

Global Product Strategy (GPS) Safety Summary

Propylene Glycol

This GPS Safety Summary is a high-level summary intended to provide the general public with an overview of product safety information on this chemical substance. It is not intended to provide emergency response, medical or treatment information, nor to provide an overview of all safety and health information. This summary is not intended to replace the Safety Data Sheet. For detailed guidance on the use or regulatory status of this substance, please consult the Safety Data Sheet and the Product Stewardship Bulletin (PSB).

Chemical Identity

Name: Propylene Glycol

Brand names: Propylene Glycol, PG, Monopropylene Glycol, MPG

Chemical name (IUPAC): 1,2-propane-diol

CAS number: 57-55-6

EC number: 200-338-0

Molecular formula: C₃H₈O₂

Uses and Applications

Propylene Glycol has a wide variety of uses, both in industrial applications and consumer products, including pharmaceuticals and food applications. Propylene Glycol is available in two grades: an Industrial grade (PGI) and a Food and Pharmaceutical grade (PG-USP/EP), which is compliant with the requirements of the United States Pharmacopeia and European Pharmacopeia and is manufactured under current Good Manufacturing Practices (cGMP).

Propylene Glycol Industrial grade is used in applications such as:

- Manufacture of thermoset polyesters for building boats, home construction components
- Antifreeze preparations (automotive, airplane de-icing and anti-icing, etc.)
- Functional fluids including heat transfer fluids, hydraulic fluids, and lubricants
- Cleaners and detergents

Propylene Glycol Food and Pharmaceutical grade is used in applications such as:

- Additive for human and animal foods, as a humectant, preservative and stabilizer
- Solvent for flavorings
- Excipient in pharmaceutical products
- Cosmetics and personal care products

Due to the specific metabolism of felines (cats and cat-like animals), Propylene Glycol should not be used in feline feed applications.

Physical / Chemical Properties

Propylene glycol is a colorless, odorless, very hygroscopic and low molecular weight liquid. The substance is considered non-flammable with a flash point of 104°C (219°F). The boiling and freezing points of Propylene Glycol are 184°C (363°F) and -20°C (-4°F) respectively. Propylene Glycol is not classified as hazardous under the Globally Harmonized System on classification and labeling (GHS) for its physical or chemical properties.

Health Effects

Propylene Glycol has very low acute toxicity by oral, dermal and inhalation routes of exposure. The U.S. Food and Drug Administration has given Propylene Glycol the classification Generally Recognized as Safe (GRAS).

Ingestion by cats, however, results in species hematological changes, thus Propylene Glycol is not GRAS for cats.

Propylene Glycol is not classified as hazardous under GHS for its health effects.

The table below gives an overview of the health effects assessment results for Propylene Glycol.

Effect Assessment	Result
Acute Toxicity Oral / inhalation / dermal	Acute toxicity is low after oral, dermal, or inhalation exposure.
Irritation / corrosion Skin / eye/ respiratory tract	Not irritating to skin, eyes, or respiratory tract
Sensitisation	Not sensitizing
Toxicity after repeated exposure Oral / inhalation / dermal	Repeated oral exposure to high doses may cause central nervous system effects. Repeated ingestion by cats may cause changes to red blood cells.
Genotoxicity / Mutagenicity	Not mutagenic
Carcinogenicity	Not carcinogenic
Toxicity for reproduction	Not toxic for reproduction

Environmental Effects

Propylene Glycol is not classified as environmentally hazardous under GHS.

The table below gives an overview of the environmental assessment results for Propylene Glycol.

Effect Assessment	Result
Aquatic Toxicity	Low toxicity to water organisms

Fate and behaviour	Result
Biodegradation	Readily biodegradable in both freshwater and seawater
Bioaccumulation potential	Not bioaccumulative
PBT / vPvB conclusion	Not considered to be either PBT nor vPvB.

PBT = Persistent, Bio-accumulative and Toxic in the environment.
vPvB = very Persistent and very Bio-accumulative in the environment.

Exposure

Human health

Consumer exposure can occur as a result of the use of products formulated with Propylene Glycol, such as coatings, cleaning agents, cosmetics and other personal care products. Consumer exposure will also occur due to use of pharmaceuticals or ingestion of foods where Propylene Glycol is an approved ingredient/additive. None of these applications are expected to pose risks to human health due to Propylene Glycol under normal use.

Exposure to Propylene Glycol of personnel in manufacturing facilities is considered very low because the process, storage and handling operations are enclosed. However, worker exposure can potentially occur during operations such as product transfer, product sampling, or maintenance / repair activities on product containing systems. The risk of accidental exposure should be controlled by selecting and applying the appropriate Risk Management Measures.

Environment

Due to its many uses in formulations, Propylene Glycol has many indoor and outdoor environmental release possibilities. None of these applications are expected to pose risks to the environment due to Propylene Glycol under normal use.

Risk Management Measures

For detailed guidance on the use of Propylene Glycol, the Safety Data Sheet should be consulted.

When using a Propylene Glycol containing consumer product at home, all provided instructions and precautions from the supplier should be read, understood and followed. It should never be used near open flames or other ignition sources.

Human health

Although Propylene Glycol is not classified as hazardous for its health effects, good Industrial Hygiene practices should always be applied when using chemicals in industrial and professional facilities. When using chemicals make sure that there is adequate ventilation. Always use appropriate chemical-resistant gloves to protect your hands and skin, always wear eye protection, such as chemical goggles, and always wear flame-retardant clothing. Do not eat, drink, or smoke where chemicals are handled, processed, or stored. Wash hands and skin following contact. If the substance gets into your eyes, rinse eyes thoroughly for at least 15 minutes with tap water and seek medical attention.

In the case of transfer or maintenance operations, always clear transfer lines prior to decoupling, and flush/drain to a closed system for recycle prior to opening equipment.

In cases where engineering controls cannot maintain airborne substance concentrations below exposure limits, or in cases with a risk of accidental exposure, additional risk management measures may be necessary for safe use, such as the use of a respirator.

Environmental

In case of accidental release or spill, do not allow the product to enter sewers, surface, or ground water.

Regulatory Information / Classification and Labeling

This substance has been registered under REACH by relevant companies of LyondellBasell in the European Union.

For a detailed overview of the regulatory status of this substance, please refer to the Product Stewardship Bulletin which is available from the LyondellBasell corporate website.

Under GHS (Globally Harmonized System on Classification and Labeling) substances are classified according to their physical, health and environmental hazards. The hazards are communicated via specific labels on the product packaging and the Safety Data Sheet. GHS attempts to standardize hazard communication so that the intended audience (workers, consumers, transport workers, and emergency responders) can better understand the hazards of the chemicals in use.

For a detailed overview of the classification and labeling of this substance, please refer to the regional Safety Data Sheet, which can be found on the LyondellBasell corporate website.

Conclusion Statements

- Propylene Glycol has a wide variety of uses, both in industrial applications and consumer products, including pharmaceuticals and food applications. It is available in two grades: an Industrial grade and a Food and Pharmaceutical grade, which is compliant with the requirements of the United States and European Pharmacopoeia and is manufactured under current Good Manufacturing Practices (cGMP).
- Propylene Glycol is not classified as hazardous; an extensive database on mammalian toxicity, ecotoxicity, and environmental fate indicates that Propylene Glycol is of negligible concern for any of these effects.
- Risks to human health and the environment from Propylene Glycol are considered low or negligible, when it is properly handled.

Contact Information within Company

For further information on this product in general, please consult the LyondellBasell corporate website (www.lyb.com).

Date of issue

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Disclaimer

Before using a product sold by a company of the LyondellBasell family of companies, users should make their own independent determination that the product is suitable for the intended use and can be used safely and legally.

SELLER MAKES NO WARRANTY; EXPRESS OR IMPLIED (INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY WARRANTY) OTHER THAN AS SEPARATELY AGREED TO BY THE PARTIES IN A CONTRACT.

This product(s) may not be used in:

(i) any U.S. FDA Class I, Health Canada Class I, and/or European Union Class I medical devices, without prior notification to Seller for each specific product and application; or
(ii) the manufacture of any of the following, without prior written approval by Seller for each specific product and application: U.S. FDA Class II Medical Devices; Health Canada Class II or Class III Medical Devices; European Union Class II Medical Devices; film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned medical devices; packaging in direct contact with a pharmaceutical active ingredient and/or dosage form that is intended for inhalation, injection, intravenous, nasal, ophthalmic (eye), digestive, or topical (skin) administration; tobacco related products and applications, electronic cigarettes and similar devices, and pressure pipe or fittings that are considered a part or component of a nuclear reactor. Additionally, the product(s) may not be used in: (i) U.S. FDA Class III Medical Devices; Health Canada Class IV Medical Devices; European Class III Medical Devices; (ii) applications involving permanent implantation into the body; (iii) life-sustaining medical applications; and (iv) lead, asbestos or MTBE related applications. All references to U.S. FDA, Health Canada, and European Union regulations include another country's equivalent regulatory classification.

Users should review the applicable Safety Data Sheet before handling the product.

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