



Methadone Hydrochloride Injection, USP

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Issue date: 04/23/2024

Version: 1.0

SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : Methadone Hydrochloride Injection, USP

1.2. Recommended use and restrictions on use

Use of the substance/mixture : Pharmaceuticals (opioid analgesic)

1.3. Supplier

Long Grove Pharmaceuticals, LLC.
9450 W. Bryn Mar Ave., Suite 200
Rosemont, IL 60018 - USA
T 847-999-0600

1.4. Emergency telephone number

Emergency number : CHEMTREC +1 (703) 527-3887 (Local), +1 (800) 424-9300 (Toll Free) 24/7

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

This product contains a potent pharmacologically active material. Exposure may cause physiological effects. Handling of this product in its final form presents minimal occupational exposure risk.

GHS-US classification

Muta. 2 H341
Repr. 2 H361

2.2. GHS Label elements, including precautionary statements

GHS US labelling

Hazard pictograms (GHS US) :



Signal word (GHS US) : Warning

Hazard statements (GHS US) : H341 - Suspected of causing genetic defects.
H361 - Suspected of damaging fertility or the unborn child.

Precautionary statements (GHS US) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves, protective clothing, chemical goggles, & face protection.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | %* |
|-------------------------|---------------------|----|
| Methadone hydrochloride | (CAS-No.) 1095-90-5 | 1 |

*In accordance with paragraph (i) of the OSHA Hazard Communication Standard (29 CFR §1910.1200), the specific chemical identity or exact weight % has been withheld as a trade secret.

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SECTION 4: First-aid measures

4.1. Description of first aid measures

- First-aid measures general : If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.
- First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if breathing is affected. If breathing is difficult, supply oxygen.
- First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes. If irritation develops or persists, get medical attention.
- First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. Continue rinsing if pain, blinking, or irritation develops or persists, get medical attention. Continue rinsing.
- First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. Get medical attention if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/effects : Suspected of causing genetic defects. Suspected of damaging fertility. Suspected of damaging the unborn child.
- Symptoms/effects after inhalation : May cause respiratory irritation.
- Symptoms/effects after skin contact : May cause minor skin irritation.
- Symptoms/effects after eye contact : Direct contact with eyes is likely to be irritating.
- Symptoms/effects after ingestion : May be harmful if swallowed.
- Chronic symptoms : Suspected of causing genetic defects. Suspected of damaging fertility. Suspected of damaging the unborn child.

4.3. Immediate medical attention and special treatment, if necessary

- Notes to physician : Treat symptomatically. Methadone Hydrochloride Injection is a Schedule II controlled substance and can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing Methadone Hydrochloride Injection in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Foam. Carbon dioxide. Dry powder. Water spray.

5.2. Specific hazards arising from the chemical

- Fire hazard : Not flammable.
- Explosion hazard : Product is not explosive.
- Reactivity : No dangerous reactions known under normal conditions of use.

5.3. Special protective equipment and precautions for fire-fighters

- Precautionary measures fire : Eliminate all ignition sources if safe to do so.
- Firefighting instructions : Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers. Do not dispose of fire-fighting water in the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. Self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Evacuate area. Ventilate area. Keep upwind. Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.1.1. For non-emergency personnel

- Protective equipment : Wear Protective equipment as described in Section 8.
- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air respirator, in case of emergency.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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6.3. Methods and material for containment and cleaning up

- For containment
- : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Prevent entry to sewers and public waters.
- Methods for cleaning up
- : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. This material and its container must be disposed of in a safe way, and as per local legislation.

6.4. Reference to other sections

See Sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling
- : In the US, Methadone Hydrochloride is a Schedule CII controlled substance. Appropriate training and procedures may be required during the routine handling of this product. Handle in accordance with product label and/or product insert information. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Keep container closed when not in use. Avoid contact with skin and eyes. Avoid contact during pregnancy/while nursing. Avoid accidental injection.
- Hygiene measures
- : Handle in accordance with good industrial hygiene and safety procedures. Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions
- : Store in original container. Keep container closed when not in use. Containers which are opened should be properly resealed and kept upright to prevent leakage. Store in a dry, cool and well-ventilated place.
- Storage temperature
- : 20 – 25 °C (68 - 77 °F) [see USP Controlled Room Temperature]
- Storage area
- : Protect from light.
- Special rules on packaging
- : Store in carton until contents have been used.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| Methadone hydrochloride (1095-90-5) | | |
|-------------------------------------|--|-----------------------|
| ACGIH | Remark (ACGIH) | OELs not established |
| OSHA | Remark (OSHA) | OELs not established |
| Long Grove | Estimated Occupational Exposure Limit (OEL) – 8 hr | 0.0037 µg/m3 |
| Long Grove | Estimated Allowable Daily Exposure (ADE) | 4,000 µg/day |
| Long Grove | Remark | Source: Internal data |

8.2. Appropriate engineering controls

- Appropriate engineering controls
- : Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment symbol(s):



Personal protective equipment:

Gloves. Safety glasses. Wear labcoat with full coverage clothing.

Hand protection:

Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Gloves should be classified under Standard EN 374 or ASTM F1296. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, PVC or vinyl. Suitable gloves for this specific application can be recommended by the glove supplier.

Eye protection:

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Wear eye protection, including chemical splash goggles and a face shield when possibility exists for eye contact due to spraying liquid or airborne particles.

Skin and body protection:

Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure.

Respiratory protection:

Respiratory protection is normally not needed during intended product use. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|-----------------------------|
| Physical state | : Liquid |
| Appearance | : Clear, colorless solution |
| Color | : Clear, colorless |
| Odor | : No data available |
| Odor threshold | : No data available |
| pH | : 4.5 – 6.5 |
| Melting point | : 235 °C (455 °F) |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Flammability (solid, gas) | : No data available |
| Vapor pressure | : No data available |
| Relative vapor density at 20°C | : No data available |
| Relative density | : No data available |
| Solubility | : Water: Soluble |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity, kinematic | : Not applicable |
| Viscosity, dynamic | : No data available |
| Explosive limits | : No data available |
| Explosive properties | : No data available |
| Oxidising properties | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

None under normal use.

10.4. Conditions to avoid

None under normal use.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|-----------------------------|------------------|
| Acute toxicity (oral) | : Not classified |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |

Methadone hydrochloride (1095-90-5)

| | |
|---------------|----------------------------|
| LD50 oral rat | 30 mg/kg (Source: NLM_CIP) |
|---------------|----------------------------|

| | |
|-------------------------------------|---|
| Skin corrosion/irritation | : Not classified |
| Serious eye damage/irritation | : Not classified |
| Respiratory or skin sensitisation | : Not classified |
| Germ cell mutagenicity | : Suspected of causing genetic defects. Methadone tested negative in tests for chromosome breakage and disjunction and sex-linked recessive lethal gene mutations in germ cells of <i>Drosophila</i> using feeding and injection procedures. In contrast, methadone tested positive in the <i>in vivo</i> mouse dominant lethal assay and the <i>in vivo</i> mammalian spermatogonial chromosome aberration test. Additionally, methadone tested positive in the <i>E. coli</i> DNA repair system and <i>Neurospora crassa</i> and mouse lymphoma forward mutation assays. |
| Carcinogenicity | : Data from published reports of carcinogenicity studies indicate that there was a significant increase in pituitary adenomas in female B6C2F1 mice consuming 15 mg/kg/day methadone for two years. This dose was approximately 0.6 times a human daily oral dose of 120 mg/day, on a body surface area basis. However, this finding was not seen in mice consuming 60 mg/kg/day (approximately 2.5 times the human daily oral dose of 120 mg/day). |
| Reproductive toxicity | : Suspected of damaging fertility or the unborn child. Pregnancy Category C. There are no controlled studies of methadone use in pregnant women that can be used to establish safety. |
| STOT-single exposure | : Based on clinical use, possible target organs include the nervous system, respiratory system, and cardiovascular system. May cause increased sensitivity, tolerance, habituation and addiction. |
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |
| Viscosity, kinematic | : Not applicable |
| Symptoms/effects | : Suspected of causing genetic defects. Suspected of damaging fertility. Suspected of damaging the unborn child. |
| Symptoms/effects after inhalation | : May cause respiratory irritation. |
| Symptoms/effects after skin contact | : May cause minor skin irritation. |
| Symptoms/effects after eye contact | : Direct contact with eyes is likely to be irritating. |
| Symptoms/effects after ingestion | : May be harmful if swallowed. |
| Chronic symptoms | : Suspected of causing genetic defects. Suspected of damaging fertility. Suspected of damaging the unborn child. |

SECTION 12: Ecological information

12.1. Toxicity

| | |
|-------------------|----------------------|
| Ecology - general | : No data available. |
|-------------------|----------------------|

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

| | |
|-----------------------|----------------------|
| Other adverse effects | : No data available. |
|-----------------------|----------------------|

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SECTION 13: Disposal considerations

13.1. Disposal methods

- Waste treatment methods : Do not discharge to public wastewater systems without permit of pollution control authorities. No discharge to surface waters is allowed without a permit.
- Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

- In accordance with DOT
- Not regulated for transport

Transport by sea (IMDG)

- Not regulated for transport

Air transport (IATA)

- Not regulated for transport

SECTION 15: Regulatory information

15.1. US Federal regulations

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This product is regulated under the United States Federal Food, Drug, and Cosmetic Act (FFDCA) and is exempt from listing on TSCA

15.2. International regulations

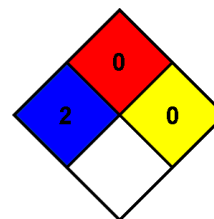
- No additional information available

15.3. US State regulations

- This product does not contain any substances known to the state of California to cause cancer and/or reproductive harm.

SECTION 16: Other information

- Other information : Author: EMA.
- NFPA health hazard : 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.
- NFPA fire hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.
- NFPA reactivity : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS Hazard Rating

- Health : 2
* - Chronic (long-term) health effects may result from repeated overexposure
- Flammability : 0
- Physical : 0

Indication of changes:

Revision 1.0: New SDS Created.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.