	Sagent Pharmaceuticals, Inc.				
	Fluconazole Injection, USP			Material Safety Data Sheet (MSDS)	
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Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier: Fluconazole Injection, USP (2 mg/mL)
Product Code: NDC 25021-113-82
 NDC 25021-113-87
Common/Trade Name: Fluconazole; Diflucan
Chemical Name: 2,4-difluoro- α,α^1 -bis(1H-1,2,4-triazol-1-ylmethyl) benzyl alcohol
Chemical Family: Synthetic triazole antifungal agent
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Plastic Bags

Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	OSHA PEL	ACGGIH TLV	Other Limits Recommended	CAS No.
Fluconazole	0.2	None	None	None	86386-73-4
Sodium Chloride	0.9	None	None	None	7647-14-5
Water for Injection	>98.0	None	None	None	7732-18-5


Section 3 - Hazards Identification

Primary Physical and Health Hazards: May be harmful if swallowed. Avoid eye contact. Avoid skin contact.

Routes of Entry: Absorbed through skin. Eye contact. Ingestion.

Signs & Symptoms of Exposure: Irritation of the eyes and skin as well as redness and local swelling after accidental injection.

Chemical Listed as Carcinogen: NTP: No IARC: No OSHA: No

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Medical Conditions Generally Aggravated by Exposure: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, burning sensation, nausea, vomiting, diarrhea, headache and abdominal pain may occur.

May cause reproductive and developmental effects in some animals.

Section 4 - First Aid Measures

Eye Exposure: Immediately flush eye with plenty of water for at least 15 minutes. Get medical attention.

Skin Exposure: 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.

Injection: Not available.

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

Notes to Physician: See package insert in case pack/carton for complete information.

Section 5 - Fire Fighting Measures


Flash Point Not Applicable

Autoignition Temperature: Not Applicable

Flammable Limits in Air Lower %: Not Established
Upper %: Not Established

Flammable Limits: Not available

Extinguishing Media Use foam or all purpose dry chemicals to extinguish.

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Special Fire Fighting Procedures:

As with all fires, evacuate personnel to a safe area. Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

Unusual Fire/Explosion Hazards:

Not available

Section 6 - Accidental Release Measures

Spill:

Dispose according to local, state, and federal guidelines. Prevent contact with sewers and waterways. Wash area with soap and water. Wear personal protective equipment.

Release to Air:

If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation. Wear respiratory protection as necessary.

Release to Water:

Refer to local and regional water authority; drain disposal is not recommended. Refer to local, state and federal guidelines.

Section 7 - Handling and Storage

General Handling:


See Section 6 above. 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 like spilled material or otherwise contain material into ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

Waste Disposal Method:

Dispose of waste in accordance with all applicable Federal, State and local laws.

Storage Conditions:

Store units in moisture barrier overwrap. Store at Controlled room temperature 20° to 25°C (68° to 77°F) [see USP] until ready to use. Avoid excessive heat. Protect from freezing.

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Section 8 - Exposure Controls / Personal Protection

Respiratory Protection:	Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.
Eye Protection:	Safety glasses or goggles.
Ventilation:	Handle product in a well ventilated area.
Skin Protection:	If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.
Other Protective Equipment:	Lab coat.
Additional Exposure Precautions:	Wash hands following use. No eating, drinking or smoking when handling this product.

Exposure Limits


<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Fluconazole	OSHA	TLV	NE
	ACGIH	PEL	NE
	-----	STEL	NE

Section 9 - Physical and Chemical Properties

Physical State:	Liquid	Specific Gravity:	Not Available
Appearance and Odor:	Clear almost colorless	Evaporation Rate:	Not Available
Boiling Point:	Not Available	Solubility in Water:	Soluble
Vapor Pressure:	Not Available	pH:	4.0-8.0
Vapor Density:	Not Available	Molecular Weight	306.3

Section 10 - Stability and Reactivity

Stability:	Stable under recommended storage conditions. Brief exposure up to 104°F (40°C) does not adversely affect the product. Protect from freezing.
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Incompatibility (Materials to avoid): See product packaging and the physician's Desk Reference (PDR) for Drug Interaction.

Hazardous Decomposition: Not available.

Hazardous Polymerization: Will not occur.

Conditions to Avoid: Do not freeze.

Section 11 - Toxicological Information

Signs & Symptoms of Exposure & Overexposure: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, burning sensation, nausea, vomiting, diarrhea, headache and abdominal pain may occur. Fluconazole has caused reproductive and developmental effects on some animals.

Acute Toxicity


Component	Type	Route	Species	Dosage
Fluconazole	LD ₅₀	Oral	Mouse	=1408 mg/kg
Fluconazole	LD ₅₀	Intravenous	Mouse	>200 mg/kg
Fluconazole	LD ₅₀	Oral	Rat	>1.27 gm/kg

Section 12 - Ecological Information

Information is currently not available on the environmental impact of Fluconazole. Handle in a manner to prevent spills or releases to the environment.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

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Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

TSCA - *Not on this list*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*


SARA 313 - *Not on this list*

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. **THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE).** In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)