



Material Safety Data Sheet

MSDS Number: 1130401
Revision date: 10/18/2005
Print date: 10/18/2005

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1130401
Product name: Azithromycin for Injection
Product code: NDC 10019-648-71, NDC 10019-648-02
Synonyms: None
Chemical Family: Antibiotic
Product Type: Regulated Prescription Drug
Container Information: 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:
Azithromycin dihydrate 117772-70-0	<50	None	None
Citric Acid Anhydrous 77-92-9	<40	None	Xi; R38, R41
Sodium Hydroxide 1310-73-2	<20	UN1823 (solid); UN1824 (solution)	C;R35

3. HAZARDS IDENTIFICATION

Emergency overview: Irritation potential to skin, eyes, and mucous membranes. May cause allergic reaction.

Principle routes of exposure: Skin. Eye contact. Inhalation. Ingestion.

Inhalation: Inhalation not likely under normal use conditions. May cause respiratory tract irritation.

Ingestion: May irritate digestive tract. Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Dermatologic effects (may include exfoliative dermatitis, photosensitivity, rash, itching). Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Nervous system effects (headache, dizziness, light headedness).

Skin contact: May cause skin irritation.

Eye contact: Can cause eye irritation.

Product id: 1130401

Product name: Azithromycin for Injection

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. 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 available
Flammable limits in air-lower (%):	Not available
Flammable limits in air-upper (%):	Not available

7. HANDLING AND STORAGE

Handling:	
Technical measures/precautions:	Wash thoroughly after handling. Avoid skin contact. Avoid eye contact. Do not ingest.
Storage:	
Technical measures/storage conditions:	Keep in a cool, well-ventilated place.
Incompatible products:	No special restrictions on storage with other products.

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 vacuum or carefully scoop up spilled materials and place in an appropriate container for disposal.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Product id: 1130401

Product name: Azithromycin for Injection

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:
Azithromycin dihydrate 117772-70-0	None	None	None	None	None	None
Citric Acid Anhydrous 77-92-9	None	None	None	None	None	None
Sodium Hydroxide 1310-73-2	= 2 mg/m ³ TWA	None	= 2 mg/m ³ Ceiling	None	None	= 2 mg/m ³ Ceiling

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 CFR 1910.134 (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. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Eye protection: Safety glasses with side-shields. Goggles, face shield, or other full-face protection if potential exists for direct exposure to dust.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid.
Appearance: Lyophilized powder
Color: White
Odor: Not available.
pH: Not available.
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: 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: Not available.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Azithromycin dihydrate 117772-70-0	Oral LD50 Rat > 2 g/kg Oral LD50 Mouse > 3 g/kg
Citric Acid Anhydrous 77-92-9	Oral LD50 Rat = 3 gm/kg Oral LD50 Mouse = 5040 mg/kg Intraperitoneal LD50 Rat = 290 mg/kg Intraperitoneal LD50 Mouse = 903 mg/kg
Sodium Hydroxide 1310-73-2	None

Acute toxicity: Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Dermatologic effects (may include exfoliative dermatitis, photosensitivity, rash, itching). Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Nervous system effects (headache, dizziness, light headedness). Irritation potential to skin, eyes, and mucous membranes.

Chronic toxicity: No data is available on the product itself.

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No data is available on the product itself.

Mutagenic effects: Not mutagenic in a standard battery of genetic toxicological tests.

Reproductive toxicity: No impairment to fertility. Not considered fetotoxic based on animal data.

FDA Pregnancy Category B

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Microtox Etoxicity Data
Azithromycin dihydrate 117772-70-0	None.	None.	None.	None.
Citric Acid Anhydrous 77-92-9	None.	None.	None.	= 14 mg/L EC50 Photobacterium phosphoreum
Sodium Hydroxide 1310-73-2	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

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 -

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:
Azithromycin dihydrate	<50	Not Listed	Not Listed	Not Listed	Not Listed
Citric Acid Anhydrous	<40	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Hydroxide	<20	Not Listed	= 1000 lb final RQ = 454 kg final RQ	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:
Azithromycin dihydrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Citric Acid Anhydrous	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Hydroxide	Not Listed	Present	Not Listed	Toxic, Flammable	Present	environmental hazard	sn 1706

CANADIAN REGULATIONS:

Canada DSL Inventory List -

This product does not comply with DSL

EU EINECS List -

This product does not comply with EINECS

Risk Phrases:

NONE

Safety Phrases:

NONE

16. OTHER INFORMATION

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

None

Additional information:

Not Available.

Prepared by:

Technology Resources, Baxter Healthcare Corporation

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: