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

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>Neurontin®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product used as anticonvulsant</td>
</tr>
</tbody>
</table>

2. 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 therapeutic use include dizziness, tiredness, swelling, and nausea.

EU Classification

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC):


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>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gabapentin</td>
<td>60142-96-3</td>
<td>262-076-3</td>
<td>Not Listed</td>
<td>74.5</td>
</tr>
<tr>
<td></td>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
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: Formation of toxic gases is possible during heating or fire.

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

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

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Gabapentin
- Pfizer OEL TWA-8 Hr: 1200µg/m³
- ACGIH Threshold Limit Value (TWA) 2 mg/m³
- Australia TWA 2.5 mg/m³
- Austria OEL - MAKs 2 mg/m³
- Belgium OEL - TWA 2 mg/m³
- Bulgaria OEL - TWA 1.0 fiber/cm³ 6.0 mg/m³ 3.0 mg/m³
- Czech Republic OEL - TWA 2 mg/m³ 10 mg/m³
- Denmark OEL - TWA 0.3 fiber/cm³
- Finland OEL - TWA 0.5 fiber/cm³
- Greece OEL - TWA 10 mg/m³ 2 mg/m³
- Hungary OEL - TWA 2 mg/m³
- Ireland OEL - TWAs 10 mg/m³ 0.8 mg/m³
- Lithuania OEL - TWA 2 mg/m³ 1 mg/m³
- Netherlands OEL - TWA 0.25 mg/m³
- OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
- Poland OEL - TWA 4.0 mg/m³ 1.0 mg/m³
- Portugal OEL - TWA 2 mg/m³
- Slovakia OEL - TWA 2 mg/m³ 10 mg/m³
- Slovenia OEL - TWA 2 mg/m³
- Spain OEL - TWA 2 mg/m³
- Sweden OEL - TWAs 2 mg/m³ 1 mg/m³

Starch
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Australia TWA 10 mg/m³
- Belgium OEL - TWA 10 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Analytical Method:**

Analytical method available for gabapentin. Contact Pfizer Inc for further information.

**Engineering Controls:**

General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.

**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

- **Physical State:** Capsule
- **Molecular Formula:** Mixture
- **Color:** Blue, orange or beige
- **Molecular Weight:** Mixture
- **Polymerization:** Will not occur

10. STABILITY AND REACTIVITY

- **Chemical 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)
11. TOXICOLOGICAL INFORMATION

Gabapentin

<table>
<thead>
<tr>
<th>Study Type, Species, Route, Dose, End Point, Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse Oral LD50 &gt; 5000 mg/kg</td>
</tr>
<tr>
<td>Rat Oral LD50 &gt; 5000 mg/kg</td>
</tr>
<tr>
<td>Rat IV LD50 &gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Mouse IV LD50 1000-2000 mg/kg</td>
</tr>
<tr>
<td>Rat Subcutaneous LD50 &gt; 4000 mg/kg</td>
</tr>
</tbody>
</table>

Lactose

<table>
<thead>
<tr>
<th>Study Type, Species, Route, Dose, End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat Oral LD50 &gt; 10 g/kg</td>
</tr>
</tbody>
</table>

Talc (non-asbestiform)

<table>
<thead>
<tr>
<th>Study Type, Species, Route, Dose, End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat Oral LD50 &gt; 1600 mg/kg</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Study Type, Species, Route, Dose, End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabapentin Eye Irritation Rabbit Non-irritating</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study Type, Species, Route, Dose, End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabapentin 52 Week(s) Rat Oral 250 mg/kg/day NOAEL Liver, Kidney</td>
</tr>
<tr>
<td>Gabapentin 52 Week(s) Monkey Oral 250 mg/kg/day NOAEL None identified</td>
</tr>
<tr>
<td>Gabapentin 13 Week(s) Mouse Oral 1000 mg/kg/day NOAEL No effects at maximum dose</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study Type, Species, Route, Dose, End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabapentin Reproductive &amp; Fertility Rat Oral 500 mg/kg/day NOAEL Negative</td>
</tr>
<tr>
<td>Gabapentin Embryo / Fetal Development Mouse Oral 3000 mg/kg/day NOAEL No effects at maximum dose</td>
</tr>
<tr>
<td>Gabapentin Embryo / Fetal Development Rat Oral 300 mg/kg/day NOAEL Developmental toxicity, Not Teratogenic</td>
</tr>
<tr>
<td>Gabapentin Embryo / Fetal Development Rabbit Oral 1500 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity</td>
</tr>
<tr>
<td>Gabapentin Peri-/Postnatal Development Rat Oral 500 mg/kg/day NOAEL Negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study Type, Cell Type/Organism, Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabapentin Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative</td>
</tr>
<tr>
<td>Gabapentin In Vitro Chromosome Aberration Hamster Lung Cells Negative</td>
</tr>
<tr>
<td>Gabapentin In Vivo Unscheduled DNA Synthesis Rat Hepatocyte Negative</td>
</tr>
<tr>
<td>Gabapentin In Vivo Chromosome Aberration Hamster Bone Marrow Negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study Type, Species, Route, Dose, End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabapentin 2 Year(s) Mouse Oral, in feed 2000 mg/kg/day NOEL Not carcinogenic</td>
</tr>
<tr>
<td>Gabapentin 2 Year(s) Male Rat Oral, in feed 1000 mg/kg/day NOEL Malignant tumors, Pancreas</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

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 (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.

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

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.
15. REGULATORY INFORMATION

Gabapentin

- California Proposition 65: Not Listed
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: 262-076-3

Hard gelatin capsules

- California Proposition 65: Not Listed

Talc (non-asbestiform)

- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 238-877-9

Starch

- 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: 232-679-6

Lactose

- 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: 200-559-2

16. OTHER INFORMATION

Data Sources:
Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision:
Updated Section 2 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage.

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