



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.3

Page 1 of 6

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

**Pfizer Inc**  
**Pfizer Pharmaceuticals Group**  
235 East 42nd Street  
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1-212-573-2222

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

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Neurontin (gabapentin) Oral Solution**

**Trade Name:** NEURONTIN(R)  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as anticonvulsant

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Gabapentin	60142-96-3	262-076-3	5.0
Glycerin, USP	56-81-5	200-289-5	*

Ingredient	CAS Number	EU EINECS List	%
Flavor	NOT ASSIGNED	Not listed	*
Xylitol	87-99-0	201-788-0	*
Water, purified	7732-18-5	231-791-2	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Clear, colorless liquid  
**Signal Word:** WARNING

**Statement of Hazard:** May cause eye irritation

### Additional Hazard Information:

**Short Term:** May cause eye irritation. Not expected to cause skin irritation . May cause respiratory tract irritation.

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

**Known Clinical Effects:** Adverse effects associated with the therapeutic use include dizziness, tiredness, swelling, and nausea.

**EU Indication of danger:** Not classified

## MATERIAL SAFETY DATA SHEET

Material Name: Neurontin (gabapentin) Oral Solution  
Revision date: 02-Jan-2007

Page 2 of 6  
Version: 1.3

**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.

### 4. FIRST AID MEASURES

**Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get 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.

### 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** May include oxides of carbon.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Not applicable

### 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 contact with eyes, skin and clothing. Wash thoroughly after handling.

**Storage Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Gabapentin  
Pfizer OEL TWA-8 Hr: 1.2 mg/m<sup>3</sup>

Glycerin, USP

## MATERIAL SAFETY DATA SHEET

Material Name: Neurontin (gabapentin) Oral Solution  
Revision date: 02-Jan-2007

Page 3 of 6  
Version: 1.3

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

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

**Engineering Controls:** Good general ventilation should be sufficient to control airborne levels. Engineering controls should be used as the primary means to control exposures.

**Personal Protective Equipment:**

**Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.  
**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.  
**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.  
**Respiratory protection:** Not required for the normal use of this product. 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>	Liquid	<b>Color:</b>	Colorless
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Solubility:** Soluble: Water

**Flash Point (Liquid) (°C):** >100

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** None known  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

**Hazardous Decomposition Products:** Thermal decomposition products may include carbon monoxide and carbon dioxide

### 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)**

**Gabapentin**

Mouse Oral LD50 > 5000 mg/kg  
Rat Oral LD50 > 5000 mg/kg  
Rat IV LD50 > 2000 mg/kg  
Mouse IV LD50 1000-2000 mg/kg  
Rat Subcutaneous LD50 > 4000 mg/kg

**Glycerin, USP**

## MATERIAL SAFETY DATA SHEET

Material Name: Neurontin (gabapentin) Oral Solution  
Revision date: 02-Jan-2007

Page 4 of 6  
Version: 1.3

Mouse Oral LD50 4090 mg/kg  
Rat Oral LD50 12.6 g/kg  
Rabbit Dermal LD50 > 10 g/kg  
Rat Inhalation LC50 1hr > 570 mg/m<sup>3</sup>  
Rat Dermal LD 50 >21.9 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)

#### **Gabapentin**

Eye Irritation Rabbit Non-irritating

#### **Glycerin, USP**

Eye Irritation Rabbit Mild

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

#### **Gabapentin**

52 Week(s) Rat Oral 250 mg/kg/day NOAEL Liver, Kidney  
52 Week(s) Monkey Oral 250 mg/kg/day NOAEL None identified  
13 Week(s) Mouse Oral 1000 mg/kg/day NOAEL No effects at maximum dose

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### **Gabapentin**

Reproductive & Fertility Rat Oral 500 mg/kg/day NOAEL Negative  
Embryo / Fetal Development Mouse Oral 3000 mg/kg/day NOAEL No effects at maximum dose  
Embryo / Fetal Development Rat Oral 300 mg/kg/day NOAEL Developmental toxicity, Not Teratogenic  
Embryo / Fetal Development Rabbit Oral 1500 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity  
Peri-/Postnatal Development Rat Oral 500 mg/kg/day NOAEL Negative

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

#### **Gabapentin**

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vitro* Chromosome Aberration Hamster Lung Cells Negative  
*In Vivo* Unscheduled DNA Synthesis Rat Hepatocyte Negative  
*In Vivo* Chromosome Aberration Hamster Bone Marrow Negative

**Mutagenicity** Not mutagenic in bacterial or mammalian cells. Not clastogenic in mammalian cells.

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### **Gabapentin**

2 Year(s) Mouse Oral, in feed 2000 mg/kg/day NOEL Not carcinogenic  
2 Year(s) Male Rat Oral, in feed 1000 mg/kg/day NOEL Malignant tumors, Pancreas

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 12. ECOLOGICAL INFORMATION

### **Environmental Overview:**

Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

## MATERIAL SAFETY DATA SHEET

Material Name: Neurontin (gabapentin) Oral Solution  
Revision date: 02-Jan-2007

Page 5 of 6  
Version: 1.3

### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

#### Glycerin, USP

*Oncorhynchus mykiss* (Rainbow Trout) LD50 96 Hours 50 mg/L

*Daphnia Magna* (Water Flea) EC50 24 Hours >500 mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

### 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

### 14. TRANSPORT INFORMATION

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

### 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

#### OSHA Label:

WARNING

May cause eye irritation

#### Canada - WHMIS: Classifications

#### WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

#### Gabapentin

Standard for the Uniform Scheduling  
for Drugs and Poisons:

Schedule 4

EU EINECS List

262-076-3

#### Xylitol

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS List

201-788-0

Water, purified

## MATERIAL SAFETY DATA SHEET

Material Name: Neurontin (gabapentin) Oral Solution  
Revision date: 02-Jan-2007

Page 6 of 6  
Version: 1.3

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

### Glycerin, USP

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-289-5

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures.  
Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**