

SAFETY DATA SHEET

Methadone Hydrochloride Oral Solution, USP (5 mg/5 mL)

1. IDENTIFICATION

Product identifier: Methadone Hydrochloride Oral Solution, USP (5 mg/5 mL)

Product Codes: 66689-711-05 & 66689-711-30

Supplier Name and Address: PAI Pharma
1700 Perimeter Road
Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug

Restrictions on use: Prescription use only

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Flammable Liquid Category 3	Not hazardous

Label Elements:

Warning!



Hazard statement(s)

Flammable liquid and vapor

Precautionary statement(s)

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Keep container tightly closed.

Ground and bond container and receiving equipment.

Precautionary statement(s)

Take **action to prevent** static discharge.

Wear protective gloves and eye protection.

In case of fire: Use water spray, carbon dioxide or alcohol-resistant foam to extinguish.

Store in a well-ventilated place. Keep cool.

Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Methadone Hydrochloride	1095-90-5	0.1%
Sorbitol Solution	50-70-4	Proprietary
Glycerin	56-81-5	Proprietary
Ethanol	64-17-5	5-10%
Citric Acid	77-92-9	0.1-1%

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Wild Cherry Flavor	Mixture	Proprietary
Benzoic Acid	65-85-0	0.1-<1%
FD&C Red No. 40	25956-17-6	<0.1%
FD&C Red No. 33	3567-66-6	<0.1%
Water	7732-18-5	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation or other symptoms occur, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: In the case of unintentional ingestion or overdose, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get immediate medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Swallowing large amounts causes central nervous system depression with drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, and sweating. Severe overdose may result in respiratory depression and cardiac effects. Methadone can cause physical and psychological dependence.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for unintended ingestion or overdose.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, CO₂, dry chemical or alcohol-resistant foam.

Specific hazards arising from the chemical: Flammable liquid. Vapors can form explosive mixtures with air in confined area.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire-exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. Eliminate ignition sources and ventilate the area.

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Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of vapors or mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Methadone Hydrochloride	None Established
Sorbitol Solution	None Established
Glycerin	5 mg/m ³ (respirable particulate) TWA OSHA PEL 15 mg/m ³ (total particulate) TWA OSHA PEL
Ethanol	1000 ppm Ceiling ACGIH TLV 1000 ppm TWA OSHA PEL
Citric Acid	None Established
Wild Cherry Flavor	None Established
Benzoic Acid	None Established
FD&C Red No. 40	None Established
FD&C Red No. 33	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved organic vapor/particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid	pH: Not determined
Odor: Cherry	Color: Red
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: Not applicable	Particle Characteristics: Not applicable for liquids
Flammability: Not flammable	VOC: Not determined
Flammable limits: LEL: None	UEL: None
Vapor pressure: Same as water	Relative vapor density: Same as water
Relative density: 1.05	Solubility(ies): Soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Kinematic Viscosity: Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and possibly symptoms similar to ingestion

Ingestion: Swallowing large amounts causes central nervous system depression with drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, and sweating. Severe overdose may result in respiratory depression and cardiac effects. Methadone can cause physical and psychological dependence.

Skin contact: May cause mild irritation.

Eye contact: May cause mild irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Components are not known to be sensitizers.

Germ Cell Mutagenicity: Components are not classified as germ cell mutagens. Methadone tested positive in the *in vivo* mouse dominant lethal assay and the *in vivo* mammalian spermatogonial chromosome aberration test. Additionally, methadone tested positive in the *E. coli* DNA repair system and *Neurospora crassa* and mouse lymphoma forward mutation assays. In contrast, methadone tested negative in tests for chromosome breakage and disjunction and sex-linked recessive lethal gene mutations in germ cells of *Drosophila* using feeding and injection procedures.

Reproductive Toxicity: Components are not classified as reproductive toxins. The majority of available data from clinical trials, observational studies, case series, and case reports on methadone use in pregnancy do not

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indicate an increased risk of major malformations specifically due to methadone. Formal reproductive and developmental toxicology studies for methadone have not been conducted in animals. No effects were reported in a study of pregnant rats and rabbits at oral doses up to 40 mg/kg. When pregnant rats were treated with intraperitoneal doses of 2.5, 5, or 7.5 mg/kg methadone from one week prior to mating, through gestation until the end of lactation period, 5 mg/kg or greater methadone resulted in decreases in litter size and live pups born and 7.5 mg/kg resulted in decreased birth weights. Additional animal data demonstrate evidence for neurochemical changes in the brains of offspring from methadone-treated pregnant rats. The effect of methadone on fertility is unknown. Use of opioids for an extended period of time may cause reduced fertility in females and males of reproductive potential. It is not known whether these effects on fertility are reversible.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA. The results of carcinogenicity assessment in B6C2F1 mice and Fischer 344 rats following dietary administration of two doses of methadone HCl have been published. Under the conditions of the assay, there was no clear evidence for a treatment-related increase in the incidence of neoplasms in either male or female rats.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg
Methadone Hydrochloride: Oral rat LD50 30mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been evaluated. Releases to the environment should be avoided.

Ecotoxicity values: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Note: This product is an aqueous alcohol solution containing <24% ethanol. It is excepted from regulation per US DOT 49CFR173.150 (e), TDG 1.36, IATA SP A58 and IMSD SP 144.

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Transport in bulk according to IMO instruments: Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Refer to Section 2 for the OSHA Hazard Classification.

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

California Proposition 65: This product is not known to contain regulated chemicals.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

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SDS Revision History: New SDS

Disclaimer : The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

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