# SAFETY DATA SHEET

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

### Product Identifier

**Material Name:** Neurontin (gabapentin) Oral Solution  
**Trade Name:** NEURONTIN  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as anticonvulsant

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

### Label Elements

- **Signal Word:** Not required
- **Hazard Statements:** Non-hazardous in accordance with international standards for workplace safety.

### Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

### 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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD082</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Flavor</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Xylitol</td>
<td>87-99-0</td>
<td>201-788-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES

**Description of 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.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**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.

**Medical Conditions Aggravated by Exposure:**
None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

5. FIRE FIGHTING MEASURES

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

**Special Hazards Arising from the Substance or Mixture**

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

**Fire / Explosion Hazards:**
Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters**
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**
6. ACCIDENTAL RELEASE MEASURES

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

Additional Consideration for Large Spills:
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:
Store as directed by product packaging.

Specific end use(s):
Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Glycerin, USP

<table>
<thead>
<tr>
<th>Country / Region</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>20 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>200 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>50 mg/m³</td>
</tr>
</tbody>
</table>

Exposure Controls

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. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| Hands: | Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.) |
| Eyes: | Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.) |
| Skin: | Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.) |
| Respiratory protection: | Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.) |

### 9. PHYSICAL AND CHEMICAL PROPERTIES

| Physical State: | Liquid | Color: Colorless |
| Odor: | No data available. | Odor Threshold: No data available. |
| Molecular Formula: | Mixture | Molecular Weight: Mixture |

- **Solvent Solubility:** No data available
- **Water Solubility:** No data available
- **Solubility:** Soluble: Water
- **pH:** No data available.
- **Melting/Freezing Point (°C):** No data available
- **Boiling Point (°C):** No data available
- **Partition Coefficient: (Method, pH, Endpoint, Value)**
  - **Gabapentin**
    - Predicted Log D: 7.4, -1.31
  - **Glycerin, USP**
    - No data available
  - **Xylitol**
    - No data available
  - **Water, purified**
    - No data available
  - **Flavor**
    - No data available

- **Decomposition Temperature (°C):** No data available
- **Evaporation Rate (Gram/s):** No data available
- **Vapor Pressure (kPa):** No data available
- **Vapor Density (g/ml):** No data available
- **Relative Density:** No data available
- **Viscosity:** No data available

- **Flammability:**
  - **Autoignition Temperature (Solid) (°C):** No data available
  - **Flammability (Solids):** No data available
  - **Flash Point (Liquid) (°C):** >100
  - **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
  - **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

Material Name: Neurontin (gabapentin) Oral Solution

Glycerin, USP

Xylitol

Water, purified

Flavor

Decomposition Temperature (°C): No data available.
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  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
  Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
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 therapeutic use include dizziness, tiredness, swelling, and nausea.

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**
Mouse Oral LD50 4090 mg/kg
Rat Oral LD50 12.6 g/kg
Rabbit Dermal LD50 > 10 g/kg
Rat Inhalation LC50 1 hr > 570 mg/m³
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
11. TOXICOLOGICAL INFORMATION

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.

Toxicity:

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

Glycerin, USP

*Oncorhynchus mykiss* (Rainbow Trout)  LC50  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.

Persistence and Degradability:  No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Gabapentin
Predicted  7.4  Log D  -1.31

Mobility in Soil:  No data available
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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Flavor

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Xylitol

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 201-788-0 |

Glycerin, USP

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
SAFETY DATA SHEET

Material Name: Neurontin (gabapentin) Oral Solution
Revision date: 09-Nov-2018

Version: 3.1

15. REGULATORY INFORMATION

REACH - Annex V - Exemptions from the obligations of Register:
Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bio accumulative, and toxic or very persistent and very bio accumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern

EU EINECS/ELINCS List
200-289-5

Water, purified

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present

16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 09-Nov-2018

Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this 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