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## Product Safety Assessment

### Glycerine

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#### Names

- CAS No. 56-81-5
- Glycerine
- OPTIM™ Glycerine
- Glycerin
- Glycerol
- 1,2,3- Propanetriol

#### Product Overview

- Glycerine is an odorless, colorless, oily, viscous liquid with a sweet taste.<sup>1</sup> Dow's synthetic product has a certified purity of greater than or equal to 99.7% and is marketed and sold under the trade name OPTIM™ Glycerine 99.7% USP/EP. For further details, see [Product Description](#).
- Due to its high and consistent quality synthetic glycerine is mainly used in pharmaceutical applications, but is also suitable for food and beverage products, nutritional supplements, personal-care products, oral-care products, and in selected industrial or laboratory uses.<sup>2</sup> For further details, see [Product Uses](#).
- Dow's synthetic glycerine is not sold for direct consumer use; however, glycerine is used in a variety of consumer products. Glycerine is classified by the U.S. Food and Drug Administration (FDA) as "generally recognized as safe" (GRAS).<sup>3</sup> For further details, see [Exposure Potential](#).
- Glycerol is an approved food additive in Europe (Registration No. E 422).<sup>3</sup>
- Eye contact may result in slight temporary irritation. Corneal injury is unlikely. Prolonged skin contact is unlikely to cause irritation or absorption of harmful amounts, unless the skin layer is damaged. Exposure to vapor by inhalation is unlikely because of the low volatility at room temperature. Vapor from heated material or mist may cause respiratory irritation. Glycerine has very low toxicity if swallowed. Swallowing large amounts may cause injury. Effects have been reported on the central nervous system and altered blood sugar levels have been reported.<sup>4</sup> For further details, see [Health Information](#).
- Glycerine is stable at normal storage and use temperatures. However, contact with air, especially at temperatures above 54°C (130°F) can result in partial decomposition (oxidation) over time, and increase of water content<sup>4</sup>. Contact with moisture and strong oxidizers should be avoided. For further details, see [Physical Hazard Information](#).

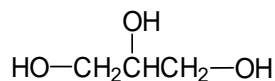
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## Manufacture of Product

- **Capacity** – World consumption of natural and synthetic glycerine combined was approximately 1.86 Mt million metric tons (4.1 billion pounds) in 2011.<sup>5</sup> Dow produces synthetic glycerine at a dedicated production facility in Stade, Germany.
- **Process** – Although glycerine can be derived from naturally occurring fats and oils, synthetic glycerine from Dow is produced from petrochemical products in a multi-step process.<sup>1</sup> Current Good Manufacturing Practices (cGMP) based on the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients<sup>6</sup> are applied to the manufacturing process. The structure of glycerine is shown below:



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## Product Description<sup>1,3</sup>

Glycerine is an odorless, colorless, oily, viscous liquid with a sweet taste. Dow's synthetic product is typically equal to or greater than 99.7% pure. It is marketed and sold under the trade name OPTIM™ Glycerine. OPTIM Glycerine is in compliance with the relevant standards set by the current *United States Pharmacopeia (USP)* and *European Pharmacopoeia (Ph. Eur. or EP)*. Additionally, it is Kosher and Halal certified.

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## Product Uses<sup>2,5</sup>

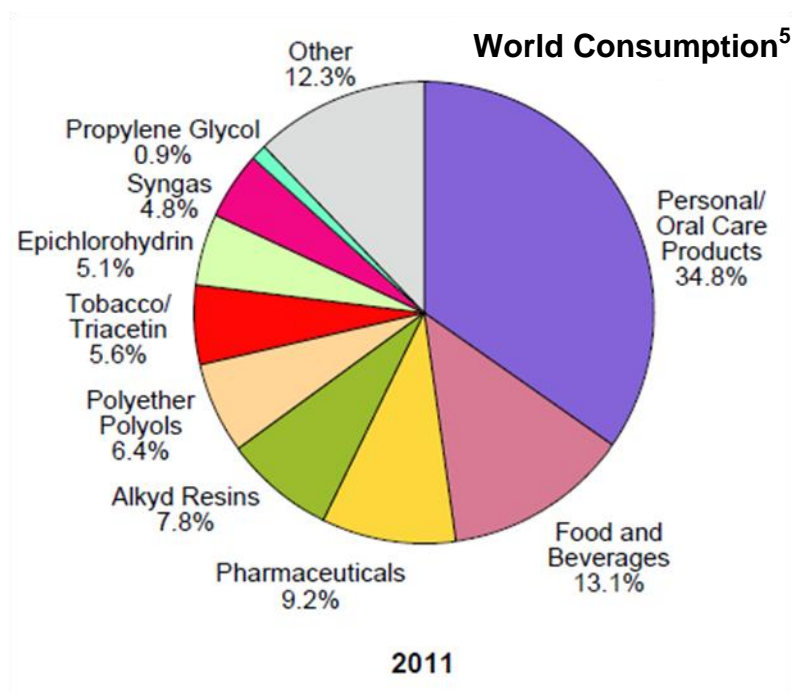
Synthetic glycerine is primarily used in:

- **Pharmaceutical products** – as a sweetener, humectant in syrups and lozenges, and as an ingredient in eyewashes, ear drops, jellies and creams, solutions, suppositories, and gel capsules
- OPTIM Glycerine may also be used in other applications which require high purity, consistency and stability such as
- **Food and beverage products** – as an additive to reduce water activity, emulsifiers for monoglycerides, heat-transfer media for frozen foods, humectants, smoothing agents, solvents for flavorings and colorings, and sweeteners.
- **Nutritional supplements**
- **Personal-care products** – as a humectant, lubricant, emollient, and suspension aid in lotions, creams, soaps, pastes, and hair-care products
- **Oral-care products**
- **Polyurethane products**
- **Other** – for selected other agricultural, industrial, and laboratory uses

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### Exposure Potential<sup>4</sup>

Glycerine is used in the production of industrial and consumer products. Based on the uses for glycerine, the public could be exposed through:

- **Workplace exposure** – Exposure can occur either in a glycerine manufacturing facility or in the various industrial or manufacturing facilities that use glycerine. Those working with glycerine in manufacturing operations could be exposed during maintenance, sampling, testing, or other procedures. Each manufacturing facility should have a thorough training program for employees and appropriate work processes and safety equipment in place to limit unnecessary exposure. See [Health Information](#).
- **Consumer exposure to products containing glycerine** – Dow's glycerine is not sold for direct consumer use, but it is used in a variety of consumer products. See [Health Information](#).
- **Environmental releases** – In the event of a spill, the focus is on containing the spill to prevent contamination of soil and surface or ground water. For small spills, glycerine should be absorbed with materials such as sand, sawdust, or soil. Sweep up and collect recovered material in suitable and properly labeled containers. See [Environmental](#), [Health](#), and [Physical Hazard Information](#).
- **Large release** – Industrial spills or releases are infrequent and generally contained. If a large spill does occur, dike the area to contain the spill. The material should be captured, collected, and reprocessed or disposed of according to applicable governmental requirements.
- **In case of fire** – Isolate the area and deny unnecessary entry. Firefighters should wear positive-pressure, self-contained breathing apparatus (SCBA) and protective clothing or fight the fire from a protected location or distance. Use water fog or fine spray, carbon-dioxide or dry-chemical extinguishers, or foam to fight the fire. Alcohol-resistant foams are preferred. Use of a direct water stream may spread fire. Follow emergency procedures carefully. See [Environmental](#), [Health](#), and [Physical Hazard Information](#).

For more information, request the relevant Safety Data Sheet from the [Dow Customer Information Group](#).

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## Health Information<sup>4,7</sup>

Glycerine is classified by the U.S. Food and Drug Administration (FDA) as “generally recognized as safe” (GRAS) and complies with specifications for the *Food Chemicals Codex (FCC)*, *United States Pharmacopeia (USP)*, and *European Pharmacopoeia (Ph. Eur. or EP) E244*. It is manufactured according to current Good Manufacturing Practices (cGMP) and is shipped according to applicable Good Trade and Distribution Practices (GTDP).

**Eye and skin contact** – Eye contact may result in slight temporary irritation. Corneal injury is unlikely. Prolonged skin contact is unlikely to cause irritation or adsorption of harmful amounts, unless the skin layer is damaged.

**Inhalation** – Inhalation exposure is unlikely because of the low volatility at room temperature. Vapor from heated material or mist may cause respiratory irritation.

**Ingestion** – Glycerine has very low toxicity if swallowed. Small amounts swallowed incidental to normal handling operations are unlikely to cause injury. Swallowing large amounts may cause injury. Effects have been reported on the central nervous system and altered blood sugar levels have been observed.

**Other** – Excessive, repeated exposure to glycerine may cause increased fat levels in the blood. Glycerine has not caused cancer in laboratory testing, nor did it cause birth defects or other fetal effects. Some reproductive effects have been observed in female animals due to the altered nutritional states resulting from extremely high doses in the diet. Genetic toxicity studies have been negative.

For more information, request the relevant Safety Data Sheet from the [Dow Customer Information Group](#).

## Environmental Information<sup>4,7</sup>

The potential for glycerine to bioconcentrate (accumulate in the food chain) is low, and the potential for mobility in soil is very high. Glycerine is classified as readily biodegradable and is considered practically non-toxic to aquatic organisms on an acute basis.

For more information, request the relevant Safety Data Sheet from the [Dow Customer Information Group](#).

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## Physical Hazard Information<sup>4,7</sup>

Glycerine is stable at normal storage and use temperatures. However, temperatures above 54°C (130°F) can result in decomposition. Decomposition products can include, but are not limited to, acrolein. Avoid contact with moisture and strong oxidizers.

For more information, request the relevant Safety Data Sheet from the [Dow Customer Information Group](#).

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## Regulatory Information

Regulations may exist that govern the manufacture, sale, transportation, use, and/or disposal of glycerine. These regulations may vary by city, state, country, or geographic region. Information may be found by consulting the relevant Safety Data Sheet or by [Contact Us](#).

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## Additional Information

- Glycerol IUCLID file on ECHA dissemination webpage:  
[http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d855cc7-316c-2a21-e044-00144f67d249/DISS-9d855cc7-316c-2a21-e044-00144f67d249\\_DISS-9d855cc7-316c-2a21-e044-00144f67d249.html](http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d855cc7-316c-2a21-e044-00144f67d249/DISS-9d855cc7-316c-2a21-e044-00144f67d249_DISS-9d855cc7-316c-2a21-e044-00144f67d249.html)
- Safety Data Sheet (request from [Dow Customer Information Group](#) at <http://www.dow.com/assistance/dowcig.htm>)
- Contact Us (<http://www.dow.com/optim/contact/>)
- *Synthetic Glycerine Products: Safety and Handling*, The Dow Chemical Company, Form No. 115-00650-1199X SMG
- *Synthetic Glycerine Products: General Storage Considerations*, The Dow Chemical Company, Form No. 115-00651-1199X SMG
- *Synthetic Glycerine Products: Product Stewardship*, The Dow Chemical Company, Form No. 115-00652-1199X SMG
- *Why Glycerin USP?*, The Soap and Detergent Association, 2000
- *The Joint IPEC / PQG Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients*, The International Pharmaceutical Excipients Council (IPEC) and Pharmaceutical Quality Group, 2006 [IPEC Guidelines](#)

For more business information about OPTIM™ Glycerine visit Dow's [Glycerine](#) site:

<http://www.dow.com/optim/>

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## References

- <sup>1</sup> *Why Glycerin USP?*, The Soap and Detergent Association, 2000
- <sup>2</sup> Glycerine applications website, The Dow Chemical Company ("Dow"):  
<http://www.dow.com/optim/optim-advantage/applications.htm>.
- <sup>3</sup> Glycerine products website, Dow: <http://www.dow.com/optim/>
- <sup>4</sup> *OPTIM Glycerine 99.7% USP/EP, Material Safety Data Sheet*, The Dow Chemical Company,
- <sup>5</sup> Dow Chemical internal data, Glycerine market study 2011
- <sup>6</sup> *The Joint IPEC / PQG Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients*, The International Pharmaceutical Excipients Council (IPEC) and Pharmaceutical Quality Group, 2006. [IPEC Guidelines](#)
- <sup>7</sup> *Synthetic Glycerine Products: Safety and Handling*, The Dow Chemical Company, Form No. 115-00650-1199X SMG

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