



MATERIAL SAFETY DATA SHEET

Revision date: 29-Nov-2012

Version: 1.1

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

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

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

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

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Ingredient	CAS Number	EU EINECS/ELINCS List	EU 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 CHLORIDE
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³

HYDROGEN CHLORIDE ANHYDROUS

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m ³
Austria OEL - MAKs	5 ppm
	8 mg/m ³
Belgium OEL - TWA	5 ppm
	8 mg/m ³
Bulgaria OEL - TWA	8.0 mg/m ³
Cyprus OEL - TWA	5 ppm
	8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³
Estonia OEL - TWA	5 ppm
	8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm
	3 mg/m ³
Germany (DFG) - MAK	2 ppm
	3.0 mg/m ³
Greece OEL - TWA	5 ppm
	7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm
	8 mg/m ³
Italy OEL - TWA	5 ppm
	8 mg/m ³
Japan - OELs - Ceilings	5 ppm
	7.5 mg/m ³
Latvia OEL - TWA	5 ppm
	8 mg/m ³
Lithuania OEL - TWA	5 ppm
	8 mg/m ³
Luxembourg OEL - TWA	5 ppm
	8 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³

Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
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:	Not required for the normal use of this product.
Eyes:	Not required under normal conditions of use.
Skin:	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:	Liquid	Color:	Colorless
Odor:	None	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable
Conditions to Avoid:	None
Incompatible 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	Sub-tenon injection (eye)	LC50/1hr	> 42 g/m ³
Rat	Oral	LD 50	3 g/kg
Mouse	Oral	LD 50	4 g/kg
Rabbit	Dermal	LD 50	> 10 g/kg

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11. TOXICOLOGICAL INFORMATION

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

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

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: Not classified

OSHA Label:

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

Canada - WHMIS: Classifications

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15. REGULATORY INFORMATION

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.

SODIUM CHLORIDE

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

Water for injection

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

SODIUM HYDROXIDE

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

HYDROGEN CHLORIDE ANHYDROUS

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R23 - Toxic by inhalation.
R35 - Causes severe burns.

Data Sources: Publicly available toxicity information.

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients.

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