



SAFETY DATA SHEET

Revision date: 08-Nov-2018

Version: 2.1

Page 1 of 10

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

Product Identifier

Material Name: Gabapentin Tablets (Neurontin)

Trade Name: NEURONTIN; NORMATOL; 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
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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 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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%

SAFETY DATA SHEET

Material Name: Gabapentin Tablets (Neurontin)
Revision date: 08-Nov-2018

Page 2 of 10
Version: 2.1

3. COMPOSITION / INFORMATION ON INGREDIENTS

Gabapentin	60142-96-3	262-076-3	Not Listed	73.0
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Poloxamer 407	9003-11-6	Not Listed	Not Listed	*
Candelilla wax	8006-44-8	232-347-0	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Purified water	7732-18-5	231-791-2	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: 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.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

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: Not known

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

SAFETY DATA SHEET

Material Name: Gabapentin Tablets (Neurontin)
Revision date: 08-Nov-2018

Page 3 of 10
Version: 2.1

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

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

Corn 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
Ireland OEL - TWAs	5 mg/m ³
	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

SAFETY DATA SHEET

Material Name: Gabapentin Tablets (Neurontin)
Revision date: 08-Nov-2018

Page 4 of 10
Version: 2.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL -TWAs	3 mg/m ³
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
Magnesium stearate	
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

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

Exposure Controls

**Engineering Controls:
Personal Protective
Equipment:**

Engineering controls should be used as the primary means to control exposures. 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.)

SAFETY DATA SHEET

Material Name: Gabapentin Tablets (Neurontin)
Revision date: 08-Nov-2018

Page 5 of 10
Version: 2.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:	Film-coated tablets	Color:	White
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

Candelilla wax

No data available

Hydroxypropyl cellulose

No data available

Povidone

No data available

Purified water

No data available

Corn Starch

No data available

Talc (non-asbestiform)

No data available

Magnesium stearate

No data available

Poloxamer 407

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

SAFETY DATA SHEET

Material Name: Gabapentin Tablets (Neurontin)
Revision date: 08-Nov-2018

Page 6 of 10
Version: 2.1

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.
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

Povidone

Rat Oral LD50 100 g/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

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

SAFETY DATA SHEET

Material Name: Gabapentin Tablets (Neurontin)
Revision date: 08-Nov-2018

Page 7 of 10
Version: 2.1

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)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Hamster Lung Cells	Negative
<i>In Vivo</i> Unscheduled DNA Synthesis	Rat Hepatocyte	Negative
<i>In Vivo</i> 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

Povidone

IARC: Group 3 (Not Classifiable)

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

SAFETY DATA SHEET

Material Name: Gabapentin Tablets (Neurontin)
Revision date: 08-Nov-2018

Page 8 of 10
Version: 2.1

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

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

Poloxamer 407

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	Not Listed

Candelilla wax

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	232-347-0

Hydroxypropyl cellulose

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

SAFETY DATA SHEET

Material Name: Gabapentin Tablets (Neurontin)
Revision date: 08-Nov-2018

Page 9 of 10
Version: 2.1

15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Povidone	
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	Not Listed
Corn 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
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
Purified water	
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	231-791-2
Magnesium stearate	
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	209-150-3

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. Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity.
Revision date:	08-Nov-2018

SAFETY DATA SHEET

Material Name: Gabapentin Tablets (Neurontin)
Revision date: 08-Nov-2018

Page 10 of 10
Version: 2.1

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

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End of Safety Data Sheet