



SAFETY DATA SHEET

Revision date: 08-Nov-2018

Version: 2.1

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

Product Identifier

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

Trade Name: NEURONTIN; NEUGABA; GANTIN; PARKETIN; GABAPENTIN PFIZER

Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as anticonvulsant

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
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CT13 9NJ
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+00 44 (0)1304 616161
Emergency telephone number:
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Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified

Hazard Statements: Not classified 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

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|------------|------------|-----------------------|--------------------|---|
| | | | | |

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3. COMPOSITION / INFORMATION ON INGREDIENTS

| | | | | |
|------------------------|------------|-----------|------------|------|
| Gabapentin | 60142-96-3 | 262-076-3 | Not Listed | 74.5 |
| Starch | 9005-25-8 | 232-679-6 | Not Listed | * |
| Talc (non-asbestiform) | 14807-96-6 | 238-877-9 | Not Listed | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|-----------------------|------------|-----------------------|--------------------|---|
| Hard gelatin capsules | MIXTURE | Not Listed | Not Listed | * |
| Lactose | 63-42-3 | 200-559-2 | Not Listed | * |

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

None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

None

5. FIRE FIGHTING MEASURES

Extinguishing Media:

Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products:

Formation of toxic gases is possible during heating or fire.

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.

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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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 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.

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

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.

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.

Gabapentin

Pfizer OEL TWA-8 Hr: 1200µg/m³

Starch

| | |
|-----------------------------------|------------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Australia TWA | 10 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Bulgaria OEL - TWA | 10.0 mg/m ³ |
| Czech Republic OEL - TWA | 4.0 mg/m ³ |
| Greece OEL - TWA | 10 mg/m ³ |
| | 5 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| | 4 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Slovakia OEL - TWA | 4 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Switzerland OEL - TWAs | 3 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Talc (non-asbestiform)

| | |
|--|---------------------------|
| ACGIH Threshold Limit Value (TWA) | 2 mg/m ³ |
| Australia TWA | 2.5 mg/m ³ |
| Austria OEL - MAKs | 2 mg/m ³ |
| Belgium OEL - TWA | 2 mg/m ³ |
| Bulgaria OEL - TWA | 1.0 fiber/cm ³ |
| | 6.0 mg/m ³ |
| | 3.0 mg/m ³ |
| Czech Republic OEL - TWA | 2.0 mg/m ³ |
| Denmark OEL - TWA | 0.3 fiber/cm ³ |
| Finland OEL - TWA | 0.5 fiber/cm ³ |
| Greece OEL - TWA | 10 mg/m ³ |
| | 2 mg/m ³ |
| Hungary OEL - TWA | 2 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| | 0.8 mg/m ³ |
| Lithuania OEL - TWA | 2 mg/m ³ |
| | 1 mg/m ³ |
| Netherlands OEL - TWA | 0.25 mg/m ³ |
| OSHA - Final PELs - Table Z-3 Mineral D: | 20 mppcf |
| Poland OEL - TWA | 4.0 mg/m ³ |
| | 1.0 mg/m ³ |
| Portugal OEL - TWA | 2 mg/m ³ |
| Romania OEL - TWA | 2 mg/m ³ |
| Slovakia OEL - TWA | 2 mg/m ³ |
| | 10 mg/m ³ |
| Slovenia OEL - TWA | 2 mg/m ³ |
| Spain OEL - TWA | 2 mg/m ³ |
| Sweden OEL - TWAs | 2 mg/m ³ |
| | 1 mg/m ³ |
| Switzerland OEL -TWAs | 2 mg/m ³ |

Exposure Controls

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.

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.

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.)

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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: | Capsule | Color: | Blue, orange or beige |
| 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 |
| 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 7.4 Log D -1.31

Hard gelatin capsules

No data available

Starch

No data available

Lactose

No data available

Talc (non-asbestiform)

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): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

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

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10. STABILITY AND REACTIVITY

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.

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.

Acute Toxicity: (Species, Route, End Point, Dose)

Gabapentin

Mouse Oral LD50 > 5000 mg/kg

Rat Oral LD50 > 5000mg/kg

Rat IV LD50 > 2000mg/kg

Mouse IV LD50 1000-2000mg/kg

Rat Subcutaneous LD50 > 4000mg/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

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11. TOXICOLOGICAL INFORMATION

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
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 (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.

Toxicity:

No data available

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.

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15. REGULATORY INFORMATION

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

Gabapentin

| | |
|--|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| 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

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

Starch

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| 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

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| 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 |

Talc (non-asbestiform)

| | |
|---|------------|
| 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 | 238-877-9 |

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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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 08-Nov-2018
Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

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