethylene glycol or ethylene glycol may be exposed by touching products such as solvents, antifreeze and feedstocks that contain this substance.
- Workers can also be exposed to low levels from diethylene glycol or ethylene glycol-containing products such as airplane de-icing solutions that have been sprayed into the air.

3. How likely are diethylene and ethylene glycol to cause cancer?

Diethylene glycol and ethylene glycol have not been classified as possible carcinogens. Studies with people who used diethylene glycol and ethylene glycol did not show carcinogenic effects. Animal studies also have not shown these chemicals to be carcinogens.

4. How can diethylene glycol and ethylene glycol affect my health?

Your health is not likely to be seriously affected by the very small amounts of diethylene glycol and ethylene glycol that could be tasted or otherwise accidentally eaten (for example, by putting your fingers in your mouth after getting them wet with antifreeze). Accidental or intentional ingestion of larger amounts of diethylene glycol and ethylene glycol can cause serious illness or death. When diethylene and ethylene glycol break down in the body it forms chemicals that crystallize and the crystals can collect in your kidneys which can affect kidney function.

Diethylene and ethylene glycol also form acidic chemicals in the body, which can change the body's acid/base balance and affect your nervous system, lungs and heart. Early diagnosis and treatment have been very successful in people drinking large amounts of diethylene and ethylene glycol.

5. How can diethylene glycol and ethylene glycol affect children?

Clinical findings in children who were poisoned by accidentally or intentionally drinking diethylene and ethylene glycol indicate that it is likely that children would show the same health effects as adults. It is not known whether children differ in their susceptibility to the effects of diethylene and ethylene glycol. It is not known whether diethylene and ethylene glycol cause birth defects in people. Skeletal defects and low birth weights have occurred in new born animals whose mothers ingested large amounts of diethylene and ethylene glycol during pregnancy.

6. What should I do in case I consume diethylene glycol or ethylene glycol?

Visit the nearest hospital or healthcare facility if you think you have mistakenly ingested diethylene glycol or ethylene glycol. Kindly take along container containing ingested product.

7. How come medicines, cosmetics and food products, become contaminated with diethylene glycol and ethylene glycol?

In the production of medicinal, food and cosmetic products, diethylene glycol and ethylene glycol could be mistaken for propylene glycol due to their similar physical characteristics which makes differentiating without chemical analysis difficult. Hence most cases of contamination are due to a deficiency in analytical processes involved to ascertain the true quality of propylene glycol used as a raw material.

Propylene glycol is an additive that is “generally recognized as safe” for use in food. It is used to absorb extra water and maintain moisture in certain medicines, cosmetics or food products. It is a solvent for food colours and flavours.

8. Has there been instances of contamination of medicinal products with diethylene glycol and ethylene glycol in recent years?

Yes.

In 1937, over 100 people died in the United States when diethylene glycol was used as a solvent for the manufacture of a common antibiotic known as Sulphanilamide. In recent time, September 2022, the World Health Organisation indicated the detection of ethylene glycol in four medical products in Indonesia and The Gambia, which led to acute renal failure and death. A similar incidence happened in Uzbekistan in December 2022.



9. What measures have been put in place by the Ghana Food and Drugs Authority (FDA) to prevent such occurrences?

The FDA carries out stringent evaluation and testing of all raw materials and finished products to ensure they are safe and of good quality. Precautionary measures have been put in place to prevent the contamination of pharmaceutical, food and cosmetic products with diethylene glycol and ethylene glycol. These measures are for both raw materials and finished pharmaceutical products (FPP) and available on the FDA website at [Notice - Importers and Manufacturers PG.pdf \(fdaghana.gov.gh\)](#).

- **For raw materials**, all imported glycerine and propylene glycol raw materials should be accompanied by a certificate of analysis that have test and limit for these solvents as per the recognized official compendia. Additionally, they will be tested at the port of entry before being released for use.
- **For Finished Pharmaceutical Products (FPP)** imported into the country that have glycerine and propylene glycol as excipients, the manufacturers are required to submit documentary proof that the FPP manufacturer controlled for diethylene glycol and ethylene glycol in the excipients used for the finished product. In the absence of this, the FDA will test these products to ensure they meet the requirements before they will be released for the market.

Additionally, the FDA has issued Dear Healthcare Professional Letters and Consumer Safety Alerts to educate the public about the products contaminated with diethylene glycol and polyethylene glycol from the Gambia and what is expected from them.

References

1. World Health Organization, Substandard (contaminated) paediatric medicines identified in WHO region of Africa, Accessed on 15/03/2023 at 14:25GMT at [https://www.who.int/news/item/05-10-2022-medical-product-alert-n-6-2022-substandard-\(contaminated\)-paediatric-medicines](https://www.who.int/news/item/05-10-2022-medical-product-alert-n-6-2022-substandard-(contaminated)-paediatric-medicines)
2. United States Food and Drugs Administration, Sulfanilamide Disaster, Accessed on 15/03/2023 at 14:30GMT at <https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf>
3. Food and Drugs Authority Ghana, Notice to Importers and Manufacturers of Pharmaceutical, Food and Cosmetic products, Accessed on 16/05/2023 at 18:30GMT at <https://fdaghana.gov.gh/img/press/Notice%20-%20Importers%20and%20Manufacturers%20PG.pdf>
4. Bijus, What is Ethylene Glycol?, accessed on 15/03/2023 at 12:30GMT at <https://byjus.com/chemistry/ethylene-glycol/#:~:text=Ethylene%20Glycol%20is%20dihydroxy%20alcohol,organic%20compound%20is%20highly%20toxic.>
5. United States Pharmacopeia, How to Help Avoid Tragedies Linked to Contaminated Cough Syrup, Accessed on 15/03/2023 at 13:10GMT at <https://qualitymatters.usp.org/avoid-tragedies-linked-contaminated-cough-syrup>