U.S. Pharmacopeial Convention

SAFETY DATA SHEET

1. Identification

Product identifier Methylergonovine Maleate

Other means of identification

 Catalog number
 1430000

 CAS number
 57432-61-8

Synonyms Methylergometrine maleate

Chemical name Ergoline-8-carboxamide, 9,10-didehydro-N-[1-(hydroxymethyl)propyl]-6-methyl-, [8beta(S)]-,

(Z)-2-butenedioate (1:1) (salt)

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

Manufacturer

Company name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway

Rockville MD 20852-1790 United States

Telephone RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 3

Reproductive toxicity Category 1

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement Toxic if swallowed. May damage fertility or the unborn child.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye

protection/face protection.

Response If swallowed: Immediately call a poison center/doctor. Rinse mouth. If exposed or concerned: Get

medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)

This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be

hazardous.

Supplemental information Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Material name: Methylergonovine Maleate

USP SDS US

CAS number **Chemical name** Common name and synonyms % Methylergonovine Maleate Methylergometrine maleate 57432-61-8 100

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.

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Ingestion

Uterine contractions. Potent pharmacologically active material. Occupational exposure to small Most important

amounts may cause physiological effects. symptoms/effects, acute and

Indication of immediate medical attention and special treatment needed

delayed

Treat symptomatically. Treatment of ergot alkaloid overdose may include the following: Do NOT induce vomiting due to potential for ergot-induced CNS depression and seizure. Administer activated charcoal as a slurry. Perform gastric lavage soon after ingestion (within one hour). Protect airway by placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation. For vasoconstriction and hypertension, administer nitroprusside. In patients with evidence of ischemia, also consider intravenous heparin, and with evidence of significant end organ ischemia, also consider intravenous nitroglycerin or phentolamine. For mild peripheral vasoconstriction, treat with nifedipine, and for mild peripheral ischemia, consider prazosin. Surgical or mechanical intervention should only be considered with caution and if gangrene is imminent. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. [Meditext 2006]

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from **General information** 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

and precautions for firefighters

Suitable extinguishing media Water, Foam, Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

None known Unsuitable extinguishing media

Specific hazards arising from Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and

the chemical in the presence of an ignition source is a potential dust explosion hazard. Special protective equipment Wear suitable protective equipment.

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Fire fighting Firefighters should use self-contained breathing equipment and protective clothing. equipment/instructions

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions. protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

Methods and materials for containment and cleaning up

For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

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. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

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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

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use

 Material
 Type
 Value

 Methylergonovine Maleate
 TWA
 0.005 mg/m3

(CAS 57432-61-8)

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

Appropriate engineering

controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary.

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

Hand protection Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When

the material is dissolved or suspended in an organic solvent, wear gloves that provide protection

against the solvent.

Other Train employees in proper gowning and degowning practices. Wear disposable lab coat,

disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head

cover for spill cleanup. Chose respiratory protection appropriate to the task and the level of

existing engineering controls.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or

quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.

Form Crystalline powder.

ColorWhite.OdorOdorless.Odor thresholdNot available.pHNot available.

Melting point/freezing point > 392 °F (> 200 °C)

365 - 384.8 °F (185 - 196 °C) (decomposes)

Initial boiling point and boiling

range

Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

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Not available.

(%)

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

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Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Slightly soluble.

Solubility (other) Ether: Very slightly soluble.

Chloroform: Very slightly soluble.

Alcohol: Soluble.

Auto-ignition temperature 986 °F (530 °C) (BAM, fluidized dust)

Decomposition temperature Not available. **Viscosity** Not available.

Other information

Chemical family Ergoline derivative (amine ergot alkaloid).

Dust explosion properties

Minimum ignition energy (MIE) - dust

3 - 10 mJ

cloud

Molecular formula C20H25N3O2.C4H4O4

Molecular weight 455.51

pH in aqueous solution 4.4 - 5.2 (0.02% solution)

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoidContact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.Eye contactKnowledge about health hazard is incomplete.

Ingestion Toxic if swallowed. This material may cause: Uterine contractions

Symptoms related to the physical, chemical, and

toxicological characteristics

Gastrointestinal disturbances. Central nervous system effects. Ringing in ears. Numbness of extremities. Seizures. Pinpoint pupils. Blurred vision. Sweating. Difficulty breathing. Bluish skin.

Itching. Muscle pain. Skin rash. Cardiovascular effects.

Information on toxicological effects

Acute toxicity Toxic if swallowed.

Product Species Test Results

Methylergonovine Maleate (CAS 57432-61-8)

Acute Oral

LD50 Mouse 187 mg/kg
Rat 93 mg/kg

Skin corrosion/irritation

Knowledge about health hazard is incomplete.

Knowledge about health hazard is incomplete.

irritation

Respiratory or skin sensitization

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Respiratory sensitization
Skin sensitization
Knowledge about health hazard is incomplete.
Knowledge about health hazard is incomplete.
Knowledge about mutagenicity is incomplete.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

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IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity May damage fertility or the unborn child. Ergot alkaloids can decrease fetal blood supply and

cause uterine contractions, possibly leading to miscarriage or fetal harm.

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause

physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available. No data available.

Other adverse effects

Mobility in soil

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructionsDispose 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

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

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). Dispose of in accordance with local

regulations.

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or

disposal.

14. Transport information

DOT

UN number UN1544

UN proper shipping name

Transport hazard class(es)

Alkaloid salts, solid, n.o.s. (Methylergonovine Maleate)

Class 6.1
Subsidiary risk Packing group III
Packaging exceptions E1

IATA

UN number UN1544

UN proper shipping name Transport hazard class(es)

Alkaloid salts, solid, n.o.s. (Methylergonovine Maleate)

Class 6.1 Subsidiary risk -Packing group III

Other information

ation

Passenger and cargo

Allowed with restrictions.

aircraft

Cargo aircraft only

Allowed with restrictions.

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

the IBC Code

Not applicable.

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General information It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - Yes Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Yes

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)
US state regulations

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)	Yes
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)	Yes
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

Country(s) or region Inventory name On inventory (yes/no)*

Philippines Philippine Inventory of Chemicals and Chemical Substances

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

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) 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, including date of preparation or last revision

 Issue date
 10-25-2007

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 10-09-2017

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Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the

Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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