



# SAFETY DATA SHEET

Revision date 15-Jun-2025

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## 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

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

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

### OSHA Classification

**Hazards not otherwise classified (HNOC)**

Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**

Not applicable

### 2.2. Label elements

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## Signal word

## Hazard statements

## Danger

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 - EU (§28, 1272/2008)

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 should not be allowed out of the workplace  
P280 - Wear protective gloves and protective clothing  
P308 + P313 - IF exposed or concerned: Get medical advice/attention  
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
P362 + P364 - Take off contaminated clothing and wash it before reuse  
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell  
P330 - Rinse mouth  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable  
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

## 2.3. Other hazards

## Other hazards

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

## PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

## Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

## 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

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## Hazardous

| Chemical name  | Weight-% | REACH registration number | EC No (EU Index 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 classified                     | No data available | No data available    |
| Voriconazole (CAS #: 137234-62-9)                                | 5-7      |                           | Not Listed          | Acute Tox.3 (H301)<br>Carc. 2 (H351)<br>Repr. 1B (H360D)<br>STOT RE 2 (H373)<br>Aquatic Acute 3 (H402) | Not classified                     | 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 mg/kg   | Dermal LD50 mg/kg | 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                    |

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## 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

|                     |  |
|---------------------|--|
| <b>Inhalation</b>   | Remove to fresh air. Seek immediate medical attention/advice.  |
| <b>Eye contact</b>  | Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician. |
| <b>Skin contact</b> | Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.              |

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## 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

Dry chemical, CO2 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

#### Explosion data

##### Sensitivity to mechanical impact

No information available.

##### Sensitivity to static discharge

No information available.

### 5.3. Advice for firefighters

#### Special protective equipment and precautions 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

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

#### 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.

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## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

#### Advice on safe handling

Avoid generation of dust. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or 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<sup>3</sup>

#### Voriconazole

Pfizer OEL TWA-8 Hr: 100 µg/m<sup>3</sup>

#### Sulfobutylether b-cyclodextrin sodium (SBECD)

Russia

MAC: 10 mg/m<sup>3</sup>

### 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.

#### 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.).

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|                                 |  |
|---------------------------------|--|
| <b>Skin and body protection</b> | 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.).

|                        |                           |
|------------------------|---------------------------|
| <b>Thermal hazards</b> | No information available. |
|------------------------|---------------------------|

|  |                           |
|--|---------------------------|
| <b>Environmental exposure controls</b> | No information available. |
|--|---------------------------|

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

|                       |                           |
|-----------------------|---------------------------|
| <b>Appearance</b>     | Lyophilized powder        |
| <b>Physical state</b> | Powder                    |
| <b>Color</b>          | White                     |
| <b>Odor</b>           | No information available. |
| <b>Odor threshold</b> | No information available. |

### Property

## Values

| Property   | Value                    |
|--|--------------------------|
| Melting point / freezing point                           | No data available        |
| Boiling point or initial boiling point and boiling range | No data available        |
| Flammability (solid, gas)                                | No data available        |
| Lower and upper explosion limit/flammability limit       |                          |
| Lower explosion limit                                    | No data available        |
| Upper explosion limit                                    | No data available        |
| Flash point  | No data available        |
| Autoignition temperature                                 | No data available        |
| Decomposition temperature                                |                          |
| SADT (°C)  | No data available        |
| pH   | 5.7-7.3                  |
| pH (as aqueous solution)                                 | No data available        |
| Kinematic viscosity                                      | No data available        |
| Dynamic viscosity  | No data available        |
| Solubility   | No data available        |
| Vapor pressure   | No data available        |
| Density and/or relative density                          | No data available        |
| Bulk density   | No data available        |
| Liquid Density   | No data available        |
| Vapor density  | No data available        |
| Particle characteristics                                 |                          |
| Particle Size  | No information available |
| Particle Size Distribution                               | No information available |

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

## Voriconazole

Measured 7 Log P 1.75

## 9.2. Other information

|                          |         |
|--------------------------|---------|
| <b>Molecular formula</b> | Mixture |
| <b>Molecular weight</b>  | Mixture |

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## 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 information available.

### 10.2. Chemical stability

Stability Stable under normal conditions.

### Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information 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.

|  |   |
|--|---|
| <b>Acute toxicity</b>                    | Classification is based on mixture calculation methods based on component data  |
| <b>Serious eye damage/eye irritation</b> | Based on available data, the classification criteria are not met.               |
| <b>Skin corrosion/irritation</b>         | Based on available data, the classification criteria are not met.               |
| <b>Respiratory or skin sensitization</b> | Classification is based on mixture calculation methods based on component data. |
| <b>STOT - single exposure</b>            | Based on available data, the classification criteria are not met.               |
| <b>STOT - repeated exposure</b>          | Classification is based on mixture calculation methods based on component data. |
| <b>Reproductive toxicity</b>             | Classification is based on mixture calculation methods based on component data. |
| <b>Germ cell mutagenicity</b>            | Based on available data, the classification criteria are not met.               |
| <b>Carcinogenicity</b>                   | Classification is based on mixture calculation methods based on component data. |
| <b>Aspiration hazard</b>                 | Based on available data, the classification criteria are not met.               |

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## **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



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## 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** Based on available data, the classification criteria are not met.

### 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 $\beta$ -cyclodextrin sodium (SBECD)

*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 hours > 220 mg/L

*Daphnia magna* (Water Flea) OECD EC50 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

*Daphnia magna* (Water Flea) OECD 48 hours 200 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

#### Terrestrial Toxicity: (Species, Method, End Point, Duration, Result)

##### Voriconazole

*Chironomus riparius* (Midges) OECD EC50 28 days > 100 mg/kg

#### 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

### 12.2. Persistence and degradability

#### Persistence and degradability

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

##### Voriconazole

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OECD Activated sludge Ultimate (CO<sub>2</sub> Evolution) -0.24 % After 28 Day(s) Not Ready  
OECD Activated sludge Ready >60 % After 28 Day(s) Ready  
OECD Water - Sediment (various) Aerobic Transformation 20 °C Total System DT50 61-69 Day(s)

## 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

#### Sorption:

##### Voriconazole (137234-62-9)

| <u>Method</u> | <u>Inoculum</u>    | <u>End Point</u> | <u>Result</u> |
|---------------|--------------------|------------------|---------------|
| OECD          | Activated sludge   | Koc              | 74.19         |
| OECD          | Soil (various)     | Koc              | 62.28-103.91  |
| OECD          | Sediment (various) | Koc              | 134.27-259.64 |

## 12.5. Results of PBT and vPvB assessment

### PBT and vPvB assessment

| Chemical name                                 | PBT and vPvB assessment |
|---|-------------------------|
| Sulfobutylether b-cyclodextrin sodium (SBECD) | Not PBT/vPvB            |

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

## 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Waste from residues/unused products

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.

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**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

## 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 |

### National regulations

#### Germany

**Chemical Prohibition Ordinance (ChemVerbotsV)**  
Not applicable

**TRGS 905** Not applicable

#### Switzerland

|   |                |
|---|----------------|
| <b>Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018</b> | Not applicable |
| <b>Storage of Hazardous Material</b>  | Not applicable |
| <b>WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20</b>                                  | Not applicable |
| <b>Major Accidents Ordinance SR 814.012</b>   | Not applicable |

#### 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

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## Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

## Explosives Precursors Marketing and Use (2019/1148)

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing Chemicals Inventory  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**NZIoC** - New Zealand Inventory of Chemicals  
**TCSI** - Taiwan Chemical Substance Inventory

### 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 any hazard and/or precautionary statements referred to under Sections 2-15**

H301 - Toxic if swallowed H351 - Suspected of causing cancer H360D - May damage the unborn child H373 - May cause damage to organs through prolonged or repeated exposure H317 - May cause an allergic skin reaction H402 - Harmful to aquatic life

**Data Sources:** Pfizer proprietary drug development information.

**Reason for revision** Updated Section 2 - Hazard Identification. Updated Section 12 - Ecological Information.

**Revision date** 15-Jun-2025

**Prepared By** Pfizer Global Environment, Health, and Safety

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