## 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

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-800-879-3477</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300</td>
<td>+00 44 (0)1304 616161</td>
</tr>
<tr>
<td>Contact E-Mail: <a href="mailto:pfizer-MSDS@pfizer.com">pfizer-MSDS@pfizer.com</a></td>
<td>Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887</td>
</tr>
</tbody>
</table>

## 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.
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM HYDROXIDE</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C; R35</td>
<td>Skin Corr. 1A (H314)</td>
<td>**</td>
</tr>
<tr>
<td>Ropivacaine hydrochloride</td>
<td>132112-35-7</td>
<td>Not Listed</td>
<td>Xn; R22</td>
<td>Acute 4; H302 Aquatic Acute 3; H402 Aquatic Chronic 3; H412</td>
<td>0.2</td>
</tr>
<tr>
<td>HYDROCHLORIC ACID</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>T; R23</td>
<td>Skin Corr.1B (H314) STOT SE 3 (H335)</td>
<td>**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Standard</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SODIUM CHLORIDE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td><strong>HYDROCHLORIC ACID</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACGIH Ceiling Threshold Limit:</td>
<td>2 ppm</td>
<td></td>
</tr>
<tr>
<td>Australia PEAK</td>
<td>5 ppm</td>
<td>7.5 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>2 ppm</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 ppm</td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>5 ppm</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Italy OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>5 ppm</td>
<td>7.5 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Ropivacaine Hydrochloride Solution for Injection
Revision date: 23-Jul-2014

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
Odor: No data available.
Molecular Formula: C16H25ClN2O

Solvent Solubility: No data available
Water Solubility: Soluble
pH: No data available.
Melting/Freezing Point (°C): No data available

PZ02415
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 Products: No data available

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
11. TOXICOLOGICAL INFORMATION

**SODIUM CHLORIDE**

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>LC50/1hr</th>
<th>Dose (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Sub-tenon injection (eye)</td>
<td>&gt; 42 g/m³</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>3 g/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>4 g/kg</td>
</tr>
<tr>
<td>Rabbit</td>
<td>Dermal</td>
<td>LD 50</td>
<td>&gt; 10 g/kg</td>
</tr>
</tbody>
</table>

**HYDROCHLORIC ACID**

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>LD 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Generation Reproductive Toxicity</td>
<td>Rat</td>
<td>No route specified</td>
</tr>
</tbody>
</table>

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))

**Carcinogen Status:**

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

**HYDROCHLORIC ACID**

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>LC50/1hr</th>
<th>pH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water Flea)</td>
<td>EC50</td>
<td>48 Hours</td>
<td>34 mg/L</td>
</tr>
<tr>
<td>Brachydanio rerio (Zebra fish)</td>
<td>LC50</td>
<td>96 Hours</td>
<td>38 mg/L</td>
</tr>
</tbody>
</table>

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
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:
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 215-185-5

PZ02415
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, 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs: 500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs: Not Listed
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, Schedule 6
EU EINECS/ELINCS List: 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
SAFETY DATA SHEET

Material Name: Ropivacaine Hydrochloride Solution for Injection
Revision date: 23-Jul-2014

R22 - Harmful if swallowed.
R35 - Causes severe burns.
R23 - Toxic by inhalation.

Data Sources: Publicly available toxicity information.

Revision date: 23-Jul-2014
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