



# SAFETY DATA SHEET

Revision date: 30-Jan-2017

Version: 3.1

Page 1 of 9

## 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:  
International CHEMTREC (24 hours): +1-703-527-3887

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

### 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%

## SAFETY DATA SHEET

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

Page 2 of 9  
Version: 3.1

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Pregabalin	148553-50-8	Not Listed	Repr. 2 (H361d)	2.0
------------	-------------	------------	-----------------	-----

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Propylparaben	94-13-3	202-307-7	Not Listed	*
Methylparaben	99-76-3	202-785-7	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	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*
Sodium phosphate, monobasic	7558-80-7	231-449-2	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 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**

## SAFETY DATA SHEET

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

Page 3 of 9  
Version: 3.1

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/m<sup>3</sup>

##### Sodium phosphate, dibasic

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

##### Sodium phosphate, monobasic

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### 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). 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.

## SAFETY DATA SHEET

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

Page 4 of 9  
Version: 3.1

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Solution	<b>Color:</b>	Clear, colorless
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	

#### Flavor

No data available

#### Water

No data available

#### Propylparaben

No data available

#### Pregabalin

Predicted 7.4 Log D -1.35

#### Methylparaben

No data available

#### Sodium phosphate, monobasic

No data available

#### Sodium phosphate, dibasic

No data available

#### Sucralose

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** 1.0076 (25 °C)

**Viscosity:** No data available

#### Flammability:

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

## SAFETY DATA SHEET

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

Page 5 of 9  
Version: 3.1

Lower Explosive Limits (Liquid) (% by Vol.): No data available

### 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, 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

## SAFETY DATA SHEET

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

Page 6 of 9  
Version: 3.1

### 11. TOXICOLOGICAL INFORMATION

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 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  
*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

## SAFETY DATA SHEET

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

Page 7 of 9  
Version: 3.1

*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**

**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**

## SAFETY DATA SHEET

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

Page 8 of 9  
Version: 3.1

### 15. REGULATORY INFORMATION

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

#### 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 V Controlled Substance Schedule 4
EU EINECS/ELINCS List	Not Listed

#### 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

#### 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

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



## SAFETY DATA SHEET

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

Page 9 of 9  
Version: 3.1

### 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

**Prepared by:** Product Stewardship 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**