

1. Identification

Product identifier	Propofol Resolution Mixture	
Other means of identification		
Catalog number	1572525	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A
	Specific target organ toxicity, single exposure	Category 3 respiratory tract irritation
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
OSHA hazard(s)	Not classified.	
Label elements		



Signal word	Warning
Hazard statement	Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. May cause drowsiness or dizziness.
Precautionary statement	
Prevention	Wash thoroughly after handling. Wear protective gloves. Wear eye/face protection. Avoid breathing mist or vapor. Use only outdoors or in a well-ventilated area.
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	Not classified.

3. Composition/information on ingredients

Mixture

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Propofol		2078-54-8	98.8
Related Impurities		No Data	1.2

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Narcotic effects. Irritant effects.
Indication of immediate medical attention and special treatment needed	Treatment of overdose should be symptomatic and supportive. For cardiovascular depression, elevate legs and administer pressor and/or anticholinergic agents. (AHFS).
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of vapors. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Absorb spillage with suitable absorbent material. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Components	Type	Value
Propofol (CAS 2078-54-8)	STEL	0.1 ppm
	TWA	0.5 mg/m ³

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for aerosol-generating procedures.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
Other	For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	Clear yellow liquid.
Physical state	Liquid.
Form	Liquid.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.

Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents. Bases. Acid chlorides. Acid anhydrides.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	May cause irritation to the respiratory system. Vapors have a narcotic effect and may cause headache, fatigue, dizziness and nausea.
Skin contact	Causes skin irritation.
Eye contact	Causes serious eye irritation.
Symptoms related to the physical, chemical, and toxicological characteristics	Slow heartbeat. Sedation. Unconsciousness. Uncontrolled movements. Headache. Nausea. Vomiting.
Delayed and immediate effects of exposure	Apnea. Low blood pressure. Respiratory depression. Central nervous system depression. Pancreatitis. Hyperlipidemia.
Medical conditions aggravated by exposure	Seizure disorders. Hypovolemia. Lipid metabolism disorders.
Acute toxicity	Harmful if swallowed.

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Components	Species	Test Results
Propofol (CAS 2078-54-8)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Mouse	1100 mg/kg
	Rat	500 mg/kg
Skin corrosion/irritation	Causes skin irritation.	
Serious eye damage/eye irritation	Causes serious eye irritation.	
Local effects		
Propofol		Irritancy test Result: Irritant. Species: Rabbit Organ: Eye. Severity: Mild. Irritancy test Result: Irritant. Species: Rabbit Organ: Skin. Severity: Mild. Irritancy test Result: Irritant. Species: Rat Organ: Skin. Severity: Severe.
Respiratory sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	Due to lack of data the classification is not possible.	
Germ cell mutagenicity	Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.	
Mutagenicity		
Propofol		Ames test in Salmonella Result: Negative. Gene mutation/gene conversion test in Saccharomyces cerevisiae Result: Negative. In vitro cytogenic studies in Chinese hamsters Result: Negative. In vivo test for chromosome aberrations in human peripheral blood lymphocytes Result: Negative.

Mutagenicity Propofol	Mouse micronucleus test Result: Negative.
Carcinogenicity	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Reproductivity Propofol	15 mg/kg/day Reproductivity and development studies Result: No evidence of impaired fertility or harm to the fetus. Species: Rabbit 15 mg/kg/day Reproductivity and development studies Result: No evidence of impaired fertility or harm to the fetus. Species: Rat
Specific target organ toxicity - single exposure	Respiratory tract irritation. Narcotic effects.
Specific target organ toxicity - repeated exposure	Due to lack of data the classification is not possible.
Aspiration hazard	Due to lack of data the classification is not possible.
12. Ecological information	
Ecotoxicity	High potential for bioaccumulation.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.
13. Disposal considerations	
Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Not available.
Hazardous waste code	Not available.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
14. Transport information	
DOT	Not regulated as a hazardous material by DOT.
IATA	Not regulated as a dangerous good.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.
15. Regulatory information	
US federal regulations	All components are on the U.S. EPA TSCA Inventory List. CERCLA/SARA Hazardous Substances - Not applicable.
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	No
SARA 311/312 Hazardous chemical	No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm. California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date 02-22-2005

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Version # 03

Further information Not available.

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Revision Information This document has undergone significant changes and should be reviewed in its entirety.