



SAFETY DATA SHEET

Revision date: 23-Jul-2014

Version: 1.0

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

Product Identifier

Material Name: Ropivacaine Hydrochloride Solution for Injection

Trade Name: ROPIVACAINE
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product used as anesthetic agent

Details of the Supplier of the Safety Data Sheet

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2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

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

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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	%
SODIUM HYDROXIDE	1310-73-2	215-185-5	C; R35	Skin Corr. 1A (H314)	**
Ropivacaine hydrochloride	132112-35-7	Not Listed	Xn;R22	Acute 4; H302 Aquatic Acute 3; H402 Aquatic Chronic 3; H412	0.2
HYDROCHLORIC ACID	7647-01-0	231-595-7	T; R23 C; R35	Skin Corr.1B (H314) STOT SE 3 (H335)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	Not Listed	*
SODIUM CHLORIDE	7647-14-5	231-598-3	Not Listed	Not Listed	*

Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. * Proprietary
** to adjust pH

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: 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.

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Medical Conditions None known
Aggravated by Exposure:

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 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 / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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 inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit: 2 mg/m³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
Switzerland OEL -TWAs	2 mg/m ³

SODIUM CHLORIDE

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

HYDROCHLORIC ACID

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
	5 ppm
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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
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
Switzerland OEL - TWAs	2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³

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.

Ropivacaine hydrochloride

Pfizer Occupational Exposure OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)
Band (OEB):

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Wear impervious gloves as minimum protection.
Eyes:	Wear safety glasses as minimum protection.
Skin:	Wear impervious protective clothing when handling this compound.
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:	Solution	Color:	No data available.
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	C16H25ClN2O	Molecular Weight:	328.88
Solvent Solubility:	No data available		
Water Solubility:	Soluble		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		

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9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): No data available.

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

Ropivacaine hydrochloride

No data available Log P 2.15

SODIUM CHLORIDE

No data available

HYDROCHLORIC ACID

No data available

SODIUM HYDROXIDE

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 at normal conditions

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

Short Term: Anesthetic drug: may cause central nervous system and cardiovascular system effects

Known Clinical Effects: May cause tingling/itching (paresthesia), allergic reaction, decrease in blood pressure (hypotension), decreased heart rate (bradycardia), respiratory depression.

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

Ropivacaine hydrochloride

Rat IV LD₅₀ 9.9 mg/kg

Rat Oral LD₅₀ 980mg/kg

Mouse Oral LD₅₀ 300mg/kg

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11. TOXICOLOGICAL INFORMATION

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³
Rat Oral LD 50 3g/kg
Mouse Oral LD 50 4g/kg
Rabbit Dermal LD 50 > 10g/kg

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

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

SODIUM CHLORIDE

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

Ropivacaine hydrochloride

2 Generation Reproductive Toxicity Rat No route specified Dose not specified Negative

Carcinogen Status:

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

HYDROCHLORIC ACID

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:

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

Ropivacaine hydrochloride

Green algae EC50 72 Hours 59 mg/L
Daphnia magna (Water Flea) EC50 48 Hours 34 mg/L
Brachydanio rerio (Zebra fish) LC50 96 Hours 38 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential:

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

Ropivacaine hydrochloride

No data available Log P 2.15

Mobility in Soil: No data available

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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

Canada - WHMIS: Classifications

WHMIS hazard class:

Non-controlled

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.

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting

Not Listed

CERCLA/SARA Hazardous Substances and their Reportable Quantities:

1000 lb

454 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 5

EU EINECS/ELINCS List

Schedule 6

215-185-5

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15. REGULATORY INFORMATION

Ropivacaine hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

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

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

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	231-595-7

16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
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
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Xn - Harmful
C - Corrosive
T - Toxic

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R22 - Harmful if swallowed.

R35 - Causes severe burns.

R23 - Toxic by inhalation.

Data Sources: Publicly available toxicity information.

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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