SAFETY DATA SHEET

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
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

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
SAFETY DATA SHEET

Material Name: Viroptic Ophthalmic Solution Sterile 1%
Revision date: 12-Apr-2018

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trifluridine</td>
<td>70-00-8</td>
<td>200-722-8</td>
<td>Carc.2 (H351)</td>
<td>1-5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Muta.2 (H341)</td>
<td></td>
</tr>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>200-580-7</td>
<td>Skin Corr.1A (H314)</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Flam. Liq. 3 (H226)</td>
<td></td>
</tr>
<tr>
<td>Thimerosal</td>
<td>54-64-8</td>
<td>200-210-4</td>
<td>Acute Tox.2 (H300)</td>
<td>&lt;.01</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 1 (H310)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT RE 2 (H373)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.2 (H330)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Aquatic 1 (H400)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Chronic Aquatic 1 (H410)</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium acetate</td>
<td>127-09-3</td>
<td>204-823-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
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 CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion: Formation of toxic gases is possible during heating or fire.
Products:
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 cleanup 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
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Material Name: Viroptic Ophthalmic Solution Sterile 1%</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acetic acid</strong></td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 ppm</td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (STEL)</td>
<td>15 ppm</td>
</tr>
<tr>
<td>Australia STEL</td>
<td>15 ppm</td>
</tr>
<tr>
<td></td>
<td>37 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>25.0 mg/m³</td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>13 mg/m³</td>
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<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>10 ppm</td>
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<td></td>
<td>25 mg/m³</td>
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<tr>
<td>Germany (DFG) - MAK</td>
<td>10 ppm</td>
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<tr>
<td></td>
<td>25 mg/m³</td>
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<tr>
<td>Greece OEL - TWA</td>
<td>10 ppm</td>
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<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
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<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 ppm</td>
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<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³</td>
</tr>
</tbody>
</table>
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Substance</th>
<th>Pfizer Occupational Exposure Band (OEB):</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)</td>
<td>Further details required.</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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/m³ to <10ug/m³)

**Sodium chloride**

**Pfizer Occupational Exposure Band (OEB):**

- OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/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.

**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.)
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Sterile solution
Odor: No data available.
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: 5.5-6.0
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available.
Vapor Pressure (kPa): No data available.
Vapor Density (g/ml): No data available.
Relative Density: No data available.
Viscosity: No data available.

Flammability:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  Upper Explosive Limits (Liquid) (% by Vol.): No data available
  Lower Explosive Limits (Liquid) (% by Vol.): No data available

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 mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
  Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
  Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
11. TOXICOLOGICAL INFORMATION

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

Short Term:

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 98 mg/kg

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

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

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
11. TOXICOLOGICAL INFORMATION

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.
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 5000 lb
  and their Reportable Quantities: 2270 kg
  California Proposition 65 Not Listed
  Inventory - United States TSCA - Sect. 8(b) Present
  Australia (AICS): Present
  Standard for the Uniform Scheduling Schedule 2
  for Drugs and Poisons: 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
SAFETY DATA SHEET

Material Name: Viroptic Ophthalmic Solution Sterile 1%
Revision date: 12-Apr-2018

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