



Humco Holding Group, Inc.  
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24-Hour Emergency Number (CHEMTREC)  
USA- 800-424-9300

All non-emergency calls should be directed to  
Customer Service at 800-662-3435

NAME: GABAPENTIN, USP

SDS NO. 8055

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Gabapentin, USP

**Synonyms:** 1-(amino methyl) cyclohexane acetic acid

**Recommended Use:** Active Pharmaceutical Ingredient

**Manufacturer by:** Humco Holding Group, Inc.

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## 2. HAZARD IDENTIFICATION

<b>Pictogram:</b>	
<b>Classification:</b>	Acute toxicity - Oral Category 3
<b>Signal Word:</b>	Danger
<b>Hazard Statements:</b>	Causes skin irritation. Causes serious eye irritation
<b>Precautionary Statements</b>	May damage fertility or the unborn child. May cause respiratory irritation, or may cause drowsiness and dizziness. Avoid contact with skin and eyes. Do not reuse this container. Use with adequate ventilation. Wash thoroughly after handling. If exposed or concerned: get medical advice/attention. Keep container tightly closed. Stored at room temperature

	Disposal: Dispose of contents and/or container in accordance with local regulations.
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### 3. COMPOSITION / INGREDIENTS

CHEMICAL NAME	CAS#
GABAPENTIN, USP	60142-96-3

The exact percentage has been withheld as a trade secret

### 4. FIRST-AID MEASURES

IN CASE OF EYE CONTACT: Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT: Wash with soap & water for 15minutes. If irritation persists seek medical aid.

IF SWALLOWED: Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

SYMPTOMS AND EFFECTS: Not expected to present a significant hazard under anticipated conditions of normal use.

### 5. FIRE-FIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: Not applicable

FLAMMABLE PROPERTIES: May be combustibile at high temperature

HAZARDOUS COMBUSTION PRODUCTS: Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA: Small fire: dry chemical, CO2 or water spray. Large fire: dry chemical, CO2, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

### 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

**METHODS & MATERIAL FOR CONTAINMENT:** On land, sweep or shovel into suitable containers. Minimize generation of dust.

**CLEANUP PROCEDURE:** Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition.

Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

## 7. HANDLING AND STORAGE

**PRECAUTIONS FOR SAFE HANDLING:** Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

**STORAGE CONDITIONS:** Store in original container, tightly sealed container, protected from direct sunlight, in a dry, cool and well ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. 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. Preserve in tight, light-resistant containers.

## 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

National occupational exposure limits

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Gabapentin 60142-96-3	N/L	N/L	N/L	N/L

**EXPOSURE GUIDELINES:** Consult local authorities for provincial or state exposure limits

**PERSONAL PROTECTIVE EQUIPMENT:** Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

**SPECIFIC ENGINEERING CONTROLS:** Adequate mechanical ventilation. Fume hood, eye wash station, and safety shower.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	White to Off-white Crystalline Powder	<b>Upper/Lower Flammability:</b>	Not determined
<b>Odor:</b>	Not determined	<b>Vapor Pressure</b>	2.94E-10 mm Hg (25°C)
<b>Odor Threshold:</b>	Not determined	<b>Vapor Density:</b>	Not determined
<b>pH:</b>	6.5 – 8.0 (2%)	<b>Relative Density:</b>	Not determined
<b>Melting point /Freezing Point:</b>	162-167°C (323.6 – 332.6 °F)	<b>Solubilities:</b>	Not determined
<b>Boiling point/range:</b>	Not determined	<b>Partition coefficient: n-octanol/water:</b>	-1.31 (20C)
<b>Flash point</b>	Not determined	<b>Auto-ignition temperature</b>	Not determined
<b>Evaporation rate</b>	Not determined	<b>Decomposition Temperature:</b>	Not determined
<b>Flammability:</b>	Not determined	<b>Viscosity</b>	Not determined

## 10. STABILITY AND REACTIVITY

REACTIVITY: Not established

STABILITY: Stable under recommended storage conditions

MATERIALS TO AVOID: Strong oxidants.

HAZARDOUS DECOMPOSITION PRODUCTS: Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

HAZARDOUS POLYMERIZATION: Will not occur

POSSIBILITY OF HAZARDOUS REACTION: Not established

CONDITIONS TO AVOID: Moisture, sunlight and extreme temperatures

## 11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY:

Oral: Rat: LD50 (mg/Kg) : >500 mg/kg

Dermal: Rabbit: LD50: Not available

Inhalation: Rat: LD50: Not available

SKIN CORROSION/IRRITATION: Not available

SERIOUS EYE DAMAGE/EYE IRRITATION: Not available

RESPIRATORY OR SKIN SENSITIZATION: Not available

GERM CELL MUTAGENICITY: Not available

CARCINOGENICITY

OSHA: Not listed.

NTP: Not listed.

IARC: Not listed.

California Proposition 65: This product is not known to the State of California to cause cancer, birth defects, or any other reproductive harm

**REPRODUCTIVE TOXICITY:**

Reproductivity study: Mouse: 1000 - 3000 mg/kg/day: Delayed bone ossification but no malformations.

Reproductivity study: Rat: 500 - 2000 mg/kg/day: At 500 mg/kg/day, increased the incidence of hydroureter and hydronephrosis in the offspring. At 2000 mg/kg/day no increase in other malformations.

Reproductivity study: Rabbit: 60 - 1500 mg/kg/day: Increased incidence of postimplantion loss but no increase in malformations of offspring.

Reproductivity study: Rat: < 2000 mg/kg/day: No adverse effects on fertility.

No adverse effects were reported in the infants from mothers taking gabapentin during pregnancy and while breast feeding, and the authors considered that gabapentin was generally safe during breast feeding. Based on available data, the classification criteria are not met

SPECIFIC TARGET ORGAN TOXICITY-SINGLE EXPOSURE: Not Available.

SPECIFIC TARGET ORGAN TOXICITY-REPEATED EXPOSURE: Not Available.

ASPIRATION HAZARDS: Not Available.

SIGNS AND SYMPTOMS OF EXPOSURE: Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms related to the physical, chemical, and toxicological characteristics: Unsteadiness.

Uncontrolled eye movements. Visual disturbances. Dizziness. Drowsiness. Tiredness. Muscle pain. Back pain. Swelling of face or extremities. Twitching. Memory loss. Mood or behavior changes. Slurred speech. Frequent, painful, or difficult urination. Constipation. Indigestion. Nausea. Diarrhea. Vomiting. Abdominal pain. Headache. Decreased sexual desire. Difficulty sleeping. Runny nose. Dry mouth. Sore throat. Ringing in ears. Weight gain. Delayed and immediate effects of exposure: High blood pressure. Medical conditions aggravated by exposure: Active alcoholism. Diabetes. Impaired kidney function.

**POTENTIAL HEALTH EFFECTS**

Inhalation: Harmful if inhaled. May cause respiratory tract irritation.

Ingestion: Toxic if swallowed.

Skin: Harmful if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

**12. ECOLOGICAL INFORMATION**

<b>Acute or chronic aquatic toxicity:</b>	No specific information available, but material is not intended to be released to the environment.
<b>Chemical degradation:</b>	Not determined.
<b>Biodegradation:</b>	Not determined.
<b>Bioaccumulation potential</b>	Not determined.

<b>Adsorption studies or leaching studies:</b>	Not determined.
<b>Other adverse effects</b>	Not determined.

### 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with federal, state and local laws and regulations. Avoid release into environment.

### 14. TRANSPORT INFORMATION

<b>DOT Hazard Classification:</b>	NOT HAZARDOUS
<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable
<b>Transport hazard class(es):</b>	Not applicable
<b>Packing group number:</b>	Not applicable
<b>Environmental hazards:</b>	Not applicable
<b>Special precautions:</b>	Do not freeze, avoid extreme heat

### 15. REGULATORY INFORMATION

Not determined

### 16. OTHER INFORMATION

The information in this SDS is considered current and reliable. However, the data is provided without any warranty, expressed or implied, regarding its correctness or accuracy. Since the conditions for use, handling, storage and disposal are beyond Humco's control, it is the responsibility of the user to determine safe conditions for use and to assume liability for loss, damage, or expenses arising from improper use. No warranty expressed or implied regarding the product described herein will be created by or inferred from any statement or omission. Various agencies may have specific regulations concerning the transportation, handling, storage, use or disposal of this product which may not be reflected in the SDS. The user should review these regulations to ensure full compliance.