Baxter

Material Safety Data Sheet

MSDS Number: 1102369
Revision date: 11/13/2003
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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1102369
Product name: Hydromorphone Hydrochloride Injection, USP
Product code: NDC 0641-0121-25, NDC 0641-2341-41, NDC 0641-0121-21, NDC 0641-2341-39
Synonyms: None
Chemical Family: Analgesic
Product Type: Regulated Prescription Drug
Container Information: 1 ml dosette® vials and 20 ml multiple dose vials
Product Use: Pharmaceutical

Supplier:
BAXTER HEALTHCARE CORPORATION
DEERFIELD, ILLINOIS 60015
(800) 422-9837 or (847) 948-4770

Emergency telephone number: PROSAR: USA (888) 990-0996 OUTSIDE USA (615)917-6114
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Hydromorphone hydrochloride 71-68-1	0.2	None	None
Methyl Paraben 99-76-3	<0.2	None	None
Propyl Paraben 94-13-3	<0.05	None	None
Edetate Disodium 139-33-3	<0.1	None	None
Water 7732-18-5	>99	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: May cause eye and skin irritation. Central Nervous System depression.

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

Inhalation: Inhalation not likely under normal use conditions.

Ingestion: Gastrointestinal effects (may include nausea, upset stomach, loss of appetite). Nervous system effects (may include drowsiness, confusion, hallucinations, convulsions, visual disturbances, headache, coma).

Skin contact: May cause skin irritation.

Eye contact: May cause eye irritation.

4. FIRST AID MEASURES

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

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. If large quantities of this material are swallowed, 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 applicable
Flammable limits in air-lower (%): Not applicable
Flammable limits in air-upper (%): Not applicable

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: Wash thoroughly after handling.

Storage:
Technical measures/storage conditions: Keep containers tightly closed in a cool, well-ventilated place. Store between 15-30°C (59 to 86°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:
Hydromorphone hydrochloride 71-68-1	None	None	None	None	None	None
Methyl Paraben 99-76-3	None	None	None	None	None	None
Propyl Paraben 94-13-3	None	None	None	None	None	None
Edetate Disodium 139-33-3	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures: No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:

Respiratory protection: Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat.

Eye protection: Safety glasses. Goggles, face shield, or other full-face protection if potential exists for direct exposure to aerosols or splashes.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Appearance: Not available.
Color: Colorless
Odor: Not available.
pH: 3.5 - 5.5
Molecular weight: Not available.
Boiling point/range: Not available.
Melting point/range: Not available.
Density: Not available.
Vapor pressure: Not available.
Evaporation rate: Not available.
Solubility: Soluble in water.

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: Not available.

Materials to avoid: Acids. Bases. Oxidizing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Hydromorphone hydrochloride 71-68-1	Subcutaneous LD50 Rat = 51 mg/kg Subcutaneous LD50 Mouse = 120 mg/kg Intravenous LD50 Mouse = 55 mg/kg
Methyl Paraben 99-76-3	Oral LD50 Mouse > 8 g/kg
Propyl Paraben 94-13-3	Oral LD50 Mouse = 6332 mg/kg
Edetate Disodium 139-33-3	Oral LD50 Rat = 2 gm/kg Oral LD50 Mouse = 2050 mg/kg
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: Target organs: Nervous System, Gastrointestinal tract.

Carcinogenic effects: No data is available on the product itself.

Mutagenic effects: No data is available on the product itself.

Reproductive toxicity: Fetotoxic at high doses based on animal data. See patient package insert for additional information.

FDA Pregnancy Catagory C

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Microtox Etoxicity Data
Hydromorphone hydrochloride 71-68-1	None.	None.	None.	None.
Methyl Paraben 99-76-3	None.	None.	None.	None.
Propyl Paraben 94-13-3	None.	None.	None.	None.
Edetate Disodium 139-33-3	None.	LC50 (96 hr) bluegill:159 mg/L:Static.	None.	None.
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Follow schedule II controlled substance requirements.

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 - 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:
Hydromorphone hydrochloride	0.2	Not Listed	Not Listed	Not Listed	Not Listed
Methyl Paraben	<0.2	Not Listed	Not Listed	Not Listed	Not Listed
Propyl Paraben	<0.05	Not Listed	Not Listed	Not Listed	Not Listed
Edetate Disodium	<0.1	Not Listed	Not Listed	Not Listed	Not Listed
Water	>99	Not Listed	Not Listed	Not Listed	Not Listed

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:
Hydromorphone hydrochloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Methyl Paraben	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Propyl Paraben	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Edetate Disodium	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:
NONE

Safety Phrases:
NONE

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s)?:
Additional product codes.

Additional information:
Not Available.

Prepared by: Technology Resources, Baxter Healthcare Corporation

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End of safety data sheet: