SAFETY DATA SHEET

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

Product Identifier

Material Name: Pregabalin Oral Solution

Trade Name: LYRICA

Chemical Family: Mixture

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

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
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CT13 9NJ
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+00 44 (0)1304 616161

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

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not required

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

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>PZ00533</td>
<td></td>
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</table>
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregabalin</td>
<td>148553-50-8</td>
<td>Not Listed</td>
<td>Repr. 2 (H361d)</td>
<td>2.0</td>
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<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
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<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
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<tr>
<td>Sucralose</td>
<td>56038-13-2</td>
<td>259-952-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Flavor</td>
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<tr>
<td>Water</td>
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<td>Sodium phosphate, monobasic</td>
<td>7558-80-7</td>
<td>231-449-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
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 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

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide and oxides of nitrogen.

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

Advice for Fire-Fighters
Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

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

<table>
<thead>
<tr>
<th>Measures for Cleaning / Collecting:</th>
<th>Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Consideration for Large Spills:</td>
<td>Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.</td>
</tr>
</tbody>
</table>

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

Conditions for Safe Storage, Including any Incompatibilities

<table>
<thead>
<tr>
<th>Storage Conditions:</th>
<th>Store as directed by product packaging.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific end use(s):</td>
<td>Pharmaceutical drug product</td>
</tr>
</tbody>
</table>

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Pregabalin

| Pfizer OEL TWA-8 Hr: | 500µg/m³ |

Sodium phosphate, dibasic

| Pfizer Occupational Exposure Band (OEB): | OEB 1 (control exposure to the range of 1000µg/m³ to 3000µg/m³) |

Sodium phosphate, monobasic

| Pfizer Occupational Exposure Band (OEB): | OEB 1 (control exposure to the range of 1000µg/m³ to 3000µg/m³) |

Exposure Controls

<table>
<thead>
<tr>
<th>Engineering Controls:</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal Protective Equipment:</td>
<td>Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Solution</td>
</tr>
<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Color</td>
<td>Clear, colorless</td>
</tr>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
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<tr>
<td>Water Solubility</td>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
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<tr>
<td>Boiling Point (°C)</td>
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</tr>
<tr>
<td>Partition Coefficient (Method, pH, Endpoint, Value)</td>
<td>Predicted 7.4 Log D -1.35</td>
</tr>
<tr>
<td>Flavor</td>
<td>No data available</td>
</tr>
<tr>
<td>Water</td>
<td>No data available</td>
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<tr>
<td>Propylparaben</td>
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<tr>
<td>Pregabalin</td>
<td>Predicted 7.4 Log D -1.35</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>No data available</td>
</tr>
<tr>
<td>Sodium phosphate, monobasic</td>
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</tr>
<tr>
<td>Sodium phosphate, dibasic</td>
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</tr>
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<td>Sucralose</td>
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<tr>
<td>Decomposition Temperature (°C):</td>
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<tr>
<td>Evaporation Rate (Gram/s)</td>
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<tr>
<td>Vapor Pressure (kPa)</td>
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<tr>
<td>Vapor Density (g/ml)</td>
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<tr>
<td>Relative Density</td>
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<td>Viscosity</td>
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<td>Flammability</td>
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<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
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<tr>
<td>Flammability (Solids):</td>
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<tr>
<td>Flash Point (Liquid) (°C):</td>
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</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
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</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
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

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Long Term: Animal studies indicate that this material may cause adverse effects on the fetus
Known Clinical Effects: Adverse effects most commonly reported in clinical use include dizziness, blurred vision, weight gain, sleepiness (somnolence), inability to concentrate, swelling, and dry mouth. Hypersensitivity reactions may also occur in susceptible individuals. Other less common effects include suicidal behavior.
Acute Toxicity: (Species, Route, End Point, Dose)

**Propylparaben**
- Mouse Oral LD50 6332 mg/kg
- Mouse Sub-tenon injection (eye) LD50 200 mg/kg

**Pregabalin**
- Rat IV LD50 > 300 mg/kg
- Mouse Oral LD50 > 5000mg/kg
- Rat Oral LD50 > 5000mg/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.

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

**Pregabalin**
- Skin Sensitization - LLNA Rat Negative
- Skin Sensitization - Beuhler Guinea Pig Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

**Propylparaben**
- 3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
- 4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

**Pregabalin**
- 13 Week(s) Rat Oral 50 mg/kg/day NOAEL Central nervous system, Male reproductive system
- 4 Week(s) Rat Oral 500 mg/kg/day LOAEL Central Nervous System, Male reproductive system
11. TOXICOLOGICAL INFORMATION

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Pregabalin
Peri-/Postnatal Development  Rat  Oral 100 mg/kg/day  NOAEL  Developmental toxicity, Fertility
Fertility & Early Embryonic Development - Males  Rat  Oral 250 mg/kg/day  NOAEL  No effects at maximum dose
Fertility & Embryonic Development-Females  Rat  Oral 1250 mg/kg/day  NOAEL  Negative
Embryo / Fetal Development  Rat  Oral 500 mg/kg/day  NOAEL  Not Teratogenic
Embryo / Fetal Development  Rabbit  Oral 500 mg/kg/day  NOAEL  Not Teratogenic

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

Pregabalin
Bacterial Mutagenicity (Ames)  Bacteria  Negative
In Vivo Unscheduled DNA Synthesis  Rat  Negative
In Vivo Micronucleus  Mouse  Negative
In Vitro Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Pregabalin
104 Week(s)  Mouse  Oral 1000 mg/kg/day  NOAEL  Not carcinogenic
104 Week(s)  Rat  Oral 450 mg/kg/day  NOAEL  Not carcinogenic
104 Week(s)  Mouse  Oral 200 mg/kg/day  NOAEL  Malignant tumors

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

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

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

Pregabalin
Daphnia magna (Water Flea)  EC50  48 Hours  > 1000 mg/L
Onchorhynchus mykiss (Rainbow Trout)  OECD LC50  96 Hours  > 1000 mg/L
Green algae  OECD EbC50  72 Hours  > 300 mg/L
Green Algae  OECD ErC50  72 Hours  > 300 mg/L

Aquatic Toxicity Comments:  A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Pregabalin
Aspergillus niger (Fungus)  OECD MIC  > 1000 mg/L
SAFETY DATA SHEET

Material Name: Pregabalin Oral Solution
Revision date: 30-Jan-2017

Persistence and Degradability:
No data available

Bio-accumulative Potential:

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

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

Propylparaben
- 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: 202-307-7

Methylparaben

PZ00533
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
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<tbody>
<tr>
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<td>Present</td>
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</tr>
<tr>
<td>Sodium phosphate, dibasic</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
<tr>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Additional Information:**
U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule V
16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 30-Jan-2017


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