



Revision date 05-Dec-2024

Version 2

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE **COMPANY/UNDERTAKING**

1.1. Product identifier

Product Name

Product Code(s) Trade Name: **Chemical Family:** PZ03186 Not applicable Synthetic class of compounds known as bis-triazoles

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use

Pharmaceutical product used as antifungal agent

Fluconazole Injection (Hospira, Inc.)

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company 275 North Field Drive Lake Forest, Illinois 60045 1-800-879-3477		Pfizer Ireland Pharmaceuticals OSG Building Ringaskiddy, Co. Cork. Ireland +353 21 4378701
E-mail address	pfizer-MSDS@pfizer.com	

E-mail address

1.4. Emergency telephone number

Emergency Telephone

Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Reproductive toxicity Effects on or via lactation	Category 1B - (H360D) Yes - (H362)
<u>2.2. Label elements</u> Signal word	Danger
Hazard statements	H360D - May damage the unborn child H362 - May cause harm to breast-fed children

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Precautionary Statements

- P201 Obtain special instructions before use
- P202 Do not handle until all safety precautions have been read and understood
- P260 Do not breathe mist
- P263 Avoid contact during pregnancy/while nursing
- P264 Wash hands thoroughly after handling
- P280 Wear protective gloves and protective clothing
- P308 + P313 IF exposed or concerned: Get medical advice/attention
- P405 Store locked up
- P501 Dispose of contents/container in accordance with all local and national regulations



2.3. Other hazards Other hazards

Note:

Additional information

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

For a more detailed discussion of potential health hazards and toxicity see Section 11.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Fluconazole (CAS #: 86386-73-4)	0.2		Not Listed	Acute Tox.4 (H302) Repr.1B (H360D) Lact. (H362) Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)	Not Listed	No data available	No data available
NonHazardous							
Chemical name	Weight-%	REACH Registration	EC No	Classification according to	Specific concentration	M-Factor	M-Factor (long-term)

		Number		Regulation (EC) No. 1272/2008 [CLP]	limit (SCL)		
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Dextrose, monohydrate (CAS #: 5996-10-1)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)		-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50		Inhalation LC50 - 4	
			hour - dust/mist - mg/L	hour - vapor - mg/L	hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3550	10000	No data available	No data available	No data available
Fluconazole 86386-73-4	1325	No data available	No data available	No data available	No data available

Additional information

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.		
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.		
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.		
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.		
4.2. Most important symptoms and	effects, both acute and delayed		
Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.		

4.3. Indication of any immediate medical attention and special treatment needed

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Note to physicians	None.			
Section 5: FIRE-FIGHTING M	EASURES			
5.1. Extinguishing media				
Suitable Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.			
5.2. Special hazards arising from the	ne substance or mixture			
Specific hazards arising from the chemical	Fine particles (such as mists) may fuel fires/explosions.			
Hazardous combustion products	Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds			
5.3. Advice for firefighters				
Special protective equipment for fire-fighters	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.			
Section 6: ACCIDENTAL REI	LEASE MEASURES			
6.1. Personal precautions, protectiv	ve equipment and emergency procedures			
Personal precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.			
For emergency responders	Use personal protection recommended in Section 8.			
6.2. Environmental precautions				
Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.			
6.3. Methods and material for conta	ainment and cleaning up			
Methods for containment Methods for cleaning up	Prevent further leakage or spillage if safe to do so. Clean spill area thoroughly. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal.			
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.			
6.4. Reference to other sections				
Reference to other sections	See section 8 for more information. See section 13 for more information.			
Section 7: HANDLING AND S	STORAGE			

7.1. Precautions for safe handling

Advice on safe handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

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Storage Conditions	Store as directed by product packaging.		
7.3. Specific end use(s)			
Specific use(s)	Pharmaceutical drug product.		
Section 8: EXPOSURE CONT	ROLS/PERSONAL PROTECTION		
8.1. Control parameters			
Exposure Limits Refer to available public information f	or specific member state Occupational Exposure Limits.		
Fluconazole Pfizer OEL TWA-8 Hr: 500 μg/r SODIUM CHLORIDE	n ³		
Latvia Russia	5 mg/m³ MAC: 5 mg/m³		
SODIUM CHLORIDE Pfizer Occupational Exposure Band (OEB): 8.2. Exposure controls	OEB 1 (control exposure to the range of 1000ug/m ³ to 3000ug/m ³)		
Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.		
Environmental exposure controls	No information available.		
Personal protective equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.		
Eye/face protection	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).		
Hand protection	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).		
Skin and body protection	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).		
Respiratory protection	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)		
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.		

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties Physical state Color Odor Odor threshold

Molecular formula Molecular weight <u>Property</u>

pH pH (as aqueous solution)

Melting point / freezing point Boiling point / boiling range Flash point Evaporation rate Flammability (solid, gas) Flammability Limit in Air Upper flammability limit:

Lower flammability limit:

Vapor pressure Vapor density Relative density Water solubility Solubility(ies) Partition coefficient Autoignition temperature Decomposition temperature Kinematic viscosity Dynamic viscosity Particle characteristics Particle Size Particle Size Particle Size Distribution Explosive properties

Partition Coefficient: (Method, pH, Endpoint, Value) <u>Fluconazole</u> Predicted Log P 5.0

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes No information available

9.2.2. Other safety characteristics

No information available

Liquid Colorless Odorless. No information available Mixture Mixture

Values

4 - 8; 3.5 - 6.5

(sodium chloride solution) (dextrose solution) No data available

No information available No data available No data available

No data available

No data available

No data available No data available No data available No data available No data available No data available No data available No data available No data available No data available

No information available No information available No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity Reactivity

No data available.

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10.2. Chemical stability Stability	Stable under normal conditions.
Explosion data Sensitivity to Mechanical Impact Sensitivity to Static Discharge	
10.3. Possibility of hazardous reaction Possibility of hazardous reactions Hazardous polymerization	
10.4. Conditions to avoid Conditions to avoid	Protect from. freezing.
10.5. Incompatible materials Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
10.6 Hazardous decomposition prov	ducts

10.6. Hazardous decomposition products Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	The information included in this section describes the potential hazards of the individual ingredients
Short term	May cause irritation (based on components)
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on liver and the developing fetus.
Known Clinical Effects:	Clinical use of this drug has caused headache, skin rash, vomiting, abdominal pain, and diarrhea. Fluconazole is found in human breast milk at concentrations similar to plasma. Therefore, nursing mothers should limit exposure. There have been reports of multiple congenital abnormalities in infants whose mothers were being treated for three or more months with high dose (400-800mg/day) fluconazole. Rare cases of serious liver damage and allergic reactions have been reported.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	May damage the unborn child. May cause harm to breast-fed children. Classification is
	based on mixture calculation methods based on component data.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

SODIUM CHLORIDERat Sub-tenon injection (eye)LC50/1hr > 42 g/m³Rat Oral LD 50 3 g/kgMouse Oral LD 50 4 g/kgRabbit Dermal LD 50 > 10 g/kgFluconazoleRat (F) Oral LD50 1575 mg/kgRat (M) Oral LD50 1325 mg/kgMouse Oral LD50 1410 mg/kgMouse (M) Oral LD50 1520 mg/kgDog Intravenous LD50 > 100 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
SODIUM CHLORIDE	= 3550 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat)1 h
Fluconazole	= 1271 mg/kg (Rat)	-	-

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Sobium CHLORIDE Skin irritation Rabbit Mild Eye irritation Rabbit Mild

<u>Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)</u> Fluconazole

3 Month(s) Rat Oral 5 mg/kg/day NOAEL Liver 6 Month(s) Dog Oral 7.5 mg/kg/day NOAEL Liver 12 Month(s) Rat Oral 10 mg/kg/day LOAEL Liver 12 Month(s) Dog Oral 2.5 mg/kg/day NOAEL Liver

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s)) Fluconazole

Reproductive & Fertility Rat Oral 20 mg/kg/day NOAEL Negative Embryo / Fetal Development Rabbit Oral 20 mg/kg/day NOAEL Maternal Toxicity, Not Teratogenic Embryo / Fetal Development Rat Oral 5 mg/kg/day NOAEL Fetotoxicity, Maternal Toxicity Embryo / Fetal Development Rat Oral 80 mg/kg/day LOAEL Maternal Toxicity, Developmental toxicity Peri-/Postnatal Development Rat Oral 10 mg/kg NOAEL Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result) Fluconazole

In Vitro Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative

In Vitro Cytogenetics Human Lymphocytes Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s)) Fluconazole

24 Month(s) Rat Female Oral 10 mg/kg/day NOAEL Not carcinogenic 24 Month(s) Rat Male Oral 5 mg/kg/day LOEL Benign tumors, Liver 24 Month(s) Mouse Oral 10 mg/kg/day NOEL Not carcinogenic **Carcinogenicity** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

11.2. Information on other hazards11.2.1. Endocrine disrupting propertiesEndocrine disrupting propertiesNo information available.

11.2.2. Other information Other adverse effects

No information available.

Section 12: ECOLOGICAL INFORMATION

Product Name Fluconazole Injection (Hospira, Inc.) Revision date 05-Dec-2024

Environmental Overview:

The environmental characteristics of this mixture have not been fully evaluated. Based on the concentration of the active ingredient in the formulation, No harmful effects to aquatic organisms are expected.

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result) Fluconazole Daphnia magna (Water Flea) LC50 48 hours 35 mg/L

Pimephales promelas (Fathead Minnow) LC50 > 50 mg/L *Cyprinodon variegatus* (Sheepshead Minnow) LC50 > 50 mg/L

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value) Fluconazole Predicted Log P 5.0

12.4. Mobility in soil

Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does
	not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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 wastewater 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

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable
Special precautions for user:	Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present
Dextrose, monohydrate	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
SODIUM CHLORIDE	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-598-3
AICS	Present
Fluconazole	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
Standard for Uniform Scheduling of Medicines and	Schedule 3
Poisons (SUSMP)	Schedule 4
. ,	

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
SODIUM CHLORIDE	RG 78	-
7647-14-5		

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This

product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report	No information available
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Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Reproductive toxicity-Cat.1B; H360D - May damage the unborn child Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.
Reason for revision	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.
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Prepared By	Pfizer Global Environment, Health, and Safety

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