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
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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
Signal Word: Not required

Other Hazards
No data available

Australian Hazard Classification (NOHSC):

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>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
</table>

PZ00533
3. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | %  
|------------|------------|-----------------------|-------------------|-------------------|------
| Pregabalin | 148553-50-8| Not Listed            | Repr. Cat. 3;R63  | Repr. 2 (H361d)   | 2.0  
| Propylparaben | 94-13-3 | 202-307-7 | Not Listed | Not Listed | *  
| Methylparaben | 99-76-3 | 202-785-7 | Not Listed | Not Listed | *  
| Sodium phosphate, monobasic | 7558-80-7 | 231-449-2 | Not Listed | Not Listed | *  
| Sodium phosphate, dibasic | 7558-79-4 | 231-448-7 | Not Listed | Not Listed | *  
| Sucralose | 56038-13-2 | 259-952-2 | Not Listed | Not Listed | *  
| Flavor | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | *  
| Water | 7732-18-5 | 231-791-2 | Not Listed | Not Listed | *  

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 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.

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

PZ00533
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**

**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.

**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**

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**

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

**Pregabalin**

- **Pfizer OEL TWA-8 Hr:** 500µg/m³

**Analytical Method:**

Analytical method available for Pregabalin. Contact Pfizer Inc for further information.

**Exposure Controls**

- **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.
- **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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State:</td>
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<td>Odor:</td>
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<tr>
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<td>Boiling Point (°C):</td>
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<tr>
<td>Pregabalin</td>
<td>Predicted 7.4 Log D -1.35</td>
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<tr>
<td>Methylparaben</td>
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<tr>
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</tr>
<tr>
<td>Sodium phosphate, dibasic</td>
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</tr>
<tr>
<td>Sucralose</td>
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<td>Evaporation Rate (Gram/s):</td>
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<td>Vapor Pressure (kPa):</td>
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</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
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</table>

10. STABILITY AND REACTIVITY

<table>
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<th>Property</th>
<th>Value</th>
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<tbody>
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<td>Reactivity:</td>
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<tr>
<td>Chemical Stability:</td>
<td>Stable under normal conditions of use.</td>
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<tr>
<td>Possibility of Hazardous Reactions</td>
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<td>Oxidizing Properties:</td>
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</tr>
<tr>
<td>Conditions to Avoid:</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Incompatible Materials:</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
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<tr>
<td>Hazardous Decomposition Products:</td>
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</tr>
</tbody>
</table>
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 LD 50 6332 mg/kg
Mouse Sub-tenon injection (eye) LD 50 200 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
4 Week(s) Monkey Oral 100 mg/kg/day NOAEL Central Nervous System
52 Week(s) Rat Oral 50 mg/kg/day LOAEL Blood forming organs

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

Pregabalin
Peri-/Postnatal Development Rat Oral100 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)

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11. TOXICOLOGICAL INFORMATION

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
_ONcorhynchus 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
_Aspargillus niger_ (Fungus)  OECD  MIC  > 1000 mg/L
_Trichoderma viride_ (Fungus)  OECD  MIC  > 1000 mg/L
_Clostridium perfringens_ (Bacterium)  OECD  MIC  > 997 mg/L
_Bacillus subtilis_ (Bacterium)  OECD  MIC  >1000 mg/L
_Nostoc sp._ (Freshwater Cyanobacteria)  OECD  MIC  > 1000 mg/L

Persistence and Degradability:  No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Pregabalin
Predicted  7.4  Log D  -1.35

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:
Class D, Division 2, Subdivision A

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
- 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: 202-785-7
### 15. REGULATORY INFORMATION

**Sodium phosphate, monobasic**
- **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**: 231-449-2

**Sodium phosphate, dibasic**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **CERCLA/SARA Hazardous Substances and their Reportable Quantities**: 5000 lb, 2270 kg
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: 231-448-7

**Sucralose**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: 259-952-2

**Flavor**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **EU EINECS/ELINCS List**: Not Listed

**Water**
- **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

**Pregabalin**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **U.S. Drug Enforcement Administration**:
  - Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- **EU EINECS/ELINCS List**: Not Listed

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

### 16. OTHER INFORMATION

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

- Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Toxic to Reproduction: Category 3

R63 - Possible risk of harm to 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 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

**Revision date:** 28-Feb-2015

**Prepared by:** Product Stewardship Hazard Communication

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