

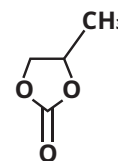


# Propylene carbonate

USP-NF

## Applications

Propylene carbonate is used mainly as a solvent, plasticizer and dispensing solvent for low dosage of active drugs in oral and topical pharmaceutical formulations. Propylene carbonate has also been used in hard gelatin capsules as a nonvolatile and stabilizing liquid carrier.



## General Information

Pharmacopeia Status	: USP-NF
CAS No.	: 108-32-7
EC No.	: 203-572-1
Appearance/Description	: Clear colourless liquid.
Molecular Formula	: C <sub>4</sub> H <sub>6</sub> O <sub>3</sub>
Molecular Mass	: 102.1 g/mol

## Marketed Formulation

Resperidone microspheres & many more...

## Quality and Regulatory Support

- GMP and ISO certification
- EXCiPACT certification
- Nitrosamine impurity risk assessment
- Elemental impurity risk assessment
- Residual solvent declaration
- Genotoxic impurity declaration
- Vendor questionnaire and site audit
- CMC documentation
- Regulatory queries

## Key Product Attributes

- Manufacturing and packing under GMP environment
- Control of sub-visible particles

## Pack Mode

- 500 ml, 2.5 Litre, 2.5 kg glass bottle
- 25 kg GI drum

## Stability and Storage Conditions

Propylene carbonate and its aqueous solutions are stable but may degrade in the presence of acids or bases, or upon heating. Store in a well-closed container in a cool, dry place.

## Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Propylene carbonate may be irritant to the eyes and mucous membranes. Eye protection and gloves are recommended.

## Pharmaceutical Specifications

Description	Clear colourless liquid (USP-NF)
Identification by IR	To comply the test (USP-NF)
Specific gravity, 20°C	1.203-1.210 (USP-NF)
pH (10% aq soln)	6.0-7.5 (USP-NF)
Residue on ignition	NMT 0.01% (USP-NF)
Assay	99.0%-100.5% (USP-NF)

### Regulatory Information

Included in the FDA Inactive Ingredients Database (topical ointments). Included in the Canadian List of Acceptable Nonmedicinal Ingredients.

See the Material Safety Data Sheet on [www.finarchemicals.com](http://www.finarchemicals.com)

Note: The information contained herein is to our best knowledge true and accurate, but all recommendations or suggestions are made without guarantees since the conditions of use are beyond our control. Finar disclaims any liability incurred with the use of this data or suggestions.

### Shipping Information

**By Sea, Air and Road**

Nature: Non Hazardous

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## Finar Limited

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