

Revision date: 01-Dec-2007 Version: 1.0 Page 1 of 6

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 United Kingdom +00 44 (0)1304 616161

Emergency telephone number: ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Sodium Chloride 0.9% Irrigation

Trade Name: Not established Chemical Family: Mixture

Intended Use: Pharmaceutical product

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless liquid

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term: Mild eye irritant in experimental animals (based on components).

EU Indication of danger: Not classified

Australian Hazard Classification

(NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

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

Tidzardous				
Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
SODIUM HYDROXIDE	1310-73-2	215-185-5	C;R35	**
HYDROGEN CHLORIDE ANHYDROUS	7647-01-0	231-595-7	C;R35 T;R23	**
SODIUM CHLORIDE	7647-14-5	231-598-3	Not Listed	0.9

Material Name: Sodium Chloride 0.9% Irrigation Page 2 of 6
Revision date: 01-Dec-2007 Version: 1.0

Volcioni dato. V. 200 2007

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	99.1

Additional Information: ** to adjust pH

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: Due to the nature of this material first aid is not normally required.

Skin Contact: Due to the nature of this material first aid is not normally required.

Ingestion: Due to the nature of this material first aid is not normally required.

Inhalation: Not an expected route of exposure.

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Hazardous Combustion Products: Not applicable
Fire Fighting Procedures: Not applicable
Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Not applicable

Measures for Cleaning / Collecting: Wipe up with a damp cloth and place in container for disposal.

Measures for Environmental

Protections:

None

Additional Consideration for Large

Spills:

None

7. HANDLING AND STORAGE

General Handling: No special handling requirements for normal use of this material.

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.

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit: = 2 mg/m³ Ceiling Australia PEAK = 2 mg/m³ Peak

Material Name: Sodium Chloride 0.9% Irrigation

Page 3 of 6 Revision date: 01-Dec-2007 Version: 1.0

Austria OEL - MAKs **Belgium OEL - TWA Bulgaria OEL - TWA** Czech Republic OEL - TWA **Finland OEL - TWA** France OEL - TWA **Greece OEL - TWA Hungary OEL - TWA** Latvia OEL - TWA **Poland OEL - TWA** Slovakia OEL - TWA Slovenia OEL - TWA

HYDROGEN CHLORIDE ANHYDROUS

Sweden OEL - TWAs

ACGIH Ceiling Threshold Limit: Australia PEAK

Austria OEL - MAKs

Belgium OEL - TWA

Bulgaria OEL - TWA Cyprus OEL - TWA

Czech Republic OEL - TWA

Estonia OEL - TWA

Germany - TRGS 900 - TWAs

Greece OEL - TWA

Hungary OEL - TWA Ireland OEL - TWAs

Italy OEL - TWA

Latvia OEL - TWA

Lithuania OEL - TWA

Luxembourg OEL - TWA

Malta OEL - TWA

Netherlands OEL - TWA

Poland OEL - TWA Romania OEL - TWA

Slovakia OEL - TWA

Slovenia OEL - TWA

 $= 2 \text{ mg/m}^3 \text{ MAK}$ = 2 mg/m³ TWA $= 2.0 \text{ mg/m}^3 \text{ TWA}$ $= 1 \text{ mg/m}^3 \text{ TWA}$ = 2 mg/m³ TWA $= 2 \text{ mg/m}^3 \text{ VME}$ $= 2 \text{ mg/m}^3 \text{ TWA}$ $= 2 \text{ mg/m}^3 \text{ TWA}$ $= 0.5 \text{ mg/m}^3 \text{ TWA}$ $= 0.5 \text{ mg/m}^3 \text{ NDS}$ $= 2 \text{ mg/m}^3 \text{ TWA}$ $= 2 \text{ mg/m}^3 \text{ TWA}$ $= 1 \text{ mg/m}^3 \text{ LLV}$

= 2 ppm Ceiling = 5 ppm Peak = 7.5 mg/m³ Peak = 5 ppm MAK $= 8 \text{ mg/m}^3 \text{ MAK}$ = 5 ppm TWA $= 8 \text{ mg/m}^3 \text{ TWA}$ $= 8.0 \text{ mg/m}^3 \text{ TWA}$ = 5.0 ppm TWA $= 8.0 \text{ mg/m}^3 \text{ TWA}$ $= 8 \text{ mg/m}^3 \text{ TWA}$ = 5 ppm TWA = 8 mg/m³ TWA = 2 ppm TWA

 $= 8 \text{ mg/m}^3 \text{ TWA}$ = 5 ppm TWA $= 7 \text{ mg/m}^3 \text{ TWA}$ = 5 ppm TWA $= 8 \text{ mg/m}^3 \text{ TWA}$ = 5 ppm TWA = 8 mg/m³ TWA = 5 ppm IPRV = 8 mg/m3 IPRV = 5 ppm TWA $= 8 \text{ mg/m}^3 \text{ TWA}$ = 5 ppm TWA

= 3 mg/m³ TWA

= 5 ppm TWA $= 7 \text{ mg/m}^3 \text{ TWA}$

 $= 8 \text{ mg/m}^3 \text{ TWA}$ = 5 ppm MAC = 8 mg/m³ MAC $= 5 \text{ mg/m}^3 \text{ NDS}$ = 5 ppm TWA $= 8 \text{ mg/m}^3 \text{ TWA}$ = 5 ppm TWA $= 8.0 \text{ mg/m}^3 \text{ TWA}$

= 5 ppm TWA anhydrous = 8 mg/m³ TWA anhydrous

Material Name: Sodium Chloride 0.9% Irrigation

Revision date: 01-Dec-2007 Version: 1.0

Spain OEL - TWA = 5 ppm VLA-ED

 $= 7.6 \text{ mg/m}^3 \text{ VLA-ED}$

Page 4 of 6

SODIUM CHLORIDE

Latvia OEL - TWA = 5 mg/m³ TWA **Lithuania OEL - TWA** = 5 mg/m³ IPRV

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

Personal Protective Equipment:

Hands:

Eyes:

Not required for the normal use of this product.

Not required under normal conditions of use.

Not required for the normal use of this product.

Respiratory protection:

None required under normal conditions of use.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:LiquidColor:ColorlessOdor:NoneMolecular Formula:Mixture

Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability:StableConditions to Avoid:NoneIncompatible Materials:None

11. TOXICOLOGICAL INFORMATION

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

ingredients.

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

SODIUM CHLORIDE

Rat Inhalation LC50/1hr > 42 g/m³

Rat Oral LD 50 3 g/kg Mouse Oral LD 50 4 g/kg Rabbit Dermal LD 50 > 10 g/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.

<u>Irritation / Sensitization: (Study Type, Species, Severity)</u>

SODIUM CHLORIDE

Skin Irritation Rabbit Mild Eye Irritation Rabbit Mild

PZ00707

Page 5 of 6

Material Name: Sodium Chloride 0.9% Irrigation

Revision date: 01-Dec-2007 Version: 1.0

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

HYDROGEN CHLORIDE ANHYDROUS

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: No harmful effects to aquatic organisms are expected.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State

specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

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.

Water for injection

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present

Material Name: Sodium Chloride 0.9% Irrigation Page 6 of 6 Revision date: 01-Dec-2007 Version: 1.0

Present

REACH - Annex IV - Exemptions from the

obligations of Register:

EU EINECS/ELINCS List 231-791-2

SODIUM HYDROXIDE

CERCLA/SARA Hazardous Substances = 1000 lb final RQ and their Reportable Quantities: = 454 kg final RQ

Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present Standard for the Uniform Scheduling Schedule 5 for Drugs and Poisons: Schedule 6 **EU EINECS/ELINCS List** 215-185-5

HYDROGEN CHLORIDE ANHYDROUS

= 1.0 % de minimis concentration acid aerosols including mists, **CERCLA/SARA 313 Emission reporting**

vapors, gas, fog, and other airborne forms of any particle size

gas only

CERCLA/SARA Hazardous Substances = 2270 kg final RQ and their Reportable Quantities: = 5000 lb final RQ

= 500 lb TPQ gas only **CERCLA/SARA - Section 302 Extremely Hazardous**

CERCLA/SARA - Section 302 Extremely Hazardous = 5000 lb EPCRA RQ

Substances EPCRA RQs

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

Australia (AICS): Present Standard for the Uniform Scheduling Schedule 5 for Drugs and Poisons: Schedule 6 **EU EINECS/ELINCS List** 231-595-7

SODIUM CHLORIDE

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

16. OTHER INFORMATION

Data Sources: Publicly available toxicity information.

Reasons for Revision: New data sheet.

Prepared by: Toxicology and Hazard Communication

Pfizer Global Environment, Health, and Safety

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