



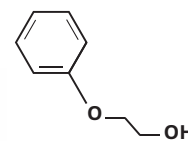
## Technical Data Sheet

# Phenoxyethanol

IP, BP, Ph.Eur, USP-NF

### Applications

Phenoxyethanol is an antimicrobial preservative used in cosmetics and topical pharmaceutical formulations at a concentration of 0.5–1.0%. It may also be used as a Preservative and Antimicrobial agent for vaccines.



### General Information

Pharmacopeia Status	: IP, BP, Ph.Eur, USP-NF
CAS No.	: 122-99-6
EC No.	: 204-589-7
Appearance/Description	: A colourless, slightly viscous liquid.
Molecular Formula	: C <sub>8</sub> H <sub>10</sub> O <sub>2</sub>
Molecular Mass	: 138.17g/mol

### Marketed Formulation

- Tretinoin cream
- Clobetasol cream & 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

- 1kg, 2.5Litre, 2.5kg glass bottle
- 25 Litre, 25 kg HDPE drum

### Stability and Storage Conditions

It should be stored 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. Eye protection and gloves are recommended as Phenoxyethanol may be an irritant to the skin and eyes.

## Pharmaceutical Specifications

Description /Appearance	A colourless, slightly viscous liquid (IP, USP-NF, BP, Ph.Eur)
Solubility	Miscible with acetone, with ethanol (95%) with glycerol; slightly soluble in water; in arachis oil and in olive oil (IP, BP, Ph.Eur, USP-NF)
Identification A (By IR)	IR spectra of the sample should be concomitant with IR spectra of the corresponding standard (IP, USP-NF)
Identification A (By Refractive index)	1.537-1.539 (BP, Ph.Eur)
Identification B1 (By UV absorption )	Specific absorbance at absorbance maxima at 269 nm : 95 to 105 (IP, BP, Ph.Eur)
Identification B2 (By UV absorption)	Specific absorbance at absorbance maxima at 275 nm :75 to 85 (IP, BP, Ph.Eur)
Identification C (By Chemical test)	After recrystallization from water, precipitate should melt between 96°C and 99°C (IP)
Identification C (By IR)	IR spectra of the sample should be concomitant with IR spectra of the corresponding standard (BP, Ph.Eur)
Identification D (By melting point)	After recrystallization, precipitate should melt between 96°C and 99°C (BP, Ph.Eur)
Refractive index, 20° C	1.537 to 1.539 (IP)
Relative density, 20°C	1.105 to 1.110 (IP, BP, Ph.Eur)
Specific gravity, 20°C	1.105-1.110 (USP-NF)
Related substances (By GC)	Not more than 1.0% (IP)
Related substance (Total impurity)	0.3% max. (BP, Ph.Eur)
Related substance (Unspecified impurities: For each impurity)	0.10% max. (BP, Ph.Eur)
Organic impurities	NMT 1.0% (USP-NF)
Phenol	Not more than 0.1% (IP, USP-NF)
Assay	99.0%-100.5% (IP, BP, Ph.Eur, USP-NF)

## Regulatory Information

Included in the FDA Inactive Ingredients Database (topical preparations). Included in non-parenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients. Under European regulations for cosmetics (76/768/EEC), the maximum authorized concentration (MAC) of 2-phenoxyethanol is 1.0%.

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.

For more information contact : [deepaklodhiya@finarchemicals.com](mailto:deepaklodhiya@finarchemicals.com)

## Shipping Information

### By Sea, Air and Road

Nature: Hazardous

UN No: UN2810

Transport Hazard class: 6.1

Packing group: II

## Finar Limited

### CORPORATE OFFICE & WORKS

184-185-186/P, Vill:Chacharwadi Vasna, Bavla 8km milestone, Sarkhej  
Bavla Highway, Sanand, Ahmedabad – 382110. Gujarat, INDIA.  
t: +91-2717-616717 | e: [sales@finarchemicals.com](mailto:sales@finarchemicals.com)  
[www.finarchemicals.com](http://www.finarchemicals.com)

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**passion &  
innovation**  
our commitment !