



MSN PHARMACEUTICAL INC
20 DUKE ROAD, PISCATAWAY, NJ-08854, USA

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SAFETY DATA SHEET (SDS)

Product Name

Vigabatrin for Oral Solution, USP 500 mg

1. Product Information

Product Name: Vigabatrin for Oral Solution, USP 500 mg

2. Composition/Information on Ingredients

Chemical Name	CAS No.	Weight (%)
Vigabatrin	60643-86-9	95 - 100
Povidone	9003-39-6	0 - 5

3. Hazards Identification

Eye: Causes serious eye irritation.

Skin: Causes eye irritation

Ingestion: May damage fertility or the unborn child.

Inhalation: May be harmful if inhaled. Causes respiratory tract irritation

4. First Aid Measures

Eye Contact: In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists

Skin Contact: In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs

Ingestion: In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person

Inhalation: Inhalation is not an anticipated route for liquid handling. For the intended use, see product label.

Self-protection of the first aider: Do not use mouth-to-mouth methods if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or another suitable proper respiratory medical device.

5. Emergency Overview

Health Hazards: Classified



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Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Reproductive toxicity	Category 1B

Physical Hazards: Not classified

OSHA Regulatory Status: This product is considered hazardous by the 2012 OSHA Hazard Communication Standard/Globally Harmonized System of Classification and Labelling of Chemicals (GHS); (29 CFR 1910.1200; Revision 3).

6. Fire Fighting Measures

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Protective equipment and precautions for firefighters: As with any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Fire / Explosion Hazards: Not applicable

7. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Avoid excessive contact. Avoid contact with eyes

Environmental precautions: See Section 14 for additional ecological information

Methods and material for containment and cleaning up: Pick up and transfer to properly labeled containers and Dispose of in accordance with local, state, and national regulations.

8. Handling and Storage


Precautions for safe handling: Handle in accordance with good industrial hygiene and safety practice

Conditions for safe storage: Store at 20°-25°C (68°-77°F). [see USP Controlled Temperature]. Other Precautions: Dispense in a tight, light-resistant container as defined in the USP/NF.

9. Exposure Controls/Personal Protection

Exposure Guidelines: This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region-specific regulatory bodies.

Engineering Controls: The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates

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should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable

Individual protection measures, such as personal protective equipment

Eye/face protection: None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are highly recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information

Skin and body protection: None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, and hood or head coverings may be necessary. Contact a health and safety professional for specific information

Respiratory protection: None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance.

General Hygiene Considerations: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment

10. Physical Properties

Physical state: Liquid

Appearance: Solution

Color: White

11. Stability and Reactivity

Stability: Stable under normal conditions of use.

Conditions to Avoid: Not available.

Incompatible Materials: Not available

Hazardous Decomposition Products: None under normal use conditions



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12. Toxicological Information

Information on toxicological effects

Symptoms: Most common adverse reactions in controlled studies include: permanent vision loss, fatigue, somnolence, nystagmus, tremors, blurred vision, memory impairment, weight gain, arthralgia, abnormal coordination, and confused state. In pediatric patients, the most common adverse reactions include: weight gain, upper respiratory tract infection, tremor, fatigue, aggression, and diplopia. Infantile Spasms adverse reactions include: somnolence, bronchitis, ear infection, and acute otitis media

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation: In clinical studies (n=4079), rashes were reported

Serious eye damage/eye irritation: Vigabatrin can cause permanent bilateral concentric visual field constriction in 30% or more of patients. Symptoms may be mild to severe, with tunnel vision to within 10 degrees of visual fixation. It may also produce central retina damage, which can decrease visual acuity. Double vision and blurred vision have been reported in 7% and 13%, respectively, of patients treated with vigabatrin 3 g/day and in 16% of patients treated with 6 g/day, compared with 3% in the placebo group

Germ cell mutagenicity: Vigabatrin was negative in in vitro (Ames, CHO/HGPRT mammalian cell forward gene mutation, chromosomal aberration in rat lymphocytes) and in in vivo (mouse bone marrow micronucleus) assays


Carcinogenicity: Vigabatrin showed no carcinogenic potential in mouse or rat when given in the diet at doses up to 150 mg/kg/day for 18 months (mouse) or at doses up to 150 mg/kg/day for 2 years (rat). These doses are less than the maximum recommended human dose (MRHD) for infantile spasms (150 mg/kg/day) and for refractory complex partial seizures (3 g/day) on a mg/m² basis

Developmental Toxicity: No adverse effects on male or female fertility were observed in rats at oral doses up to 150 mg/kg/day (approximately 1/2 the MRHD of 3 g/day on a mg/m² basis) for adults treated with refractory complex partial seizures

Rat experiments reported associations between the administration of vigabatrin and alterations of postnatal development (10) and male fertility profiles, but both of these studies acknowledged that drug effects on food intake and weight gain might have mediated the observed effects.

Teratogenicity: Vigabatrin administered orally to pregnant rabbits at dose levels of 50 to 200 mg/kg resulted in cleft palate and embryo-lethality, with a no-effect dose of 100 mg/kg/day. The no-effect dose was one-half the maximum recommended human dose of 3 g/day on a body surface area basis

Aspiration hazard: Due to the physical form of the product, it is not an aspiration hazard

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13. Ecological Information

Ecotoxicity: no data available
Persistence and degradability: no data available
Bioaccumulativ potential: no data available
Mobility in soil: no data available
Other adverse effects: no data available

14. Disposal Considerations

Product: Observe all federal, state, and local environmental regulations.
Contaminated packaging: Dispose of as unused product, Disposal should be in accordance with applicable regional, national and local laws and regulations

15. Transport Information

IATA: Not Regulated.
ICAO (Air): Not Regulated.
RID/ADR: Not Regulated
MEX: Not Regulated

16. Regulatory Information


US Federal Regulations

SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	Yes
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act): This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

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CERCLA: This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65; No component is on the prop 65-list.

U.S. State Right-to-Know Regulations: This product does not contain any substances regulated by state right-to-know regulations

Disclaimer: This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. It is not meant to be an all-inclusive document on worldwide hazard communications regulations. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment.