

Revision date: 03-Apr-2015 Version: 2.0 Page 1 of 13

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

Product Identifier

Material Name: NEOSPORIN Ophthalmic Solution Sterile (neomycin and polymyxin B sulfates and gramicidin ophthalmic solution, USP)

Trade Name: NEOSPORIN

Synonyms: Neomycin and polymyxin B sulfates and gramicidin ophthalmic solution, USP

Chemical Family: Not applicable

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent

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

1-800-879-3477

United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24

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

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1 Skin Sensitization: Category 1

EU Classification:

EU Indication of danger: Irritant

EU Risk Phrases:

R42/43 - May cause sensitization by inhalation and skin contact.

Pfizer Ltd

CT13 9NJ

Ramsgate Road

Sandwich, Kent

Label Elements

Signal Word: Danger

Hazard Statements: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H317 - May cause an allergic skin reaction

Material Name: NEOSPORIN Ophthalmic Solution Sterile (neomycin and polymyxin B sulfates and gramicidin

(neomycin and polymyxin B sulfates and gramicidin ophthalmic solution, USP)

Revision date: 03-Apr-2015 Version: 2.0

Precautionary Statements: P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P285 - In case of inadequate ventilation wear respiratory protection

P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a

Page 2 of 13

position comfortable for breathing

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or

doctor/physician

P302+ P352 - IF ON SKIN: Wash with plenty of soap and water

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention



Other Hazards
Australian Hazard Classification
(NOHSC):

No data available

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	%
Alcohol	64-17-5	200-578-6	F; R11	Flam. Liq. 2 (H225)	0.1 - 1
Gramicidin	1405-97-6	215-790-4	Not Listed	Not Listed	< 0.01
Neomycin Sulfate	1405-10-3	215-773-1	Xn;R42/43 Repr.Cat.3;R63	Resp. Sens. 1 (H334) Skin Sens.1(H317) Repro. 2 (H361d) Aq. Acute 3 (H402) Aq. Chronic 3 (H412)	<0.01
Polymyxin B sulfate	1405-20-5	215-774-7	Xn;R22 Xn;R42 Xi; R43	Acute Tox.4 (H302) Skin Sens.1 (H317) Resp Sens.1 (H334)	0.1 - 1
Propylene glycol	57-55-6	200-338-0	Not Listed	Not Listed	*

Page 3 of 13

Material Name: NEOSPORIN Ophthalmic Solution Sterile

(neomycin and polymyxin B sulfates and gramicidin

ophthalmic solution, USP)

Revision date: 03-Apr-2015 Version: 2.0

3. COMPOSITION / INFO	RMATION ON INGRED	DIENTS			
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)	

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Polyoxyethylene-polyoxypropylene block copolymer	106392-12-5	Not Listed	Not Listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	Not Listed	*

* Proprietary **Additional Information:**

> 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

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention

immediately.

Skin Contact: If irritation occurs or persists, get medical attention. Remove clothing and wash affected skin

with soap and water.

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

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Symptoms and Effects of

Identification and/or Section 11 - Toxicological Information. **Exposure:**

Medical Conditions None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Material Name: NEOSPORIN Ophthalmic Solution Sterile Page 4 of 13

(neomycin and polymyxin B sulfates and gramicidin

ophthalmic solution, USP)

Revision date: 03-Apr-2015 Version: 2.0

Hazardous Combustion

Formation of toxic gases is possible during heating or fire.

Products:

Fire / Explosion Hazards: Fine particles (such as dust and 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 / Absorb spills with non-combustible absorbent material and transfer into a labeled container for

Collecting: disposal.

Additional Consideration for Non-essential personnel should be evacuated from affected area. Report emergency

Large Spills: situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Pharmaceutical product used as antibiotic agent Specific end use(s):

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Alcohol

ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm
	1880 mg/m ³
Austria OEL - MAKs	1000 ppm
	1900 mg/m ³
Belgium OEL - TWA	1000 ppm
	1907 mg/m ³
Bulgaria OEL - TWA	1000.0 mg/m ³
Czech Republic OEL - TWA	1000 mg/m ³
Denmark OEL - TWA	1000 ppm
	1900 mg/m ³
Estonia OEL - TWA	500 ppm
	1000 mg/m ³
Finland OEL - TWA	1000 ppm

1900 mg/m³

Page 5 of 13

Material Name: NEOSPORIN Ophthalmic Solution Sterile

(neomycin and polymyxin B sulfates and gramicidin

ophthalmic solution, USP)

Revision date: 03-Apr-2015 Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION France OEL - TWA 1000 ppm 1900 mg/m³ 500 ppm Germany - TRGS 900 - TWAs 960 mg/m³ 500 ppm Germany (DFG) - MAK 960 mg/m³ **Greece OEL - TWA** 1000 ppm 1900 mg/m³ **Hungary OEL - TWA** 1900 mg/m³ 1000 mg/m³ Latvia OEL - TWA Lithuania OEL - TWA 500 ppm 1000 mg/m³ 260 mg/m³ **Netherlands OEL - TWA OSHA - Final PELS - TWAs:** 1000 ppm 1900 mg/m³ **Poland OEL - TWA** 1900 mg/m³ Portugal OEL - TWA 1000 ppm Romania OEL - TWA 1000 ppm 1900 mg/m³ **Russia OEL - TWA** 1000 mg/m³ Slovakia OEL - TWA 500 ppm 960 mg/m³ 1000 ppm 1900 mg/m³ Spain OEL - TWA 1000 ppm 1910 mg/m³

Slovenia OEL - TWA

Sweden OEL - TWAs 500 ppm 1000 mg/m³ **Switzerland OEL -TWAs** 500 ppm

960 mg/m³ Vietnam OEL - TWAs 1000 mg/m³

Sodium chloride

5 mg/m³ Latvia OEL - TWA 5 mg/m³ Lithuania OEL - TWA

Neomycin Sulfate

Pfizer OEL TWA-8 Hr: 100 µg/m³, Sensitizer

Propylene glycol

Australia TWA 150 ppm

474 mg/m³ 10 mg/m³ 150 ppm

Ireland OEL - TWAs 470 mg/m³

10 mg/m³

Latvia OEL - TWA 7 mg/m^3 Lithuania OEL - TWA 7 mg/m³

Material Name: NEOSPORIN Ophthalmic Solution Sterile

(neomycin and polymyxin B sulfates and gramicidin

ophthalmic solution, USP)

Revision date: 03-Apr-2015 Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

Gramicidin

Pfizer Occupational Exposure Default (control exposure to the range of 1ug/m³ to <10ug/m³)

Band (OEB):

Polymyxin B sulfate

Pfizer Occupational Exposure OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide

Band (OEB): additional precautions to protect from skin contact)

Exposure Controls

Engineering controls should be used as the primary means to control exposures. General **Engineering Controls:**

room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne

Page 6 of 13

contamination levels below the exposure limits listed above in this section.

Refer to applicable national standards and regulations in the selection and use of personal **Personal Protective**

Equipment: 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.

Impervious protective clothing is recommended if skin contact with drug product is possible and Skin:

for bulk processing operations.

Respiratory protection: 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.

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

No data available **Solvent Solubility:** Water Solubility: No data available No data available. pH: **Melting/Freezing Point (°C):** No data available **Boiling Point (°C):** No data available. Partition Coefficient: (Method, pH, Endpoint, Value)

Water for injection No data available Propylene glycol No data available

Polyoxyethylene-polyoxypropylene block copolymer

No data available Sodium chloride No data available

Alcohol

No data available

Material Name: NEOSPORIN Ophthalmic Solution Sterile Page 7 of 13

(neomycin and polymyxin B sulfates and gramicidin

ophthalmic solution, USP)

Revision date: 03-Apr-2015 Version: 2.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Gramicidin

No data available

Neomycin Sulfate

Predicted 7.4 Log D 1.20

Polymyxin B sulfate No data available

Thimerosal

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):

Vapor Pressure (kPa):

Vapor Density (g/ml):

Relative Density:

No data available

Flammablity:

Autoignition Temperature (Solid) (°C):

Flammability (Solids):

Flash Point (Liquid) (°C):

Upper Explosive Limits (Liquid) (% by Vol.):

Lower Explosive Limits (Liquid) (% by Vol.):

Polymerization:

No data available
No data available
Will not occur

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 dust and mists) may fuel fires/explosions. **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition No data available

Products:

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: May be harmful if swallowed. May cause allergic reaction (based on components). **Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on

developing fetus (based on components) .

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

Propylene glycol

Rat Oral LD 50 22,000 mg/kg Mouse Oral LD 50 24,900mg/kg Rabbit Dermal LD 50 20,800mg/kg

Material Name: NEOSPORIN Ophthalmic Solution Sterile Page 8 of 13

(neomycin and polymyxin B sulfates and gramicidin

ophthalmic solution, USP)

Revision date: 03-Apr-2015 Version: 2.0

11. TOXICOLOGICAL INFORMATION

Polyoxyethylene-polyoxypropylene block copolymer

Rat Para-periosteal LD50 > 320 mg/kg Mouse Para-periosteal LD50 129mg/kg Rat Oral LD50 9380mg/kg

Sodium chloride

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

Alcohol

Rat Inhalation LC50 20,000mg/L

Neomycin Sulfate

Rat Oral LD 50 2750 mg/kg

Mouse Oral LD 50 2880mg/kg

Mouse Intraperitoneal LD 50 116mg/kg

Rat Subcutaneous LD 50 633mg/kg

Mouse Subcutaneous LD 50 275mg/kg

Polymyxin B sulfate

Mouse Oral LD50 790 mg/kg Rat SC LD50 50mg/kg Rat IV LD50 3.98mg/kg

Thimerosal

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

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

Propylene glycol

Skin Irritation Rabbit Mild Eye Irritation Rabbit Mild

Polyoxyethylene-polyoxypropylene block copolymer

Eye Irritation Rabbit Mild Skin Irritation Rabbit Mild

Sodium chloride

Eye Irritation Rabbit Moderate Skin Irritation Rabbit Mild

Page 9 of 13

Material Name: NEOSPORIN Ophthalmic Solution Sterile

(neomycin and polymyxin B sulfates and gramicidin

ophthalmic solution, USP)

Revision date: 03-Apr-2015 Version: 2.0

11. TOXICOLOGICAL INFORMATION

Alcohol

Eye Irritation Rabbit Severe

Neomycin Sulfate

Skin Irritation Rabbit Moderate Eye Irritation Rabbit Minimal Skin Sensitization Positive

Thimerosal

Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Neomycin Sulfate

6 Week(s) Dog Oral 100 mg/kg/day NOAEL No effects at maximum dose

3 Month(s) Guinea Pig Oral 10 mg/kg/day NOAEL No effects at maximum dose

3 Month(s) Dog Subcutaneous 20 mg/kg/day LOAEL Kidney

12 Month(s) Cat Oral 12 mg/kg/day NOAEL Blood forming organs

3 Month(s) Guinea Pig Subcutaneous 10 mg/kg/day LOAEL Kidney

Polymyxin B sulfate

9 Day(s) Mouse Subcutaneous 284 mg/kg LOAEL Skin

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Neomycin Sulfate

Reproductive & Fertility Oral 4000 mg/L NOAEL No effects at maximum dose Mouse 2 Generation Reproductive Toxicity Rat Oral 25 mg/kg/day NOAEL Fetotoxicity Reproductive & Fertility NOAEL Rat Oral 25 mg/kg/day No effects at maximum dose

Prenatal & Postnatal Development Rat Subcutaneous 6 mg/kg/day LOAEL Developmental toxicity,

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

Neomycin Sulfate

Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative

Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative

In Vivo Cytogenetics Mouse Negative

In Vitro Chromosome Aberration Human Lymphocytes Positive

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

Neomycin Sulfate

2 Year(s) Rat Oral 25 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: None of the components present in this material at concentrations equal to or greater than

0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

PZ02104

Page 10 of 13

Material Name: NEOSPORIN Ophthalmic Solution Sterile

(neomycin and polymyxin B sulfates and gramicidin

ophthalmic solution, USP)

Revision date: 03-Apr-2015 Version: 2.0

11. TOXICOLOGICAL INFORMATION

Alcohol

IARC: Group 1 (Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to

the environment should be avoided.

Toxicity:

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

Neomycin Sulfate

Daphnia magna (Water Flea) OECD EC50 48 Hours 68 mg/L Salmo gairdneri (Trout) OECD NOEC 96 Hours >1000 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Neomycin Sulfate

Activated sludge OECD EC50 399 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential:

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

Neomycin Sulfate

Predicted 7.4 Log D 1.20

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. This product contains trace quantities of mercury and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP).

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.

Material Name: NEOSPORIN Ophthalmic Solution Sterile

(neomycin and polymyxin B sulfates and gramicidin

ophthalmic solution, USP)

Revision date: 03-Apr-2015 Version: 2.0

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

D2a very toxic materials

D2b toxic materials

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



Alcohol

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 carcinogen initial date 4/29/11 in alcoholic beverages

developmental toxicity initial date 10/1/87 in alcoholic beverages

Page 11 of 13

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

200-578-6

Gramicidin

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Standard for the Uniform Scheduling

Not Listed

Not Listed

Present

Schedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List 215-790-4

Polyoxyethylene-polyoxypropylene block copolymer

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Sodium chloride

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Not Listed

Not Listed

Present

Present

Page 12 of 13

Material Name: NEOSPORIN Ophthalmic Solution Sterile

(neomycin and polymyxin B sulfates and gramicidin

ophthalmic solution, USP)

Revision date: 03-Apr-2015 Version: 2.0

15. REGULATORY INFORMATION

EU EINECS/ELINCS List 231-598-3

Neomycin Sulfate

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 developmental toxicity initial date 10/1/92 internal use

Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present **EU EINECS/ELINCS List** 215-773-1

Polymyxin B sulfate

CERCLA/SARA 313 Emission reporting Not Listed **California Proposition 65** Not Listed Australia (AICS): Present **EU EINECS/ELINCS List** 215-774-7

Propylene glycol

Not Listed **CERCLA/SARA 313 Emission reporting California Proposition 65** Not Listed Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present **EU EINECS/ELINCS List** 200-338-0

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 Use restricted. See item 18.

Dangerous Substances:

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** Present obligations of Register:

231-791-2 **EU EINECS/ELINCS List**

Additional Information: White petrolatum is not classified as a carcinogen. Nota N applies since the full refining history

is known and it can be shown that the substances from which the petroleum jelly was produced

are not a carcinogen.

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Material Name: NEOSPORIN Ophthalmic Solution Sterile Page 13 of 13

(neomycin and polymyxin B sulfates and gramicidin

ophthalmic solution, USP)

Revision date: 03-Apr-2015 Version: 2.0

Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed 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

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

Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

Xn - Harmful Xi - Irritant

Toxic to Reproduction: Category 3

F - Highly flammable

N - Dangerous for the environment

T+ - Very toxic

R22 - Harmful if swallowed.

R63 - Possible risk of harm to the unborn child.

R33 - Danger of cumulative effects.

R11 - Highly flammable.

R42/43 - May cause sensitization by inhalation and skin contact.

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.

Data Sources: Pfizer proprietary drug development 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.

Revision date: 03-Apr-2015

Product Stewardship Hazard Communication

Prepared by: 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
