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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Vfend (Voriconazole) Powder For Oral Suspension

Trade Name: Vfend; SPIONIC; Voriconazole Pfizer

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antifungal agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc Pfizer Pharmaceuticals Group 235 East 42nd Street New York, New York 10017

1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd Ramsgate Road Sandwich, Kent

CT13 9NJ United Kingdom +00 44 (0)1304 616161

Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B Carcinogenicity: Category 2

Specific target organ systemic toxicity (repeated exposure): Category 2

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger

Hazard Statements: H360D - May damage the unborn child

H350 - May cause cancer

H373 - May cause damage to organs through prolonged or repeated exposure May form

combustible dust concentrations in air

Precautionary Statements: P202 - Do not handle until all safety precautions have been read and understood

P260 - Do not breathe dust/fume/gas/mist/vapors/spray P281 - Use personal protective equipment as required

P308 + P313 - IF exposed or concerned: Get medical attention/advice

P405 - Store locked up

P501 - Dispose of contents/container in accordance with all local and national regulations

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Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see

Section 8).

Note: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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS	GHS Classification	%
		List		
Voriconazole	137234-62-9	Not Listed	Acute Tox.3 (H301) Carc. 2 (H351) Repr. 1B (H360D) STOT RE 2 (H373) Aquatic Acute 3 (H402)	6.67
Sucrose	57-50-1	200-334-9	Not Listed	*
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	*
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium citrate, dihydrate	6132-04-3	Not Listed	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	*
Xanthan gum	11138-66-2	234-394-2	Not Listed	*
Natural orange flavor	NOT ASSIGNED	Not Listed	Not Listed	*

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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures
Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention

immediately.

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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.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Exposure: Identification and/or Section 11 - Toxicological Information.

Medical Conditions None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds

Products:

carzon monorale, carzon alexado, imagen exade ana nacimo comaming competin

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning /

Collecting:

Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of

dry solids. Clean spill area thoroughly.

Additional Consideration for

Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

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Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Voriconazole

Pfizer OEL TWA-8 Hr: 100µg/m³

Sucrose

10 mg/m ³
10 mg/m ³
10 mg/m ³
10.0 mg/m ³
10 mg/m ³
10 mg/m ³
10 mg/m ³
5 mg/m ³
10 mg/m ³
15 mg/m ³
10 mg/m ³
6 mg/m ³
10 mg/m ³

Silicon dioxide, colloidal NF

ii dioxido, concidai iii	
Australia TWA	2 mg/m ³
Austria OEL - MAKs	4 mg/m³
Czech Republic OEL - TWA	0.1 mg/m ³
	4.0 mg/m ³
Estonia OEL - TWA	2 mg/m³
Finland OEL - TWA	5 mg/m³
Germany - TRGS 900 - TWAs	4 mg/m ³
Germany (DFG) - MAK	4 mg/m ³
Ireland OEL - TWAs	6 mg/m³
	2.4 mg/m ³
Latvia OEL - TWA	1 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed

Titanium dioxide

idiii diexido	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	5 mg/m³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Denmark OEL - TWA	6 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Estonia OEL - TWA 5 mg/m³ France OEL - TWA 10 mg/m³ **Greece OEL - TWA** 10 mg/m³ 5 mg/m³

Ireland OEL - TWAs 10 mg/m³ 4 mg/m³

Latvia OEL - TWA 10 mg/m³ Lithuania OEL - TWA 5 mg/m³ **OSHA - Final PELS - TWAs:** 15 mg/m³ 10.0 mg/m³ **Poland OEL - TWA** 10 mg/m³ Portugal OEL - TWA Romania OEL - TWA 10 mg/m³ **Russia OEL - TWA** 10 mg/m³ Spain OEL - TWA 10 mg/m³ **Sweden OEL - TWAs** 5 mg/m^3 **Switzerland OEL -TWAs** 3 mg/m³ Vietnam OEL - TWAs 6 mg/m³ 5 mg/m³

Exposure Controls

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.

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.

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is Hands:

possible and for bulk processing operations. (Protective gloves must meet the standards in

accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: 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.)

Skin: 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.)

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is Respiratory protection:

> 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.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Powder Color: White to off-white Odor: No data available. **Odor Threshold:** No data available.

Molecular Formula: Mixture **Molecular Weight:** Mixture

Solvent Solubility: No data available No data available Water Solubility: 3.5-4.5 (reconstituted)

Melting/Freezing Point (°C): No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): No data available. Partition Coefficient: (Method, pH, Endpoint, Value)

Voriconazole

Measured 7 Log P 1.75 Silicon dioxide, colloidal NF

No data available **Titanium dioxide** No data available **Xanthan gum** No data available

Sodium citrate, dihydrate

No data available

Sodium benzoate

No data available

Citric acid, anhydrous

No data available

Natural orange flavor

No data available

Sucrose

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):

Vapor Pressure (kPa):

Vapor Density (g/ml):

Relative Density:

No data available

Flammablity:

Autoignition Temperature (Solid) (°C):

Flammability (Solids):

Flash Point (Liquid) (°C):

Upper Explosive Limits (Liquid) (% by Vol.):

Lower Explosive Limits (Liquid) (% by Vol.):

Polymerization:

No data available
No data available
No data available
Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions. **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition No data available

Products:

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual

ingredients.

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11. TOXICOLOGICAL INFORMATION

Short Term: Harmful if swallowed . May produce slight eye irritation., (based on components) . Accidental

ingestion may cause effects similar to those seen in clinical use.

Long Term: Adverse reproductive effects seen in repeat-dose animal studies are consistent with the

pharmacologic action of this drug and are expected to be relevant to humans. Animal studies

indicate that this material may cause adverse effects on the liver, the developing fetus.

Known Clinical Effects:

The most common adverse effects reported with clinical use of voriconazole include visual

disturbances, elevations of liver function tests and skin rash. Voriconazole has been associated with photosensitivity skin reactions especially during long term therapy.

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

Voriconazole

Rat/Mouse Oral LD50 < 300 mg/kg Rat/Mouse Oral LDmin. > 100mg/kg

Rat IV LD50 > 100mg/kg Rat Dermal LD50 > 2000mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg Rat Subcutaneous LD50 50 mg/kg

Xanthan gum

Rat Oral LD50 > 5000 mg/kg

Sodium benzoate

Rat Oral LD50 4,070 mg/kg Mouse Oral LD50 1600mg/kg

Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

Sucrose

Rat Oral LD50 29.7 g/kg

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)

Voriconazole

Skin Irritation Rabbit Non-irritating

Skin Sensitization - GPMT Guinea Pig Negative

Eye Irritation Rabbit Minimal

Citric acid, anhydrous

Eye Irritation Rabbit Severe Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

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11. TOXICOLOGICAL INFORMATION

Voriconazole

1 Month(s) Rat Oral30 mg/kg/day NOAEL Liver

6 Month(s) Rat Oral 3 mg/kg/day NOAEL Liver, Kidney

12 Month(s) Dog Oral 8 mg/kg/day NOAEL Liver

6 Month(s) Rat Intravenous 10 mg/kg/day NOAEL Liver

6 Month(s) Dog Oral 6 mg/kg/day NOAEL Liver

Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood

10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Voriconazole

Reproductive & Fertility Rat Oral3 mg/kg/day NOAEL Fetotoxicity

Embryo / Fetal Development Rat Oral 10 mg/kg/day LOAEL Teratogenic

Sodium benzoate

Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

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

Voriconazole

Bacterial Mutagenicity (Ames) Bacteria Negative

In Vitro Human Lymphocytes Equivocal In Vivo Micronucleus Mouse Negative

Sucrose

Bacterial Mutagenicity (Ames) Salmonella Negative

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

Voriconazole

2 Year(s) Rat Oral 18 mg/kg/day NOEL Benign tumors, Liver

2 Year(s) Mouse Oral 30 mg/kg/day NOAEL Malignant tumors, Liver

Carcinogen Status: See below

Silicon dioxide, colloidal NF

IARC: Group 3 (Not Classifiable)

NTP: Reasonably Anticipated To Be A Human Carcinogen

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

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12. ECOLOGICAL INFORMATION

Environmental Overview: In the environment, the active ingredient in this formulation is expected to remain in water or

migrate through the soil to groundwater and degrade slowly . Harmful effects to aquatic

organisms could occur.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Voriconazole

Mysidopsis bahia (Mysid Shrimp) NPDES LC50 48 Hours 62 mg/L

Red Algae IC50 73 mg/L

Skeletonema costatum (Marine Diatom) NPDES IC-50 48 Hours 74.7 mg/L Green Algae OECD EbC50/72hr (OECD) EC50 72 Hours > 97 mg/L Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours 110 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum

dose tested.

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Voriconazole

Activated sludge OECD EC50 > 810 mg/L

Polytox MIC > 100 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Voriconazole

Daphnia magna (Water Flea) OECD 21 Day(s) NOEC > 1 mg/L

Pimephales promelas (Fathead Minnow) OECD 32 Day(s) NOEC 1.2 mg/L

Chironomus riparius (Sediment-Dwelling Midges) OECD 28 Day(s) NOEC 100 mg/L

Persistence and Degradability:

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Voriconazole

OECD Activated sludge Ultimate (CO2 Evolution) -0.24% After 28 Day(s) Not Ready

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Voriconazole

Measured 7 Log P 1.75

Mobility in Soil: No data available

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13. DISPOSAL CONSIDERATIONS

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 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.

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.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Voriconazole

CERCLA/SARA 313 Emission reportingNot ListedCalifornia Proposition 65Not ListedStandard for the Uniform SchedulingSchedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List Not Listed

Sucrose

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the

Not Listed
Present
Present

obligations of Register:

EU EINECS/ELINCS List 200-334-9

Citric acid, anhydrous

CERCLA/SARA 313 Emission reporting

California Proposition 65
Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed
201-069-1

Silicon dioxide, colloidal NF

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15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Eisted

Not Listed

Not

Titanium dioxide

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 carcinogen 9/2/2011 airborne, unbound particles of respirable size

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS/ELINCS List

Present
236-675-5

Sodium citrate, dihydrate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Sodium benzoate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Present

208-534-8

Xanthan gum

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Not Listed

Not Listed

Not Listed

Not Listed

Not Eisted

234-394-2

Natural orange flavor

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Carcinogenicity-Cat.2; H350 - May cause cancer

Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

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Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal

Protection.

Revision date: 22-Mar-2018

Product Stewardship Hazard Communication Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet