MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
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+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Viroptic Ophthalmic Solution Sterile 1%

Trade Name:	VIROPTIC
Synonyms:	Trifluridine Ophthalmic Solution
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product

2. HAZARDS IDENTIFICATION

Appearance: Sterile solution
Signal Word: WARNING

Statement of Hazard:
Suspected of causing cancer.
Suspected of causing genetic defects.

Additional Hazard Information:
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).

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

EU Hazard Symbols:

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect.
R68 - Possible risk of irreversible effects.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Thimerosal	54-64-8	200-210-4	N; R50/53 R33 T+; R26/27/28	0.001
Acetic acid	64-19-7	200-580-7	C;R35 R10	<1.0
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Trifluridine	70-00-8	Not Listed	Mut. Cat.3,R68; Carc. Cat.3,R40	1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium acetate	127-09-3	204-823-8	Not Listed	*

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

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.

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.

5. FIRE FIGHTING MEASURES

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

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

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

General 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
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

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/m^3 to <10ug/m^3)

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: Refer to specific Member State legislation for requirements under Community environmental legislation.

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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture
pH:	5.5-6.0		

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

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

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

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

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

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

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

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

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.

11. TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

Thimerosal
Eye Irritation Rabbit Mild

Sodium chloride
Eye Irritation Rabbit Moderate
Skin 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.

12. ECOLOGICAL INFORMATION

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

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

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

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.

OSHA Label:
WARNING
Suspected of causing cancer.
Suspected of causing genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required

Thimerosal

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-210-4

Acetic acid

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
Inventory - United States TSCA - Sect. 8(b)	Present

15. REGULATORY INFORMATION

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 chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Sodium acetate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-823-8

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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.

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