



# SAFETY DATA SHEET

Revision date: 12-Apr-2018

Version: 2.1

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

### Product Identifier

**Material Name:** Viroptic Ophthalmic Solution Sterile 1%

**Trade Name:** VIROPTIC  
**Synonyms:** Trifluridine Ophthalmic Solution  
**Chemical Family:** Not determined

**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use:** Pharmaceutical product

### Details of the Supplier of the Safety Data Sheet

Pfizer Inc  
Pfizer Pharmaceuticals Group  
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## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Germ Cell Mutagenicity: Category 2  
Carcinogenicity: Category 2

### Label Elements

**Signal Word:** Warning  
**Hazard Statements:** H341 - Suspected of causing genetic defects  
H351 - Suspected of causing cancer

**Precautionary Statements:** P201 - Obtain special instructions before use  
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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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 List	GHS Classification	%
Trifluridine	70-00-8	200-722-8	Carc.2 (H351) Muta.2 (H341)	1-5
Acetic acid	64-19-7	200-580-7	Skin Corr.1A (H314) Flam. Liq. 3 (H226)	<1.0
Thimerosal	54-64-8	200-210-4	Acute Tox.2 (H300) Acute Tox. 1(H310) STOT RE 2 (H373) Acute Tox.2 (H330) Acute Aquatic 1 (H400) Chronic Aquatic 1 (H410)	<.01
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium acetate	127-09-3	204-823-8	Not Listed	*
Water for Injection	7732-18-5	231-791-2	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.

**Skin Contact:**

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.

**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 Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as 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 spill with absorbent material. 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 generating airborne mists and vapors. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. 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.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical product

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Acetic acid

ACGIH Threshold Limit Value (TWA)	10 ppm
ACGIH Threshold Limit Value (STEL)	15 ppm
Australia STEL	15 ppm
	37 mg/m <sup>3</sup>
Australia TWA	10 ppm
	25 mg/m <sup>3</sup>
Austria OEL - MAKs	10 ppm
	25 mg/m <sup>3</sup>
Belgium OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Bulgaria OEL - TWA	25.0 mg/m <sup>3</sup>
Cyprus OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Czech Republic OEL - TWA	25 mg/m <sup>3</sup>
Denmark OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Estonia OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Finland OEL - TWA	5 ppm
	13 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	10 ppm
	25 mg/m <sup>3</sup>
Germany (DFG) - MAK	10 ppm
	25 mg/m <sup>3</sup>
Greece OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Hungary OEL - TWA	25 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 ppm
	25 mg/m <sup>3</sup>
Latvia OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Luxembourg OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Malta OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Netherlands OEL - TWA	25 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	10 ppm
	25 mg/m <sup>3</sup>
Poland OEL - TWA	25 mg/m <sup>3</sup>
Portugal OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Romania OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Slovakia OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Slovenia OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 ppm 13 mg/m <sup>3</sup>
Switzerland OEL - TWAs	10 ppm 25 mg/m <sup>3</sup>
Vietnam OEL - TWAs	25 mg/m <sup>3</sup>
<b>Sodium chloride</b>	
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### Trifluridine

**Pfizer Occupational Exposure Band (OEB):** OEB 4 (control exposure to the range of 1ug/m<sup>3</sup> to <10ug/m<sup>3</sup>)

#### Sodium chloride

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### 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.

##### Hands:

Impervious disposable gloves (e.g. Nitrile, etc.) (double 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.)

##### 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 disposable 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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Sterile solution	<b>Color:</b>	No data available.
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	5.5-6.0		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Sodium acetate</b>	No data available		
<b>Sodium chloride</b>	No data available		
<b>Thimerosal</b>	No data available		
<b>Trifluridine</b>	No data available		
<b>Acetic acid</b>	No data available		
<b>Water for Injection</b>	No data available		
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>		No data available	
<b>Flammability (Solids):</b>		No data available	
<b>Flash Point (Liquid) (°C):</b>		No data available	
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>		No data available	

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

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### 11. TOXICOLOGICAL INFORMATION

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

**Short Term:** Mild eye irritation.

**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include burning/stinging of the eyes, irritation, swelling of the eye hypersensitivity reactions, increased intra-ocular pressure (glaucoma).

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

##### **Sodium chloride**

Rat Oral LD50 3000 mg/kg  
Mouse Oral LD50 4000 mg/kg

##### **Thimerosal**

Rat Oral LD50 75 mg/kg  
Mouse Oral LD50 91 mg/kg  
Rat Subcutaneous LD50 98mg/kg

##### **Trifluridine**

Rat Intravenous LD50 2946 mg/kg  
Rat Oral LD50 > 4379mg/kg  
Mouse Oral LD50 > 4379mg/kg

##### **Acetic acid**

Rat Oral LD50 3530 mg/kg  
Mouse Inhalation LC50 5000ppm

**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)

##### **Sodium chloride**

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

##### **Thimerosal**

Eye Irritation Rabbit Mild

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

##### **Trifluridine**

Embryo / Fetal Development Rat Subcutaneous 1 mg/kg/day NOAEL Fetotoxicity, Not teratogenic  
Embryo / Fetal Development Rabbit Subcutaneous 1 mg/kg/day NOAEL Fetotoxicity, Not Teratogenic, Fetal mortality

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

##### **Trifluridine**

*In Vitro* Sister Chromatid Exchange Hamster Lymphocytes Positive

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### 11. TOXICOLOGICAL INFORMATION

Cell Transformation Assay Mouse Negative  
Forward Mutation Assay Hamster Lung Cells Negative  
Chromosome Aberration Rat Positive

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

##### Trifluridine

2 Year(s) Rat Subcutaneous 1.5 mg/kg/day LOAEL Tumors, Mammary gland, Gastrointestinal system, Liver, Spleen  
2 Year(s) Mouse Subcutaneous 1 mg/kg/day LOAEL Tumors, Gastrointestinal system, Female reproductive system, Male reproductive system

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

#### Product Level Toxicity Data

##### Reproduction & Development Toxicity

Study Type	Species	Route	Dosage (mg/kg/day)	End Point	Effect(s)
Embryo/Fetal Development	Rabbit	Topical, eye	1%	NOAEL	Not teratogenic

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided.

#### Toxicity:

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

##### Acetic acid

*Pimephales promelas* (Fathead Minnow) LC-50 1 Hours > 315 mg/L  
*Pimephales promelas* (Fathead Minnow) LC-50 24 Hours 122 mg/L  
*Mysidopsis bahia* (Mysid Shrimp) LC-50 48 Hours 100-300 mg/L

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

### 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.



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### 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

#### Trifluridine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	200-722-8

#### Acetic acid

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-580-7

#### Sodium acetate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-823-8

#### Thimerosal

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-210-4

#### Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present

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### 15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

#### Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects  
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer  
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage  
Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed  
Acute toxicity, dermal-Cat.1; H310 - Fatal in contact with skin  
Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled  
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure  
Flammable liquids-Cat.3; H226 - Flammable liquid and vapor  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

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

**Revision date:** 12-Apr-2018

**Prepared by:** 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**