US - OSHA SAFETY DATA SHEET

Issue Date 17-Jul-2017 **Revision Date** **Version** 1

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

Product identifier

Product Name Vigabatrin for Oral Solution, USP 500 mg

Other means of identification

Synonyms Not available.

Recommended use of the chemical and restrictions on use

Recommended Use Vigabatrin is used for the treatment of refractory complex partial seizures in adults. It is indicated as an adjunctive therapy in patients that fail to respond to other therapies. It is also used to treat infantile spasms in children 1 month to 2 years.

Uses advised against Not available.

Details of the supplier of the safety data sheet

Supplier Address

Par Pharmaceutical
1 Ram Ridge Rd.
Chestnut Ridge, NY 10977

Emergency telephone number

24 Hour Emergency Phone Number Chemtrec (US): 1-800-424-9300
Emergency Telephone 1-845-425-7100

2. HAZARDS IDENTIFICATION

Classification

Health Hazards

Classified.

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).

Label elements

Emergency Overview

Danger

Hazard statements
Causes skin irritation.
Causes serious eye irritation.
May damage fertility or the unborn child.

Appearance Solution **Physical state** Liquid **Odor** Not available.

Precautionary Statements - Prevention
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Use personal protective equipment as required.
Wash face, hands and any exposed skin thoroughly after handling.

Precautionary Statements - Response
If exposed or concerned: Get medical attention.
Specific treatment (see on this label)
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical attention.
If on skin: Wash with plenty of soap and water
If skin irritation occurs: Get medical attention.
Take off contaminated clothing and wash it before reuse.

Precautionary Statements - Storage
Store locked up.

Precautionary Statements - Disposal
Dispose of contents/container in compliance with state and local regulations

Hazards not otherwise classified (HNOC)
None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

4. FIRST AID MEASURES

First aid measures

General advice Consult a physician. Show this safety data sheet to the doctor in attendance.

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.

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

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.

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.

Most important symptoms and effects, both acute and delayed

Symptoms Most common adverse reactions in controlled studies include: permanent vision loss, fatigue, somnolence, nystagmus, tremor, blurred vision, memory impairment, weight gain, arthralgia, abnormal coordination, and confusional 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.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical
Not available.

Hazardous combustion products Not available.

Explosion data
Sensitivity to Mechanical Impact Not available.
Sensitivity to Static Discharge None known.

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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid excessive contact. Avoid contact with eyes.

Environmental precautions

Environmental precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for containment Pick up and transfer to properly labeled containers.

Methods for cleaning up Dispose of in accordance with local, state, and national regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions 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.

Incompatible materials Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

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

Appropriate engineering controls

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 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid		
Appearance	Solution	**Odor**	Not available.
Color	White	**Odor threshold**	Not available.

Property	**Values**	**Remarks**
pH	6.9	(Vigabatrin)
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	Not available.	
Lower flammability limit:	Not available.	
Vapor pressure	Not available.	
Vapor density	Not available.	
Specific Gravity	Not available.	
Water solubility	Soluble in water.	(Vigabatrin)
Solubility in other solvents	Not available.	
Partition coefficient	Not available.	
Autoignition temperature	Not available.	
Decomposition temperature	Not available.	
Kinematic viscosity	Not available.	
Dynamic viscosity	Not available.	
Explosive properties	Not available.	
Oxidizing properties	Not available.	

Other Information

Softening point	Not available.
Molecular weight	129.16
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY

Reactivity
Stable at normal conditions.

Chemical stability
Stable at ambient temperatures and atmospheric pressures under recommended storage and handling conditions.

Possibility of Hazardous Reactions
None under normal processing.

Hazardous polymerization
Hazardous polymerization does not occur.

Conditions to avoid
Not available.

Incompatible materials
Not available.

Hazardous Decomposition Products
None under normal use conditions.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Vigabatrin 60643-86-9	3 g/kg (Rat)	-	-	-

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.

Sensitization Not available.

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.

STOT - single exposure Not classified.

STOT - repeated exposure	Not classified.
Target Organ Effects	Not available.
Neurological effects	Not available.
Aspiration hazard	Due to the physical form of the product, it is not an aspiration hazard.

12. ECOLOGICAL INFORMATION

Ecotoxicity
Not available.

Persistence and degradability
Not available.

Bioaccumulation
Not available.

Mobility
Not available.

Other adverse effects
Not available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes	Disposal should be in accordance with applicable regional, national and local laws and regulations.
Contaminated packaging	Disposal should be in accordance with applicable regional, national and local laws and regulations.
US EPA Waste Number	Not available.
California Hazardous Waste Codes	Not available.

14. TRANSPORT INFORMATION

DOT	Not regulated.
TDG	Not regulated.
MEX	Not regulated.
ICAO (air)	Not regulated.
IATA	Not regulated.
IMDG	Not regulated.
RID	Not regulated.
ADR	Not regulated.
ADN	Not regulated.

15. REGULATORY INFORMATION

International Inventories

TSCA	Does not comply
DSL/NDSL	Does not comply

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

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).

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.

16. OTHER INFORMATION

Prepared By	IES Engineers
Issue Date	17-Jul-2017

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.

End of Safety Data Sheet