

# SAFETY DATA SHEET



## Vigabatrin Tablets USP, 500 mg

### Section 1. Identification

- GHS product identifier** : Vigabatrin Tablets USP, 500 mg
- Product code** : Not available.
- Other means of identification** : 500 mg tablets are white film coated, modified oval, bi-convex with "54 444" debossed on one side and scored on the other.
- Product type** : Regulated prescription drug.
- Relevant identified uses of the substance or mixture and uses advised against**

#### Identified uses

Regulated prescription medication. See package insert for more information.

- Supplier's details** : Hikma Pharmaceuticals USA Inc.  
1809 Wilson Road  
Columbus, Ohio 43228  
Tel: (614) 276-4000

- Emergency telephone number (with hours of operation)** : CHEMTREC, U.S.: 1-800-424-9300 International: +1-703-527-3887  
24/7

### Section 2. Hazards identification

- OSHA/HCS status** : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
- Classification of the substance or mixture** : SKIN CORROSION/IRRITATION - Category 2  
SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A  
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

#### GHS label elements

##### Hazard pictograms



- Signal word** : Warning
- Hazard statements** : H315 - Causes skin irritation.  
H319 - Causes serious eye irritation.  
H335 - May cause respiratory irritation.

**This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.**

#### Precautionary statements

- Prevention** : P280 - Wear protective gloves. Wear eye or face protection.  
P271 - Use only outdoors or in a well-ventilated area.  
P261 - Avoid breathing dust.  
P264 - Wash thoroughly after handling.

## Section 2. Hazards identification

<b>Response</b>	: P304 + P340, P312 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell. P362 + P364 - Take off contaminated clothing and wash it before reuse. P302 + P352 - IF ON SKIN: Wash with plenty of water. P332 + P313 - If skin irritation occurs: Get medical advice or attention. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice or attention.
<b>Storage</b>	: P405 - Store locked up. P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.
<b>Disposal</b>	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
<b>Hazards not otherwise classified</b>	: None known.

## Section 3. Composition/information on ingredients

<b>Substance/mixture</b>	: Mixture
<b>Other means of identification</b>	: 500 mg tablets are white film coated, modified oval, bi-convex with "54 444" debossed on one side and scored on the other.

Ingredient name	%	CAS number
Vigabatrin	≥50 - ≤75	60643-86-9
Cellulose	≥10 - ≤25	9004-34-6

  

Active pharmaceutical ingredient	%	CAS number
Vigabatrin	≥50 - ≤75	60643-86-9

Any concentration shown as a range is to protect confidentiality or is due to batch variation. If a generic chemical name is shown and/or the CAS number is not disclosed, the specific chemical identity has been withheld as a trade secret.

**There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.**

Occupational exposure limits, if available, are listed in Section 8.

See Package Insert for further information.

## Section 4. First aid measures

### Description of necessary first aid measures

<b>Eye contact</b>	: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.
<b>Inhalation</b>	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

## Section 4. First aid measures

- Skin contact** : Flush contaminated skin with plenty of water. Continue to rinse for at least 20 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

### Most important symptoms/effects, acute and delayed

#### Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : May cause respiratory irritation.
- Skin contact** : Causes skin irritation.
- Ingestion** : No known significant effects or critical hazards.

#### Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:  
pain or irritation  
watering  
redness
- Inhalation** : Adverse symptoms may include the following:  
respiratory tract irritation  
coughing
- Skin contact** : Adverse symptoms may include the following:  
irritation  
redness
- Ingestion** : No known significant effects or critical hazards.

### Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

## Section 5. Fire-fighting measures

### Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

## Section 5. Fire-fighting measures

- Specific hazards arising from the chemical** : No specific fire or explosion hazard.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials:  
carbon dioxide  
carbon monoxide  
nitrogen oxides  
metal oxide/oxides
- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### Methods and materials for containment and cleaning up

- Small spill** : Move containers from spill area. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

## Section 7. Handling and storage

### Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

## Section 7. Handling and storage

**Conditions for safe storage, including any incompatibilities** : Store between the following temperatures: 20 to 25°C (68 to 77°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

## Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Vigabatrin Cellulose	None. <b>ACGIH TLV (United States, 3/2020).</b> TWA: 10 mg/m <sup>3</sup> 8 hours. <b>NIOSH REL (United States, 10/2016).</b> TWA: 5 mg/m <sup>3</sup> 10 hours. Form: Respirable fraction TWA: 10 mg/m <sup>3</sup> 10 hours. Form: Total <b>OSHA PEL (United States, 5/2018).</b> TWA: 5 mg/m <sup>3</sup> 8 hours. Form: Respirable fraction TWA: 15 mg/m <sup>3</sup> 8 hours. Form: Total dust

**Appropriate engineering controls** : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

**Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

**Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

**Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: Regular safety glasses are appropriate.

Skin protection

**Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

## Section 8. Exposure controls/personal protection

- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

## Section 9. Physical and chemical properties and safety characteristics

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

### Appearance

- Physical state** : Solid. [500 mg tablets are white film coated, modified oval, bi-convex with "54 444" debossed on one side and scored on the other.]
- Color** : White film coated, modified oval, bi-convex with "54 444" debossed on one side and scored on the other.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point/freezing point** : Not available.
- Boiling point, initial boiling point, and boiling range** : Not available.
- Flash point** : Not applicable.
- Evaporation rate** : Not available.
- Flammability** : Not available.
- Lower and upper explosion limit/flammability limit** : Not applicable.
- Vapor pressure** : Not available.
- Relative vapor density** : Not applicable.
- Relative density** : Not available.
- Solubility** : Not available.
- Solubility in water** : Not available.
- Partition coefficient: n-octanol/water** : Not applicable.
- Auto-ignition temperature** : Not applicable.
- Decomposition temperature** : Not available.
- Viscosity** : Not applicable.
- Flow time (ISO 2431)** : Not available.
- Particle characteristics**
- Median particle size** : Not available.

## Section 10. Stability and reactivity

- Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- Chemical stability** : The product is stable.
- Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
- Conditions to avoid** : No specific data.
- Incompatible materials** : Reactive or incompatible with the following materials: oxidizing materials.
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Cellulose	LD50 Oral	Rat	>5 g/kg	-

#### Irritation/Corrosion

There is no data available.

#### Sensitization

There is no data available.

#### Mutagenicity

There is no data available.

#### Carcinogenicity

There is no data available.

#### Reproductive toxicity

There is no data available.

#### Teratogenicity

There is no data available.

#### Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Vigabatrin	Category 3	-	Respiratory tract irritation

#### Specific target organ toxicity (repeated exposure)

There is no data available.

#### Aspiration hazard

There is no data available.

## **Section 11. Toxicological information**

**Information on the likely routes of exposure** : Routes of entry anticipated: Oral, Dermal, Inhalation.

### **Potential acute health effects**

**Eye contact** : Causes serious eye irritation.  
**Inhalation** : May cause respiratory irritation.  
**Skin contact** : Causes skin irritation.  
**Ingestion** : No known significant effects or critical hazards.

### **Symptoms related to the physical, chemical and toxicological characteristics**

**Eye contact** : Adverse symptoms may include the following:  
pain or irritation  
watering  
redness  
**Inhalation** : Adverse symptoms may include the following:  
respiratory tract irritation  
coughing  
**Skin contact** : Adverse symptoms may include the following:  
irritation  
redness  
**Ingestion** : No known significant effects or critical hazards.

### **Delayed and immediate effects and also chronic effects from short and long term exposure**

#### **Short term exposure**

**Potential immediate effects** : No known significant effects or critical hazards.  
**Potential delayed effects** : No known significant effects or critical hazards.

#### **Long term exposure**

**Potential immediate effects** : No known significant effects or critical hazards.  
**Potential delayed effects** : No known significant effects or critical hazards.

#### **Potential chronic health effects**

**General** : No known significant effects or critical hazards.  
**Carcinogenicity** : No known significant effects or critical hazards.  
**Mutagenicity** : No known significant effects or critical hazards.  
**Reproductive toxicity** : No known significant effects or critical hazards.

### **Numerical measures of toxicity**

#### **Acute toxicity estimates**

There is no data available.



## Section 12. Ecological information

### Toxicity

There is no data available.

### Persistence and degradability

There is no data available.

### Bioaccumulative potential

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
Vigabatrin	-2.16	-	low

### Mobility in soil

**Soil/water partition coefficient (K<sub>oc</sub>)** : Not available.

**Other adverse effects** : No known significant effects or critical hazards.

## Section 13. Disposal considerations

**Disposal methods** : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

## Section 14. Transport information

	DOT Classification	IMDG	IATA
<b>UN number</b>	Not regulated.	Not regulated.	Not regulated.
<b>UN proper shipping name</b>	-	-	-
<b>Transport hazard class(es)</b>	-	-	-
<b>Packing group</b>	-	-	-
<b>Environmental hazards</b>	No.	No.	No.

**AERG** : Not applicable

## Section 14. Transport information

**Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport in bulk according to IMO instruments** : Not available.

## Section 15. Regulatory information

Drug products are considered exempt from hazard communication labeling under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

**FDA** : Vigabatrin Tablets USP, 500mg is an approved prescription medication.

**U.S. Federal regulations** : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined

**Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)** : Not listed

**Clean Air Act Section 602 Class I Substances** : Not listed

**Clean Air Act Section 602 Class II Substances** : Not listed

**DEA List I Chemicals (Precursor Chemicals)** : Not listed

**DEA List II Chemicals (Essential Chemicals)** : Not listed

**SARA 302/304**

**Composition/information on ingredients**

No products were found.

**SARA 304 RQ** : Not applicable.

**SARA 311/312**

**Classification** : SKIN CORROSION/IRRITATION - Category 2  
 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A  
 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

**Composition/information on ingredients**

Name	%	Classification
Vigabatrin	≥50 - ≤75	SKIN CORROSION/IRRITATION - Category 2 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

**State regulations**

**Massachusetts** : The following components are listed: Cellulose

**New York** : None of the components are listed.

**New Jersey** : The following components are listed: Cellulose

**Pennsylvania** : The following components are listed: Cellulose

**California Prop. 65**

## Section 15. Regulatory information

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

### International regulations

#### Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

#### Montreal Protocol

Not listed.

#### Stockholm Convention on Persistent Organic Pollutants

Not listed.

#### Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

#### UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

### Inventory list

**United States (TSCA 8b)** : All components are active or exempted.

## Section 16. Other information

### Procedure used to derive the classification

Classification	Justification
SKIN CORROSION/IRRITATION - Category 2	Calculation method
SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A	Calculation method
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3	Calculation method

### History

- Date of issue/Date of revision** : 03/15/2022
- Date of previous issue** : Not applicable
- Version** : 1
- Prepared by** : KMK Regulatory Services Inc.
- Key to abbreviations** :
  - ATE = Acute Toxicity Estimate
  - BCF = Bioconcentration Factor
  - GHS = Globally Harmonized System of Classification and Labelling of Chemicals
  - IATA = International Air Transport Association
  - IBC = Intermediate Bulk Container
  - IMDG = International Maritime Dangerous Goods
  - LogPow = logarithm of the octanol/water partition coefficient
  - MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
  - N/A = Not available
  - SGG = Segregation Group
  - UN = United Nations

### Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.