

**Material Safety Data Sheet**

Revision date: 10/25/2011

Print date: 10/25/2011

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name: Meperidine Hydrochloride Injection, USP
Product Codes: NDC 0641-6052-01, NDC 0641-6052-25, NDC 0641-6053-01, NDC 0641-6053-25, NDC 0641-6054-01, NDC 0641-6054-25
Synonyms: None
Chemical Family: Analgesic
Product Type: Regulated Prescription Drug
Container Information: 1 ml vial
Product Use: Pharmaceutical.

Supplier:
 WEST-WARD PHARMACEUTICALS
 EATONTOWN, NJ 07724

Emergency telephone number: CHEMTREC: USA & Canada (800) 424-9300 OUTSIDE USA +1 703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Meperidine Hydrochloride 50-13-5	2.5-10	None	T
Acetic Acid 64-19-7	0-0.5	UN2790	C; R10 R35
Sodium Acetate Trihydrate 6131-90-4	0-0.15	None	None
Water 7732-18-5	89-98	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: HARMFUL IF SWALLOWED. Do not ingest. May cause eye and skin irritation. Central Nervous System depression. May cause allergic reactions.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation: Inhalation not likely under normal use conditions.

Ingestion: Harmful if swallowed.

Skin contact: May cause skin irritation. May cause allergic reaction.

Eye contact: May cause eye irritation.

Product name: Meperidine Hydrochloride Injection, USP

4. FIRST AID MEASURES

Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.
Skin contact:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention if irritation develops.
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Call a physician immediately.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
Notes to physician:	See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Use foam or all purpose dry chemicals to extinguish.
Special protective equipment for firefighters:	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Specific methods:	No information available.
Flash point:	Not determined
Autoignition temperature:	Not available
Flammable limits in air-lower (%):	Not available
Flammable limits in air-upper (%):	Not available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).
Environmental precautions:	No information available.
Methods for cleaning up:	If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Handling:	
Technical measures/precautions:	Do not ingest. Wash thoroughly after handling.
Storage:	
Technical measures/Storage conditions:	Keep containers tightly closed in a dry, cool and well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F). Follow Schedule II controlled substance requirements.
Incompatible products:	No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Meperidine Hydrochloride 50-13-5	None	None	None	None	None	None
Acetic Acid 64-19-7	10 ppm TWA= 25mg/ m ³	15 ppm	None	10 ppm	15 ppm	None
Sodium Acetate Trihydrate 6131-90-4	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures: Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:

Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat.

Eye protection: Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Appearance: Aqueous solution
Color: Colorless
Odor: Not available.
pH: 3.5-6.0
Molecular weight: Not applicable
Boiling point/range: Not available.
Melting point/range: Not available.
Density: Not available.
Vapor pressure: Not available.
Evaporation rate: Not available.
Solubility: Not available.
Partition coefficient (n-octanol/water): Not available.
Viscosity: Not available.
% Volatile by Volume: Not available.

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.
Polymerization: Not applicable
Hazardous decomposition products: Thermal decomposition products: miscellaneous decomposition products.
Materials to avoid: Acids. Bases. Oxidizing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Meperidine Hydrochloride 50-13-5	Oral LD50 Rat = 170 mg/kg Oral LD50 Mouse = 178 mg/kg Intravenous LD50 Rat = 30 mg/kg Intravenous LD50 Mouse = 32 mg/kg
Acetic Acid 64-19-7	Oral LD50 Rat = 3310 mg/kg Inhalation LC 50 Mouse = 5620 ppm 1h Intravenous LD 50 Mouse = 525 mg/kg Dermal LD 50 Rabbit = 1060 uL/kg
Sodium Acetate Trihydrate 6131-90-4	None.
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg

Acute toxicity:	Signs and symptoms of overexposure to narcotic analgesics may include respiratory depression, drowsiness progressing to stupor or coma, rash, itching, headache, nausea, vomiting, muscle relaxation, cold and clammy skin, slow heart rate, low blood pressure, apnea, circulatory collapse, cardiac arrest, and possibly death.
Chronic toxicity:	Contains material which causes damage to the following organs: kidneys, lungs, liver, mucous membranes, spleen, skin, eye, lens or cornea, and pancreas. Target Organs: Nervous system.
Carcinogenic effects:	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No data is available on the product itself.
Mutagenic effects:	No data is available on the product itself.
Reproductive toxicity:	No data is available on the product itself.
FDA Pregnancy Category	Not available.

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Meperidine Hydrochloride 50-13-5	None.	None.	None.	None.
Acetic acid 64-19-7	None.	LC50 (96 hr) fathead minnow: 88 mg/L :Static, 18-22 °C; LC50 (96 hr) bluegill sunfish: 75 mg/L.; LC50 (24 hr) goldfish: 423 mg/L	None.	= 8.8 mg/L EC50 Photobacterium phosphoreum
Sodium Acetate Trihydrate 6131-90-4	None	None.	None.	None.
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

Product name: Meperidine Hydrochloride Injection, USP

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name: None
 UN Number: None
 DOT Packing Group: None
 DOT Hazard class: None

TDG (Canada):

TDG Proper shipping name: None
 TDG UN/NA Number: None
 TDG Packing Group: None
 TDG Hazard class: None

ADR/RID:

ADR Official Transport Name: None
 ADR Proper shipping name: None
 ADR UN/NA number: None
 ADR Hazard Class: None

ICAO / IATA:

IATA Proper shipping name: None
 IATA UN NUMBER: None
 IATA Primary Hazard: None
 IATA Packing group: None
 ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: None
 IMDG Hazard Class and Division: None
 IMDG Packing Group: None
 IMDG Subsidiary Risks: None

_ 15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List - OTHER REGULATIONS: The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Japanese Inventory (ENCS) This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Meperidine Hydrochloride	2.5-10	Not Listed	Not Listed	Not Listed	Not Listed
Acetic Acid	<.01	Not listed	= 2270 kg final RQ =5000 lb final RQ	Not Listed	Not Listed
Sodium Acetate Trihydrate	0-0.15	Not Listed	Not Listed	Not Listed	Not Listed
Water	89-98	Not Listed	Not Listed	Not Listed	Not Listed

 Product name: Meperidine Hydrochloride Injection, USP

STATE REGULATIONS:

Component	California Prop 65:	Minnesota Right-To - Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Meperidine Hydrochloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Acetic Acid	Not Listed	Present	Not Listed	Toxic, Flammable	Present	Environmental hazard	Sn 0004
Sodium Acetate Trihydrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

EU EINECS List - This product complies with EINECS

Risk Phrases:
Not determined

Safety Phrases:
Not Determined

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):
Change company name from Baxter to West-Ward.

Additional information:
Not Available.

Prepared by: West-Ward Pharmaceuticals

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of safety data sheet:

Product name: Meperidine Hydrochloride Injection, USP