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

Material Name: Lignocaine 2% Gel
Trade Name: Lignocaine 2% Gel
Synonyms: Lidocaine Gel
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as anesthetic agent

2. HAZARDS IDENTIFICATION

Appearance: Clear Colorless gel

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

Additional Hazard Information:
- Short Term: May cause slight irritation, Harmful if swallowed (based on components). May cause mild eye irritation. May cause numbing effects to skin.
- Known Clinical Effects: Adverse effects associated with therapeutic use include dizziness, nervousness, agitation, drowsiness, apprehension, euphoria, blurred/double vision, slurred speech, tremors, convulsions, and seizure. Respiratory depression and arrest may follow. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are cardiovascular collapse, central nervous system depression, and/or hypotension.

EU Indication of danger: Not classified


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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
</table>
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine Hydrochloride</td>
<td>73-78-9</td>
<td>200-803-8</td>
<td>Xn; R22</td>
<td>2</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C; R35</td>
<td>**</td>
</tr>
<tr>
<td>Acetic acid USP - glacial</td>
<td>64-19-7</td>
<td>200-580-7</td>
<td>C; R35 R10</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Hydroxyethyl cellulose</td>
<td>9004-62-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:  
* Proprietary  
** 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: 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 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.

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: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal.

7. HANDLING AND STORAGE

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Contents under pressure, do not puncture or incinerate. Releases to the environment should be avoided.

Storage Conditions: Protect from light. Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Propylene glycol

- **Australia TWA**: 150 ppm, 474 mg/m³, 10 mg/m³
- **Ireland OEL - TWAs**: 150 ppm, 470 mg/m³, 10 mg/m³
- **Latvia OEL - TWA**: 7 mg/m³
- **Lithuania OEL - TWA**: 7 mg/m³

Sodium hydroxide

ACGIH Ceiling Threshold Limit: 2 mg/m³

- **Australia PEAK**: 2 mg/m³
- **Austria OEL - MAKs**: 2 mg/m³
- **Bulgaria OEL - TWA**: 2.0 mg/m³
- **Czech Republic OEL - TWA**: 1 mg/m³
- **Estonia OEL - TWA**: 1 mg/m³
- **France OEL - TWA**: 2 mg/m³
- **Greece OEL - TWA**: 2 mg/m³
- **Hungary OEL - TWA**: 2 mg/m³
- **Japan - OELs - Ceilings**: 2 mg/m³
- **Latvia OEL - TWA**: 0.5 mg/m³
- **OSHA - Final PELS - TWAs**: 2 mg/m³
- **Poland OEL - TWA**: 0.5 mg/m³
- **Slovakia OEL - TWA**: 2 mg/m³
- **Slovenia OEL - TWA**: 2 mg/m³
- **Sweden OEL - TWAs**: 1 mg/m³

Acetic acid USP - glacial

ACGIH Threshold Limit Value (TWA): 10 ppm

ACGIH Threshold Limit Value (STEL): 15 ppm

- **Australia STEL**: 15 ppm, 37 mg/m³
- **Austria TWA**: 10 ppm, 25 mg/m³
- **Austria OEL - MAKs**: 10 ppm, 25 mg/m³
# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
<th>Lidocaine Hydrochloride</th>
<th>OEB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td>OEB 2 (control exposure to the range of 100μg/m³ to &lt; 1000μg/m³)</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>25.0 mg/m³</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>25 mg/m³</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>5 ppm</td>
<td>13 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>25 mg/m³</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
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<tr>
<td>Luxembourg OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>15 mg/m³</td>
<td>13 mg/m³</td>
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</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
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<tr>
<td>Slovakia OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
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<tr>
<td>Slovenia OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
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</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 ppm</td>
<td>13 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

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.

**Lidocaine Hydrochloride**

**Pfizer Occupational Exposure Band (OEB):**

OEB 2 (control exposure to the range of 100μg/m³ to < 1000μg/m³)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

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:** 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.
- **Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and 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:** Gel
- **Molecular Formula:** Mixture
- **Color:** Clear, colorless
- **Molecular Weight:** Mixture
- **Solubility:** Soluble: Water

10. STABILITY AND REACTIVITY

- **Chemical Stability:** Stable under normal conditions of use.
- **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

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)**

- **Propylene glycol**
  - Mouse Oral LD50 22,000 mg/kg
  - Rat Oral LD50 20,000 mg/kg
  - Rabbit Dermal LD50 20,800 mg/kg

- **Lidocaine Hydrochloride**
  - Rat Oral LD50 317 mg/kg
  - Rat Para-periosteal LD50 25 mg/kg
  - Rat Intraperitoneal LD50 133 mg/kg
  - Mouse Oral LD50 292 mg/kg
  - Mouse Intravenous LD50 19.5 mg/kg

- **Sodium hydroxide**
  - Mouse IP LD50 40 mg/kg
11. TOXICOLOGICAL INFORMATION

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

- **Propylene glycol**
  - Skin Irritation: Rabbit, Mild
  - Eye Irritation: Rabbit, Mild

- **Lidocaine Hydrochloride**
  - Eye Irritation: Rabbit, Mild
  - Skin Irritation: Rabbit, Mild

- **Sodium hydroxide**
  - Eye Irritation: Rabbit, Severe
  - Skin Irritation: Rabbit, Severe

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

- **Lidocaine Hydrochloride**
  - Embryo / Fetal Development (Rat, Subcutaneous): 30 mg/kg NOAEL, Not teratogenic
  - Embryo / Fetal Development (Rat, Intraperitoneal): 56 mg/kg NOAEL, Not Teratogenic
  - Embryo / Fetal Development (Rat, Intraperitoneal): 72 mg/kg/day NOAEL, Not Teratogenic
  - Embryo / Fetal Development (Rat, Intravenous): 500 mg/kg/day LOAEL, Fetotoxicity
  - Embryo / Fetal Development (Rat, Intraperitoneal): 6 mg/kg LOAEL, Developmental toxicity

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

- **Lidocaine Hydrochloride**
  - Bacterial Mutagenicity (Ames) *Salmonella, E. coli*: Negative
  - In Vitro Chromosome Aberration: Human Lymphocytes, Negative
  - In Vivo Micronucleus: Mouse, Negative

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

12. ECOLOGICAL INFORMATION

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

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

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.

Lidocaine Hydrochloride

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 200-803-8

Propylene glycol

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 200-338-0

Hydroxyethyl cellulose

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

Water

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
15. REGULATORY INFORMATION

Sodium hydroxide

| CERCLA/SARA Hazardous Substances | 1000 lb |
| and their Reportable Quantities: | 454 kg |
| 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 |

Acetic acid USP - glacial

| CERCLA/SARA Hazardous Substances | 5000 lb |
| and their Reportable Quantities: | 2270 kg |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 2 |
| EU EINECS/ELINCS List | 200-580-7 |

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R10 - Flammable.
R22 - Harmful if swallowed.
R35 - Causes severe burns.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

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

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