



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.2

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

**Pfizer Inc**  
**Pfizer Pharmaceuticals Group**  
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Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

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

**Material Name: Gabapentin Capsules (100 mg, 300 mg and 400 mg)**

**Trade Name:** Neurontin®  
**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	74.5
Starch	9005-25-8	232-679-6	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*

Ingredient	CAS Number	EU EINECS List	%
Hard gelatin capsules	MIXTURE	Not listed	*
Lactose	63-42-3	200-559-2	*

**Additional Information:** \* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Blue , orange or beige capsules

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

### Additional Hazard Information:

**Short Term:** Dust may cause irritation (based on components) The active ingredient is not acutely toxic.  
**Known Clinical Effects:** Adverse effects associated with the therapeutic use include dizziness, tiredness, swelling, and nausea.  
**EU Indication of danger:** Not classified

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**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 contaminated clothing and shoes. Wash skin with soap and water. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

**Notes to Physician:** Consider further flushing of eyes with large amounts of water or saline. For combustion products, refer to section number 5.

### 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** Not known

**Fire Fighting Procedures:** Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

**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 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.

**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:** If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

**Storage Conditions:** Store in a cool, dry place away from direct sunlight.

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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Gabapentin

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

#### Starch

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

#### Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA  
ACGIH Threshold Limit Value (TWA) = 2 mg/m<sup>3</sup> TWA  
Australia TWA = 2.5 mg/m<sup>3</sup> TWA containing no asbestos fibers

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

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

**Engineering Controls:** 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>	Capsule	<b>Color:</b>	Blue, orange or beige
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** None known

**Incompatible Materials:** None known

**Hazardous Decomposition Products:** None known

**Polymerization:** Will not occur

### 11. TOXICOLOGICAL INFORMATION

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**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

#### **Starch**

Mouse IP LD50 6600 mg/kg

#### **Lactose**

Rat Oral LD50 > 10 g/kg

#### **Talc (non-asbestiform)**

Rat Oral LD50 > 1600 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)

#### **Gabapentin**

Eye Irritation Rabbit Non-irritating

### 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

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

#### **Gabapentin**

2 Year(s) Mouse Oral, in feed 2000 mg/kg/day NOEL Not carcinogenic

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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. See below

**Talc (non-asbestiform)**  
**IARC:** Group 3

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

### 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:**  
Non-hazardous in accordance with international standards for workplace safety.

#### 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

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EU EINECS List	262-076-3
<b>Starch</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6
<b>Lactose</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-559-2
<b>Talc (non-asbestiform)</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	238-877-9

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

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

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**End of Safety Data Sheet**