SAFETY DATA SHEET

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

1.1. Product identifier

Product Name Voriconazole for IV infusion

Product Code(s) 556
Trade Name: Vfend: SPIONIC; VIMERO; Voriconazole pfizer
Item Code H000009795,H000029241,H000029242,H000029246,H000029247,H000029248,R000131200;H000401162;H000005052;H000006963;H000008202;H000008203;H000008204;H000008207;H000008268;
Chemical Family: Mixture

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

Recommended Use Pharmaceutical product used as antifungal agent

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

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

Acute toxicity - Oral Category 4 - H302
Skin sensitization Category 1 - H317
Carcinogenicity Category 2 - H351
Reproductive toxicity Category 1B - H360D
Specific target organ toxicity (repeated exposure) Category 2 - H373

2.2. Label elements

Signal word Danger

Hazard statements
H302 - Harmful if swallowed
H317 - May cause an allergic skin reaction
H351 - Suspected of causing cancer
H360D - May damage the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure: liver

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 dust
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves and protective clothing
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P363 - Wash contaminated clothing before reuse
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

2.3. Other hazards

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.

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)
Sulfobutylether b-cyclodextrin sodium (SBECD) (CAS #: 7585-39-9)	*		231-493-2	Skin Sens. 1 (H317)	Not Listed	No data available	No data available
Voriconazole (CAS #: 137234-62-9)	5-7		Not Listed	Acute Tox.3 (H301) Carc. 2 (H351) Repr. 1B (H360D) STOT RE 2 (H373) Aquatic Acute 3 (H402)	Not Listed	No data available	No data available

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

Acute Toxicity Estimate
No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sulfobutylether b-cyclodextrin sodium (SBECD) 7585-39-9	No data available	2000	4.9	No data available	No data available
Voriconazole 137234-62-9	100	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

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and 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 Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective 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 containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

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 STORAGE

7.1. Precautions for safe handling

Advice on safe handling
Avoid generating airborne dust. 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. 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

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Sulfobutylether b-cyclodextrin sodium (SBECD)
Pfizer OEL TWA-8 Hr: 3000 µg/m^3

Voriconazole
Pfizer OEL TWA-8 Hr: 100 µg/m³
Sulfobutylether b-cyclodextrin sodium (SBECD)
Russia MAC: 10 mg/m³

8.2. 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.
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	Lyophilized powder
Color	White
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

Property	**Values**
pH	5.7-7.3
pH (as aqueous solution)	(reconstituted)
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available

Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)
Voriconazole
Measured 7 Log P 1.75

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

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity	No data available.

10.2. Chemical stability

Stability	Stable under normal conditions.
Explosion data	
Sensitivity to Mechanical Impact	No data available.
Sensitivity to Static Discharge	No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	No information available.
Hazardous polymerization	Will not occur.

10.4. Conditions to avoid

Conditions to avoid	Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials	As a precautionary measure, keep away from strong oxidizers.

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 produce slight eye irritation. May be harmful if swallowed (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	Classification is based on mixture calculation methods based on component data
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	Classification is based on mixture calculation methods based on component data.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Classification is based on mixture calculation methods based on component data.
Reproductive toxicity	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	Classification is based on mixture calculation methods based on component data.
Aspiration hazard	Based on available data, the classification criteria are not met.

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

Sulfobutylether b-cyclodextrin sodium (SBECD)

Rat Oral LD50 > 2000 mg/kg
Rat/Mouse IV LD50 > 2000 mg/kg

Voriconazole

Rat/Mouse Oral LD50 < 300 mg/kg
Rat/Mouse Oral LDmin. > 100 mg/kg
Rat IV LD50 > 100 mg/kg
Rat Dermal LD50 > 2000 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sulfobutylether b-cyclodextrin sodium (SBECD)		> 2000 mg/kg (Rat)	> 4.9 mg/L (Rat) 4 h

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)

Sulfobutylether b-cyclodextrin sodium (SBECD)

Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Non-irritating
Skin Sensitization - GPMT Guinea Pig Positive

Voriconazole

Skin irritation Rabbit Non-irritating
Skin Sensitization - GPMT Guinea Pig Negative
Eye Irritation Rabbit Minimal

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

Sulfobutylether b-cyclodextrin sodium (SBECD)

6 Month(s) Rat Intravenous 600 mg/kg/day NOAEL Kidney, Liver
1 Month(s) Rat Intravenous 160 mg/kg/day NOAEL Kidney
6 Month(s) Dog Intravenous 600 mg/kg/day NOAEL Kidney
1 Month(s) Dog Intravenous 120 mg/kg/day NOAEL Kidney

Voriconazole

1 Month(s) Rat Oral 30 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

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Sulfobutylether b-cyclodextrin sodium (SBECD)
Fertility and Embryonic Development Rat Intravenous 1500 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rabbit Intravenous 1500 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Rat Intravenous 600 mg/kg/day NOAEL Maternal Toxicity
Voriconazole
Reproductive & Fertility Rat Oral 3 mg/kg/day NOAEL Fetotoxicity
Embryo / Fetal Development Rat Oral 10 mg/kg/day LOAEL Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Sulfobutylether b-cyclodextrin sodium (SBECD)
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells HGPRT Negative
In Vivo Micronucleus Mouse Bone Marrow Negative
Voriconazole
Bacterial Mutagenicity (Ames) Bacteria Negative
In Vitro Human Lymphocytes Equivocal
In Vivo Micronucleus Mouse 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
Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

11.2. Information on other hazards
11.2.1. Endocrine disrupting properties
Endocrine disrupting properties No information available.

11.2.2. Other information
Other adverse effects No information available.

Section 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.

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
Sulfobutylether b-cyclodextrin sodium (SBECD)
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 hours > 220 mg/L
Daphnia magna (Water Flea) OECD EC-50 48 > 96 mg/L
Green algae OECD IC50 72 hours > 100 mg/L
Voriconazole
Mysidopsis bahia (Mysid Shrimp) NPDES LC50 48 hours 62 mg/L
Red Algae IC50 73 mg/L
Skeletonema costatum (Marine Diatom) NPDES IC50 48 hours 74.7 mg/L
Green Algae OECD EC10 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

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)
Voriconazole
Measured 7 Log P 1.75

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
Sulfobutylether b-cyclodextrin sodium (SBECD)	The substance is not PBT / vPvB

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

Sulfobutylether b-cyclodextrin sodium (SBECD)

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-493-2
AICS	Present

Voriconazole

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

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

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

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.3; H301 - Toxic if swallowed Carcinogenicity-Cat.2; H351 - Suspected of causing cancer Reproductive toxicity-Cat.1B; H360D - May damage the unborn child Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

Data Sources:	Pfizer proprietary drug development information.
Reason for revision	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.
Revision date	06-Nov-2022
Prepared By	Pfizer Global Environment, Health, and Safety

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