

Safety Data Sheet



Revision: 1.0
Issued: 01 Mar 2024

1. Identification

Product Identifier	Papaverine Hydrochloride
Other means of identification	
Internal item number	82393-0402
CAS number	61-25-6
Chemical name	Isoquinoline, 1-[(3,4-dimethoxyphenyl)methyl]-6,7-dimethoxy-, hydrochloride
Relevant use and restrictions:	No further information available.
Application of substance:	Active pharmaceutical ingredient.
Manufacturer/Supplier information	
Company name	Pharma Source Direct
Address	8591 Prairie Trail Drive, Ste C-600 Englewood, CO 80112
Website	www.pharmasd.com
Emergency phone number	Infotrac: 1-800-535-5053

2. Hazard(s) Identification

Physical hazards	Not classified	
Health hazards	Acute toxicity, oral	Category 3
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		
Signal word	Danger	
Hazard statement	Toxic if swallowed.	
Precautionary statement		
Prevention	Wash thoroughly after handling.	
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth.	
Storage	Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/ international regulations.	
Hazards not otherwise classified (HNOC)	Not classified.	
Other hazards which do not result in classification	None known.	

3. Composition/Information on Ingredients

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Substance

Chemical name	Common name and synonyms	CAS number	%
Papaverine Hydrochloride	Papaverine chlorohydrate	61-25-6	100

4. First-aid Measures

Inhalation	Move to fresh air. 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	Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Most important symptoms/effects, acute and delayed	Cardiovascular effects. Gastrointestinal disturbances.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Administer activated charcoal as a slurry. Monitor blood gases. For severe metabolic acidosis, administer sodium bicarbonate intravenously. For hypotension, infuse 10- 20 mL/kg isotonic fluid. Administer dopamine or norepinephrine if hypotension persists. Hemodialysis may be of benefit. Administer antiarrhythmic medication if necessary.
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	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ .
Unsuitable extinguishing media	None known.
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	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

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Specific methods Cool containers exposed to flames with water until well after the fire is out.

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. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

Environmental precautions Do not allow to enter sewers/surface or ground water.

7. Handling and Storage

Precautions for safe handling As a general rule, 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. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure Controls & Personal Protection

Biological limit values No biological exposure limits noted for the ingredient(s)

Exposure guidelines No exposure standards allocated.

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. 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 grinding, crushing, weighing, or other dust-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

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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.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing 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).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and Chemical Properties

Appearance	White crystals or white crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless
Odor threshold	Not available.
pH	3 - 4.5 (2% aqueous solution) 3.9 (0.05 molar solution)
Melting point/freezing point	428 - 438.8 °F (220 - 226 °C) (decomposes)
Initial boiling point and boiling range	Not available.
Flash point	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 pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Soluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Isoquinoline; alkaloid.
Molecular formula	C20H21NO4 . HCl

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Molecular weight	375.85
Solubility (other)	Soluble in chloroform; slightly soluble in alcohol; practically insoluble in ether.

10. Stability and Reactivity

Reactivity	Not available.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Direct solar radiation.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. HCl.

11. Toxicological Information

Information on likely routes of exposure

Ingestion	Toxic if swallowed.
Inhalation	Classification not possible.
Skin contact	Classification not possible.
Eye contact	Classification not possible.
Symptoms related to the physical, chemical, and toxicological characteristics	General feeling of discomfort or illness. Nausea. Abdominal pain. Loss of appetite. Headache. Constipation. Diarrhea. Skin rash. Dizziness. Flushing. Sweating. Fast heartbeat. Irregular heartbeat. Shallow breathing. Weakness. Blurred vision. Double vision. Tiredness. Vomiting.

Delayed and immediate effects of exposure	Metabolic acidosis.
Medical conditions aggravated by exposure	Impaired liver function. Glaucoma. Heart problems.

Acute toxicity Toxic if swallowed.

Product	Species	Test Results
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Papaverine Hydrochloride (CAS 61-25-6)

Acute

Oral

LD50

Rat

68800 µg/kg
360 mg/kg

Skin corrosion/irritation Classification not possible.

Serious eye damage/eye irritation Classification not possible.

Respiratory or skin sensitization

Respiratory sensitization Classification not possible.

Skin sensitization Classification not possible.

Germ cell mutagenicity Classification not possible.

Mutagenicity

Ames test (S. typhimurium TA 100)
Result: Weakly mutagenic with activation.
Ames test (S. typhimurium TA 98)
Result: Negative.

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Carcinogenicity	Classification not possible.
400 mg/kg/day Carcinogenicity study	
Result: No evidence of carcinogenicity.	
Species: Mouse	
Test Duration: 2 years	
400 mg/kg/day Carcinogenicity study	
Result: No evidence of carcinogenicity.	
Species: Rat	
Test Duration: 2 years	
Reproductive toxicity	Classification not possible.
Reproductivity	
140 mg/kg Gestational study (day 9, subcutaneous injection)	
Result: Increased fetal mortality, retardation, and neural defects.	
Species: Mouse	
In vitro developmental study (chick and mouse embryos)	
Result: Neural tube defects following 50-75 micrograms/mL exposure in culture medium.	
Specific target organ toxicity - single exposure	Classification not possible.
Specific target organ toxicity - repeated exposure	Classification not possible.
Aspiration hazard	Based on available data, the classification criteria are not met.

12. Ecological Information

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this substance.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

13. Disposal Considerations

Disposal instructions	This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Not available.
Hazardous waste code	Not regulated.
Waste from residues / unused products	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.

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14. Transport Information

DOT

UN number	UN1544
UN proper shipping name	Alkaloids, solid, n.o.s. (Papaverine hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	III
Packaging exceptions	153
Packaging non bulk	213
Packaging bulk	240

IATA

UN number	UN1544
UN proper shipping name	Alkaloids, solid, n.o.s. (Papaverine hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	III
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not available.

DOT;IATA



15. Regulatory Information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.
All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)

Not regulated.

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Other federal regulations

Safe Drinking Water Act (SDWA)	Not regulated
Food and Drug Administration	Not regulated.

US state regulations

California Proposition 65	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.
	Not Listed.

International Inventories

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

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

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other Information

Disclaimer	The information in this SDS has been compiled from sources considered dependable but has not been independently verified. The company cannot guarantee the accuracy of information herein, and the statements contained should not be considered an official expression. The company will not assume liability for any loss, damage, and/or expense resulting from the use and/or misuse of this product in regards to handling, storage, and/or disposal.
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