Section 1 - Identification

(a) Product Identifier: Fluconazole Injection, USP (2 mg/mL)

(b) Product Code: 25021-113, 25021-184

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

(c) Product Use: antifungal agent

Product Type: Regulated Prescription Drug

Container Information: Plastic Bags

(d) Distributor: Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 450, Schaumburg, IL 60195, 847-908-1600

(e) Emergency Telephone: 866-625-1618

Section 2 - Hazards Identification

(a) Classification: US OSHA: Target Organ Toxin, Possible Irritant

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	**(c) Description of Hazards:**

GHS Precautionary Statements

Prevention

- P260: Do not breathe dust/fume/vapors/spray

Response

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention
- Get medical attention if you feel unwell

(d) Unknown Acute Toxicity: N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
2,4-difluoro-α,α[1]-bis(1H-1,2,4-triazol-1-	Fluconazole	0.2%	86386-73-4	N/A

ylmethyl) benzyl alcohol				
Sodium Chloride	Sodium Chloride	0.9%	7647-14-5	N/A
Water	Water for Injection	>98.0%	7732-18-5	N/A

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

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

(b) Hazardous Combustion Products: Not available

(c) Special Protective Equipment / Precautions: 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.

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.

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.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Fluconazole	OSHA	PEL	NE
	ACGIH	TLV	NE
Sodium Chloride	OSHA	PEL	NE
	ACGIH	TLV	NE
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE

(b) Engineering Controls

Ventilation: Handle product in a well ventilated area.

(c) Individual Protection Measures

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.
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.

Section 9 - Physical and Chemical Properties

(a)	**Appearance**	Liquid, clear almost colorless
(b)	**Odor**	N/A
(c)	**Odor Threshold**	N/A
(d)	**pH**	4.0 – 8.0
(e)	**Melting Point:**	Not Applicable
(f)	**Initial Boiling Point:**	Not available
(g)	**Flash Point**	Not Applicable
(h)	**Evaporation Rate:**	Not available
(i)	**Flammability**	Not Applicable
(j)	**Upper Lower Flammability or Explosion Limits**	Not Applicable
(k)	**Vapor Pressure:**	Not available
(l)	**Vapor Density:**	Not available
(m)	**Relative Density**	Not available
(n)	**Solubility(ies)**	Soluble in water
(o)	**Partition Coefficient: n-octanol/water**	Not available
(p)	**Auto-ignition Temperature**	Not Applicable
(q)	**Decomposition Temperature**	Not available
(r)	**Viscosity**	Not available

Section 10 - Stability and Reactivity

(a)	**Reactivity**	Not Available
(b)	**Chemical Stability**	Stable under recommended storage conditions. Brief exposure up to 104°F (40°C) does not adversely affect the product. Protect from freezing.
(c)	**Possibility of Hazardous Reactions**	Hazardous polymerization will not occur.
(d)	**Conditions to Avoid**	Do not freeze.
(e)	**Incompatible Materials**	See product packaging and the physician's Desk Reference (PDR) for Drug Interaction.
(f)	**Hazardous Decomposition Products**	Not available.

Section 11 - Toxicological Information

(a)	**Likely Routes of Exposure**	Absorbed through skin. Eye contact. Ingestion.
(b)	**Symptoms related to the physical, chemical and toxicological characteristics**	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.
(c)	**Delayed and immediate effects and also chronic effects from short and long term exposure**	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.

(d) 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
Fluconazole	LD_{50}	Intraperitoneal	Mouse	1273 mg/kg
Fluconazole	LD_{50}	Intraperitoneal	Rat	>941 mg/kg
Fluconazole	LD_{50}	Intravenous	Rat	>200 mg/kg
Fluconazole	LD_{50}	Intravenous	Dog	>100 mg/kg

(e) Hazardous Chemical Listings

NTP: Not Listed IARC: Not Listed OSHA: Not Listed

Section 12 - Ecological Information

(a)	**Ecotoxicity**	Not considered a DOT Marine Pollutant.
(b)	**Persistence and degradability**	Not established
(c)	**Bioaccumulative potential**	Not established
(d)	**Mobility in soil**	Not established
(e)	**Other Adverse Effects**	Not established

Section 13 - Disposal Considerations

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater

Section 14 - Transport Information

(a)	**UN Number**	Not Available
(b)	**UN Proper Shipping Name**	Not Available
(c)	**Transport Hazard Class(es)**	Not Available
(d)	**Packing Group**	Not Available
(e)	**Environmental Hazards**	Not Available
(f)	**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)**	Not Available
(g)	**Special Precautions**	Not Available

DOT: Not regulated
ICAO/IATA: Not regulated
IMDG: 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 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:
Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 450
Schaumburg, IL 60195
847-908-1600

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

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
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
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMDG	International Maritime Dangerous Goods
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
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
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
SDS	Safety Data Sheet

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)
WHMIS	Workplace Hazardous Materials Information System