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

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification
Reproductive Toxicity: Category 2

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

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>
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<tbody>
<tr>
<td>Pregabalin</td>
<td>148553-50-8</td>
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<td>Repr. 2 (H361d)</td>
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<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
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<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
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<tbody>
<tr>
<td>Hard gelatin capsules</td>
<td>MIXTURE</td>
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<td>64044-51-5</td>
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</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
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:
Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters
During all firefighting 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. Cleanup 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): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Pregabalin
Pfizer OEL TWA-8 Hr: 500µg/m³

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
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls:
Exposure 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). 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.
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>Capsule</td>
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<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
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<tr>
<td>Water Solubility</td>
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<tr>
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<tr>
<td>Boiling Point (°C)</td>
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<td>Partition Coefficient (Method, pH, Endpoint, Value)</td>
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<tr>
<td>Lactose NF, monohydrate</td>
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</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>No data available</td>
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<tr>
<td>Corn Starch</td>
<td>No data available</td>
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<tr>
<td>Pregabalin</td>
<td>Predicted 7.4 Log D -1.35</td>
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<tr>
<td>Hard gelatin capsules</td>
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<tr>
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<td>Flammability:</td>
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<td>Flammability (Solids):</td>
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<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
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<tr>
<td>Polymerization:</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 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 > 5000 mg/kg
  Rat Oral LD50 > 5000 mg/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 - Beuehler Guinea Pig Negative

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

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 & Developmental Toxicity: (Study Type, 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
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
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.

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

Hard gelatin capsules
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
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

Corn Starch
CERCLA/SARA 313 Emission reporting Not Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>California Proposition 65</td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<tr>
<td>Australia (AICS):</td>
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<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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<td>EU EINECS/ELINCS List</td>
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<tr>
<td>Talc (non-asbestiform)</td>
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Lactose NF, monohydrate

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</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

H361d - Suspected of damaging 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.

Revision date: 21-Jun-2018

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