Safety Data Sheet (MSDS) for Propylene Glycol

Manufacturer: Shandong Ruisheng Pharmaceutical Excipients Co., Ltd.

Packaging Specification: 25KG/drum, 210KG/drum

Manufacturer's Address: Middle Section of Xihuan Road, Dong'e County, Liaocheng City, Shandong Province

Contact Number: 0635-5018008

Section 1: Chemical Product and Company Identification

Chemical Name

Propylene Glycol

This product is 1,2-Propylene Glycol, containing not less than 98.5% of $C_3H_8O_2$.

Chemical English Name

Propylene Glycol

Section 2: Composition/Information on Ingredients

Property: Mixture

This product is a colorless, clear and viscous liquid.

Section 3: Hazards Identification

Hazard Class

Not defined by national regulations

Routes of Exposure

Ingestion

Health Hazards

Harmful to the human body if ingested

Environmental Hazards

Slight

Section 4: First-Aid Measures

General Instructions

No special measures required.

Inhalation

Supply fresh air, drink plenty of clean water, induce vomiting and seek medical attention immediately.

Skin Contact

Rinse the affected area thoroughly with water and soap at once.

Eye Contact

Rinse eyes with running water for several minutes with eyes open. Consult a doctor if symptoms persist.

Ingestion

Rinse the mouth and drink plenty of clean water. **Do not induce vomiting**; seek medical assistance immediately.

Information for Doctors

No detailed data available on the most important acute and chronic symptoms and their effects.

- No detailed data available on symptoms requiring immediate medical treatment and special handling.

Section 5: Fire-Fighting Measures

Extinguishing Methods and Media

Property: This product is not a flammable substance.

Extinguishing Measures

Use carbon dioxide (CO_2), dry chemical powder or water spray. Use alcohol-resistant foam to extinguish large fires. Sand can also be used.

Special Hazards

In case of fire, the release of other toxic gases cannot be excluded (e.g., carbon monoxide (CO)).

Special Fire-Fighting Procedures

Avoid inhaling dust/smoke/gases/fumes/vapours/spray.

Special Protective Equipment for Firefighters

Wear appropriate respiratory protection in case of insufficient ventilation.

Section 6: Accidental Release Measures

Protective Measures

Wear protective clothing and use respiratory protection to avoid exposure to smoke/dust/aerosols.

Environmental Precautions

Do not allow the product to enter sewage systems or any water sources.

Containment and Clean-up Methods

Absorb the liquid with liquid-absorbent materials. Dispose of the collected materials in accordance with relevant regulations.

Section 7: Handling and Storage

Handling

Store away from heat and direct sunlight.

Fire and explosion prevention: Keep away from ignition sources and no smoking.

Storage

Container requirements: Store only in the original container.

General storage requirements: The storage area must be away from oxidants.

Additional storage conditions:

The indicators such as oxidizing substances, moisture and diethylene glycol of this product are susceptible to high temperature, high humidity and strong light exposure. Therefore, this product shall be sealed and stored in a dry place away from light.

Section 8: Exposure Controls/Personal Protection

Engineering Controls

No further data available.

Control Parameters

No monitoring limits required for ingredients in the workplace.

Personal Protective Equipment (PPE)

- General hygiene and protective measures: Observe general precautionary measures when handling chemicals.

Respiratory protection: Not required.

- Hand protection: Gloves must be impermeable and resistant to the product; select suitable glove materials.

Eye protection: Safety goggles.

Section 9: Physical and Chemical Properties

Main Component: Compound

Physical State

Colorless, clear and viscous liquid

Relative Density

1.035 ~ 1.037 at 25℃

Section 10: Stability and Reactivity

Reactivity

The indicators such as oxidizing substances, moisture and diethylene glycol of this product are susceptible to high temperature, high humidity and strong light exposure. Therefore, this product shall be sealed and stored in a dry place away from light.

Stability

Stable at room temperature.

Section 11: Toxicological and Pharmacological

Information

Propylene Glycol is widely used in pharmaceutical preparations and is relatively non-toxic. It is less toxic than other diol materials, probably due to its metabolism and excretion in the body. Propylene Glycol is rapidly absorbed in the gastrointestinal tract and can also be absorbed locally through damaged skin; it is metabolized to lactic acid and pyruvic acid in the liver and excreted in urine in its original form.

In topical preparations, Propylene Glycol has slight irritancy (though higher than glycerol); it may cause local irritation when used for mucosal administration or under occlusive conditions. Injection at high concentrations may cause pain or irritation.

Excessive ingestion of Propylene Glycol can cause adverse reactions of the central nervous system, especially in neonates and children, with an excitatory effect about 1/3 that of ethanol. Other adverse reactions have been reported occasionally, including ototoxicity, cardiovascular effects, seizures, hyperosmolality and lactic acidosis, which are particularly likely to occur in patients with renal insufficiency. Excessive intake or administration to neonates, children under 4 years old, pregnant women, and patients with renal or hepatic insufficiency is highly likely to cause adverse reactions; adverse reactions may also occur in patients treated with disulfiram or metronidazole.

Based on metabolic and toxicological test data, the World Health Organization (WHO) has set the acceptable daily intake (ADI) of Propylene Glycol at 25mg per kilogram of body weight. Formulations containing 35% Propylene Glycol may cause hemolysis.

(1) Non-clinical Pharmacokinetic Test Data and Literature Data

Excessive ingestion of Propylene Glycol can cause adverse reactions of the central nervous system, especially in neonates and children, with an excitatory effect about 1/3 that of ethanol. Other adverse reactions have been reported occasionally, including ototoxicity, cardiovascular effects, seizures, hyperosmolality and lactic acidosis, which are particularly likely to occur in patients with renal insufficiency. Excessive intake or administration to neonates, children under 4 years old, pregnant women, and patients with renal or hepatic insufficiency is highly likely to cause adverse reactions; adverse reactions may also occur in patients treated with disulfiram or metronidazole.

WHO has set the ADI of Propylene Glycol at 25mg per kilogram of body weight based on metabolic and toxicological test data. Formulations containing 35% Propylene Glycol may cause hemolysis.

(2) Safety Pharmacology Test Data and Literature Data

Animal experiments have shown that Propylene Glycol has no teratogenic or mutagenic effects. Rats tolerated continuous oral administration of Propylene Glycol at a daily dose of 30mL/kg body weight for up to 6 months; dogs showed no adverse

reactions within 2 years with continuous oral administration at a daily dose of 2g per kilogram of body weight.

LD50:

Mouse (IP): 9.72g/kg

Mouse (IV): 6.63g/kg

Mouse (Oral): 22.0g/kg

Mouse (SC): 17.34g/kg

Rat (IM): 0.01g/kg

Rat (IP): 6.66g/kg

Rat (IV): 6.42g/kg

Rat (Oral): 0.02g/kg

Rat (SC): 22.5g/kg

WHO has set the ADI of Propylene Glycol at 25mg per kilogram of body weight based on metabolic and toxicological test data. Formulations containing 35% Propylene Glycol may cause hemolysis.

Reference

[1] FDA Inactive Ingredients Database for Approved Drug Products. [2010-07-02]. http://www.drugfuture.com/fda/IIG_query.aspx

Section 12: Ecological Information

Persistence and Degradability

Readily biodegradable

Other Information

Potential for Bioaccumulation: No expected accumulation in organisms.

Mobility in Soil: No detailed relevant data available.

Additional Ecological Information: Do not allow undiluted or large quantities of the product to contact groundwater, water courses or sewage systems; Water Hazard Class: Slightly hazardous to water.

PBT (Persistent, Bioaccumulative, Toxic): Not applicable.

vPvB (very Persistent, very Bioaccumulative): Not applicable.

Other Adverse Effects: No detailed relevant data available.

Section 13: Disposal Considerations

Disposal Methods

It is recommended to dispose of the product in strict accordance with government regulations.

Contaminated Containers and Packaging

It is recommended to discard contaminated containers and packaging in accordance with official rules and regulations.

Section 14: Transport Information

Transport Hazard Class

Not specified

Environmentally Hazardous

No

Marine Pollutant

No

Special Precautions for Users

Not applicable

Section 15: Regulatory Information

- Not listed in the Hazardous Chemicals Catalogue.
- Chemical Safety Assessment: Not yet conducted.

Section 16: Other Information

None

Shandong Ruisheng Pharmaceutical Excipients Co., Ltd.

October 14, 2025