MATERIAL SAFETY DATA SHEET

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

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Material Name: Neurontin (gabapentin) Oral Solution

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

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless liquid

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

Additional Hazard Information:
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.
EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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	EU Classification	%
Gabapentin	60142-96-3	262-076-3	Not Listed	5.0
Glycerin, USP	56-81-5	200-289-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Flavor	NOT ASSIGNED	Not Listed	Not Listed	*

Xylitol	87-99-0	201-788-0	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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: May include oxides of carbon.

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 spill with absorbent material. 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: 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.

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/m^3

Glycerin, USP

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	50 mg/m^3 MAK
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELS - TWAs:	15 mg/m^3 total 5 mg/m^3
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

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. 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.

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:	Liquid	**Color:**	Colorless
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solubility: Soluble: Water

Flash Point (Liquid) (°C): >100

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)

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 1hr > 570 mg/m^3
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.

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

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout)	LD50	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.

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.

Gabapentin

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	262-076-3

Xylitol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	201-788-0

Glycerin, USP

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-289-5

Water, purified

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

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

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End of Safety Data Sheet