



SAFETY DATA SHEET

Revision date: 21-Apr-2015

Version: 2.0

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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

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2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 2
Carcinogenicity: Category 2

EU Classification:

EU Indication of danger: Mutagenic: Category 3
Carcinogenic: Category 3

EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect.
R68 - Possible risk of irreversible effects.

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

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Other Hazards No data available
Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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	EU Classification	GHS Classification	%
Trifluridine	70-00-8	200-722-8	Mut. Cat.3,R68; Carc. Cat.3,R40	Carc.2 (H351) Muta.2 (H341)	1-5
Acetic acid	64-19-7	200-580-7	R10 C; R35	Skin Corr.1A (H314) Flam. Liq. 3 (H226)	<1.0
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	*
Thimerosal	54-64-8	200-210-4	T+; R26/27/28; R33 N; R50/53	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

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

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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

4. FIRST AID MEASURES

Description of First Aid Measures

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4. 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 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 fire fighting 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. Clean up 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.

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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.

Acetic acid

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Slovakia OEL - TWA	10 ppm 25 mg/m ³
Slovenia OEL - TWA	10 ppm 25 mg/m ³
Spain OEL - TWA	10 ppm 25 mg/m ³
Sweden OEL - TWAs	5 ppm 13 mg/m ³
Switzerland OEL -TWAs	10 ppm 25 mg/m ³
Vietnam OEL - TWAs	25 mg/m ³

Sodium chloride

Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

Trifluridine

Pfizer Occupational Exposure Band (OEB): OEB 4 (control exposure to the range of 1ug/m³ to <10ug/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).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Sterile solution	Color:	No data available.
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	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)	

Sodium acetate

No data available

Sodium chloride

No data available

Thimerosal

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9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Trifluridine

No data available

Acetic acid

No data available

Water for Injection

No data available

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

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

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11. TOXICOLOGICAL INFORMATION

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
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

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11. TOXICOLOGICAL INFORMATION

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

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15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:

D2a very toxic materials

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



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

Sodium chloride

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	231-598-3

Thimerosal

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 XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 18.

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15. REGULATORY INFORMATION

EU EINECS/ELINCS List 200-210-4

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 R phrases and 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

Carcinogenic: Category 3
Mutagenic: Category 3
C - Corrosive
T+ - Very toxic
N - Dangerous for the environment

R10 - Flammable.
R33 - Danger of cumulative effects.
R35 - Causes severe burns.
R40 - Limited evidence of a carcinogenic effect
R68 - Possible risks of irreversible effects.
R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

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

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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