



# MATERIAL SAFETY DATA SHEET

Revision date: 08-Jan-2010

Version: 2.0

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
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New York, New York 10017  
1-212-573-2222

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

Pfizer Ltd  
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Sandwich, Kent  
CT13 9NJ  
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Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

### 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

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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	Classification	%
Pregabalin	148553-50-8	Not listed	Repr. Cat. 3;R63 Xn;R48/22	2.0

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
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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.

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### 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/m<sup>3</sup>

**Analytical Method:** Analytical method available for Pregabalin. Contact Pfizer Inc for further information.

**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

<b>Physical State:</b>	Solution	<b>Color:</b>	Clear, colorless
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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

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### 11. TOXICOLOGICAL INFORMATION

Mouse Oral LD 50 6332 mg/kg  
Mouse Intraperitoneal LD 50 200 mg/kg

#### Pregabalin

Rat IV LD50 > 300 mg/kg  
Mouse Oral LD50 > 5000 mg/kg  
Rat Oral LD50 > 5000 mg/kg

#### Methylparaben

Mouse Oral LD50 > 8000 mg/kg  
Rat Oral LD50 2280 mg/kg

#### Sodium phosphate, monobasic

Rat Oral LD 50 8290 mg/kg

#### Sodium phosphate, dibasic

Rat Oral LD 50 17 g/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

##### Sodium phosphate, dibasic

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

#### 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 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)

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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.

#### 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.

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## 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: Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule V Controlled Substance Schedule 4
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### 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

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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**