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.

<table>
<thead>
<tr>
<th></th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin corrosion/irritation</td>
<td>Category 2</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Category 2A</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Category 1B</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vigabatrin</td>
<td>60643-86-9</td>
<td>95 - 100</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-6</td>
<td>0 - 5</td>
</tr>
</tbody>
</table>

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

**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

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
<td></td>
</tr>
<tr>
<td>Appearance</td>
<td>Solution</td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>White</td>
<td>Odor threshold Not available.</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>6.9</td>
<td>(Vigabatrin)</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Upper flammability limit:</td>
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<td></td>
</tr>
<tr>
<td>Lower flammability limit:</td>
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<td></td>
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<tr>
<td>Vapor pressure</td>
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<td></td>
</tr>
<tr>
<td>Vapor density</td>
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<td></td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>Soluble in water.</td>
<td>(Vigabatrin)</td>
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<tr>
<td>Solubility in other solvents</td>
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<td></td>
</tr>
<tr>
<td>Partition coefficient</td>
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<tr>
<td>Autoignition temperature</td>
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<td></td>
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<tr>
<td>Decomposition temperature</td>
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<tr>
<td>Kinematic viscosity</td>
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<td></td>
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<tr>
<td>Dynamic viscosity</td>
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<tr>
<td>Explosive properties</td>
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<tr>
<td>Oxidizing properties</td>
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</table>

Other Information

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Softening point</td>
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<tr>
<td>Molecular weight</td>
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<td>VOC Content (%)</td>
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</tr>
<tr>
<td>Density</td>
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</tr>
<tr>
<td>Bulk density</td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
<th>Intravenous LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vigabatrin 60643-86-9</td>
<td>3 g/kg (Rat)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

#### 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
<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute health hazard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic Health Hazard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fire hazard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sudden release of pressure hazard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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