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

Product Identifier

Material Name: Pregabalin Capsules
Trade Name: LYRICA, ALOND, BRILLIOR
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
Reproductive Toxicity: Category 2

EU Classification:
EU Indication of danger: Harmful
Toxic to Reproduction: Category 3

EU Risk Phrases:
R63 - Possible risk of harm to the unborn child.

Label Elements
Signal Word: Warning
Hazard Statements: H361d - Suspected of damaging the unborn child

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards
Australian Hazard Classification (NOHSC):

No data available

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>
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</thead>
<tbody>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
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<tr>
<td>Pregabalin</td>
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<td>Repr. 2 (H361d)</td>
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<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
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<td>Not Listed</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>Hard gelatin capsules</td>
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<tr>
<td>Lactose NF, monohydrate</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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</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 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
SAFETY DATA SHEET

Material Name: Pregabalin Capsules
Revision date: 12-Jun-2014

6. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Not applicable

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
If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Use appropriate ventilation. Avoid generating airborne dust. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Corn Starch

- **ACGIH Threshold Limit Value (TWA)**: 10 mg/m³
- **Australia TWA**: 10 mg/m³
- **Belgium OEL - TWA**: 10 mg/m³
- **Bulgaria OEL - TWA**: 10.0 mg/m³
- **Czech Republic OEL - TWA**: 4.0 mg/m³
- **Greece OEL - TWA**: 10 mg/m³
- **Ireland OEL - TWA**: 10 mg/m³
- **OSHA - Final PELS - TWA**: 15 mg/m³
- **Portugal OEL - TWA**: 10 mg/m³
- **Slovakia OEL - TWA**: 4 mg/m³
- **Spain OEL - TWA**: 10 mg/m³
- **Switzerland OEL - TWA**: 3 mg/m³

#### Pregabalin

- **Pfizer OEL TWA-8 Hr**: 500 µg/m³

#### Talc (non-asbestiform)

- **ACGIH Threshold Limit Value (TWA)**: 2 mg/m³
- **Australia TWA**: 2.5 mg/m³
- **Austria OEL - MAKs**: 2 mg/m³
- **Belgium OEL - TWA**: 2 mg/m³
- **Bulgaria OEL - TWA**: 1.0 fiber/cm³
- **Czech Republic OEL - TWA**: 2.0 mg/m³
- **Denmark OEL - TWA**: 0.3 fiber/cm³
- **Finland OEL - TWA**: 0.5 fiber/cm³
- **Greece OEL - TWA**: 10 mg/m³
- **Hungary OEL - TWA**: 2 mg/m³
- **Ireland OEL - TWA**: 10 mg/m³
- **Lithuania OEL - TWA**: 2 mg/m³
- **Netherlands OEL - TWA**: 0.25 mg/m³
- **OSHA - Final PELs - Table Z-3 Mineral D**: 20 mppcf
- **Poland OEL - TWA**: 4.0 mg/m³
- **Portugal OEL - TWA**: 1.0 mg/m³
- **Romania OEL - TWA**: 2 mg/m³
- **Slovakia OEL - TWA**: 2 mg/m³
- **Slovenia OEL - TWA**: 10 mg/m³
- **Spain OEL - TWA**: 2 mg/m³
- **Sweden OEL - TWA**: 2 mg/m³
- **Switzerland OEL - TWA**: 1 mg/m³

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**Exposure Controls**
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.

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>
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</tr>
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<td>Polymerization:</td>
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</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 Products: 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, dry mouth. Hypersensitivity reactions may also occur in susceptible individuals. Other less common effects include suicidal behavior.

Acute Toxicity: (Species, Route, End Point, Dose)

- Talc (non-asbestiform)
  Rat Oral LD50 > 1600 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)

- Pregabalin
  13 Week(s) Rat Oral50 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 & Developmental Toxicity: (Study Type, 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
11. TOXICOLOGICAL INFORMATION

Fertility & Embryonic Development-Females

Rat Oral 1250 mg/kg/day NOAEL Negative

Embryo / Fetal Development

Rat Oral 500 mg/kg/day NOAEL Not Teratogenic

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.

Talc (non-asbestiform)

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material 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

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

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

Corn Starch
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 232-679-6
15. REGULATORY INFORMATION

Hard gelatin capsules
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
EU EINECS/ELINCS List: Not Listed

Lactose NF, monohydrate
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register:
EU EINECS/ELINCS List: Not Listed

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

Talc (non-asbestiform)
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: 238-877-9

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

H361d - Suspected of damaging the unborn child

Toxic to Reproduction: Category 3
R63 - Possible risk of harm to the unborn child.

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 15 - Regulatory Information.

Revision date: 12-Jun-2014

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