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

Material Name: Gabapentin Tablets (Neurontin)

Trade Name: Neurontin®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as anticonvulsant

2. HAZARDS IDENTIFICATION

Appearance: White, elliptical, film-coated tablets

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

Additiona 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 Indication of danger: Not classified

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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabapentin</td>
<td>60142-96-3</td>
<td>262-076-3</td>
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<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
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<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
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<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
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</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Poloxamer 407</td>
<td>9003-11-6</td>
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<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
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.

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. 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.
7. HANDLING AND STORAGE

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

Corn Starch

- ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA
- Australia TWA 10 mg/m³
- Belgium OEL - TWA Listed
- Bulgaria OEL - TWA Listed
- Czech Republic OEL - TWA Listed
- Greece OEL - TWA Listed
- Ireland OEL - TWA Listed
- OSHA - Final PELS - TWAs: 15 mg/m³ total
  5 mg/m³
- Portugal OEL - TWA Listed
- Spain OEL - TWA Listed

Talc (non-asbestiform)

- ACGIH Threshold Limit Value (TWA) 2 mg/m³ TWA
- ACGIH OELs - Notice of Intended Changes Listed
- Australia TWA 2.5 mg/m³ containing no asbestos fibers
- Austria OEL - MAKs Listed
- Belgium OEL - TWA Listed
- Bulgaria OEL - TWA Listed
- Czech Republic OEL - TWA Listed
- Denmark OEL - TWA Listed
- Estonia OEL - TWA Listed
- Finland OEL - TWA Listed
- Greece OEL - TWA Listed
- Hungary OEL - TWA Listed
- Ireland OEL - TWAs Listed
- Netherlands OEL - TWA Listed
- OSHA - Final PELs - Table Z-3 Mineral D: TWA-20 mppcf
- Poland OEL - TWA Listed
- Portugal OEL - TWA Listed
- Romania OEL - TWA Listed
- Slovenia OEL - TWA Listed
- Spain OEL - TWA Listed
- Sweden OEL - TWAs Listed

Magnesium stearate

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

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.

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:
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

Physical State: Film-coated tablets  
Color: White  
Molecular Formula: Mixture  
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
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)

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

Povidone

PZ01158
11. TOXICOLOGICAL INFORMATION

**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:**
- **Gabapentin**
  - Eye Irritation: Rabbit, Non-irritating

**Repeated Dose Toxicity:**
- **Gabapentin**
  - 52 Week(s) 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:**
- **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:**
- **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:**
- **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. See below

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

**Povidone**
- **IARC:** Group 3
11. TOXICOLOGICAL INFORMATION

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

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
- EU EINECS/ELINCS List: 262-076-3

Corn Starch
- Inventory - United States TSCA - Sect. 8(b) Listed
- Australia (AICS): Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>EU EINECS/ELINCS List</th>
<th>United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
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<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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<td>Listed</td>
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<tr>
<td>Poloxamer 407</td>
<td>232-679-6</td>
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<tr>
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<tr>
<td>Povidone</td>
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<td></td>
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<tr>
<td>Purified water</td>
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<tr>
<td>Hydroxypropyl cellulose</td>
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<tr>
<td>Magnesium stearate</td>
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</tbody>
</table>

16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

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

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End of Safety Data Sheet