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

Material Name: Pregabalin Oral Solution

Trade Name: LYRICA
Chemical Family: Mixture
Intended Use: Pharmaceutical product

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution

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

Additional Hazard Information:

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.

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 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>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregabalin</td>
<td>148553-50-8</td>
<td>Not listed</td>
<td>Repr. Cat. 3;R63 Xn;R48/22</td>
<td>2.0</td>
</tr>
</tbody>
</table>

PZ00533
Propylparaben  94-13-3  202-307-7  Not Listed  *
Methylparaben  99-76-3  202-785-7  Not Listed  *
Sodium phosphate, monobasic  7558-80-7  231-449-2  Not Listed  *
Sodium phosphate, dibasic  7558-79-4  231-448-7  Not Listed  *
Sucralose  56038-13-2  259-952-2  Not Listed  *
Flavor  NOT ASSIGNED  Not listed  Not Listed  *
Water  7732-18-5  231-791-2  Not Listed  *

Additional Information:  * Proprietary
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 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.

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:  Emits toxic fumes of carbon monoxide and oxides of nitrogen.

Fire Fighting Procedures:  Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

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:  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

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

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Pregabalin

Pfizer OEL TWA-8 Hr: 500µg/m³


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.

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: Solution
- Molecular Formula: Mixture
- Color: Clear, colorless
- Molecular Weight: Mixture
- Relative Density: 1.0076 (25 °C)

10. STABILITY AND REACTIVITY

- 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)
  - Propylparaben
11. TOXICOLOGICAL INFORMATION

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)

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

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

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

**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: (Species, Method, End Point, Duration, Result)**

**Pregabalin**

Aspergillus 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

13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:**

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

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
14. TRANSPORT INFORMATION

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:
Class D, Division 2, Subdivision A

Pregabalin
U.S. Drug Enforcement Administration: Schedule V Controlled Substance
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4

Propylparaben
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 202-307-7

Methylparaben
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 202-785-7

Sodium phosphate, monobasic
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 231-449-2

Sodium phosphate, dibasic
CERCLA/SARA Hazardous Substances and their Reportable Quantities:
2270 kg final RQ
5000 lb final RQ
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 231-448-7

Material Name: Pregabalin Oral Solution
Revision date: 08-Jan-2010
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15. REGULATORY INFORMATION

Sucralose

Australia (AICS): Listed
EU EINECS/ELINCS List 259-952-2

Water

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List 231-791-2

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

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R63 - Possible risk of harm to the unborn child.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

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

Reasons for Revision: Updated Section 2 - Hazard Identification.

Prepared by: Toxicology and 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