

Material Safety Data Sheet

MSDS Number: 1117937 Revision date: 06/05/2011 Print date: 06/05/2011

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1117937

Product name: Fluconazole Injection

Product Codes: 2J1446, 2J1445, NDC 0338-6046-48, NDC 0338-6045-37

Synonyms: None **Chemical Family:** Antifungal

Product Type: Regulated Prescription Drug **Container Information:** INTRAVIA plastic container.

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:
Fluconazole	0.2	None	None
86386-73-4			
Sodium Chloride	0.9	None	Xi; R38
7647-14-5			
Water	>98	None	None
7732-18-5			

3. HAZARDS IDENTIFICATION

Emergency overview: MAY BE HARMFUL IF SWALLOWED. Avoid eye contact. Avoid skin contact.

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 (headache, dizziness, light headedness). Dermatologic effects (may include exfoliative dermatitis, photosensitivity, rash, itching). Liver function effects (may include increased levels of SGOT, SGPT, serum LDH, jaundice). May be harmful

if swallowed.

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.

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.

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:

Autoignition temperature:

Flammable limits

Not determined
Not available.
Not available.

in air-lower (%):
Flammable limits

Not available.

in air-upper (%):

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: 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: Avoid eye contact. Avoid skin contact. Wash thoroughly after handling.

Storage:

Technical measures /Storage conditions:

Store between 5-25°C (41-77°F). Protect from freezing. Avoid excessive heat.

Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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:
Fluconazole 86386-73-4	None	None	None	None	None	None
Sodium Chloride 7647-14-5	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:No personal respiratory protective equipment normally required.

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: 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: Clear

Odor: Not available. 4.0 - 8.0:Ha Molecular weight: Not applicable. Not available. Boiling point/range: Not available. Melting point/range: Density: Not available. Not available. Vapor pressure: **Evaporation rate:** Not available. Soluble in water. Solubility:

Partition coefficient (n-

octanol/water):

Not available.

Viscosity: Not available. Wolatile by Volume: Not available.

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Polymerization: Not applicable

Hazardous decomposition

products:

Not available.

10. STABILITY AND REACTIVITY

Materials to avoid: Not available.

11. TOXICOLOGICAL INFORMATION

Component	LD50 Dermal	LC50 Inhalation	LD50 Oral
Fluconazole 86386-73-4	-	-	-
Sodium Chloride 7647-14-5	10 g/kg (rabbit)	42 g/m³ (rat)	3 g/kg (rat)
Water 7732-18-5	-	-	90 mL/kg (rat)

Acute toxicity: Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry

mouth, colic). Nervous system effects (headache, dizziness, light headedness). Dermatologic effects (may include exfoliative dermatitis, photosensitivity, rash, itching). Liver function effects (may include increased levels of SGOT, SGPT, serum LDH,

jaundice).

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

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. Not carcinogenic based

on animal data. See patient package insert for additional information.

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

Reproductive toxicity: No impairment to fertility based on animal data. May be teratogenic based on animal

data.

FDA Pregnancy Catagory C

12. ECOLOGICAL INFORMATION

Environmental properties:

	Ecotoxicity - Water Flea Data	Ecotoxicity	•	Ecotoxicity - Microtox Data
Fluconazole 86386-73-4	None.	None.	None.	None.

	12. ECOLOGICAL INFORMATION						
Sodium Chloride 7647-14-5	340.7 - 469.2 mg/L EC50 48 h 1000 mg/L EC50 48 h	4747-7824 mg/L LC50 Oncorhynchus	None.	None.			
Water 7732-18-5	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:NoneUN Number:NoneDOT Packing Group:NoneDOT Hazard class:None

TDG (Canada):

TDG Proper shipping name:

TDG UN/NA Number:

None
TDG Packing Group:

None
TDG Hazard class:

None

ADR/RID:

ADR Official Transport Name:

ADR Proper shipping name:

ADR UN/NA number:

ADR Hazard Class:

None

None

ICAO / IATA:

IATA Proper shipping name:NoneIATA UN Number:NoneIATA Primary Hazard:NoneIATA Packing group:None

14. TRANSPORT INFORMATION

ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name:NoneIMDG Hazard Class and Division:NoneIMDG Packing Group:NoneIMDG 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:
Fluconazole	0.2	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride	0.9	Not Listed	Not Listed	Not Listed	Not Listed
Water	>98	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California	Minnesota	Florida Right-	Rhode Island	Massachusetts	Pennsylvania	New Jersey Right-to-
	Prop. 65	Right-To -	to-Know	Right-to-Know	Right-to-Know	Right-to-Know:	Know:
		Know:	Reporting List:	List:	List:		
Fluconazole	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride	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 does not comply with EINECS

Risk Phrases:

NONE

Safety Phrases:

NONÉ

16. OTHER INFORMATION

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

Changes to Section 8.

Additional information:

Not Available.

16. OTHER INFORMATION

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: