SAFETY DATA SHEET

1. Identification

Product identifier Gabapentin Related Compound A

Other means of identification

Catalog number 1287325
CAS number 64744-50-9
Synonyms 3,3-Pentamethylene-4-butyrolactam * Gabapentin lactam
Chemical name 2-Azaspiro[4.5]decan-3-one

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
United States
Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number
CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.
Health hazards Acute toxicity, oral Category 3
Environmental hazards Not classified.
OSHA defined hazards Not classified.

Label elements

Signal word Danger
Hazard statement Toxic if swallowed.
Precautionary statement
Prevention Wash thoroughly after handling.
Response If swallowed: Immediately call a poison center/doctor. Rinse mouth.
Storage Store locked up.
Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information Pharmaceutical related compound of unknown potency.

3. Composition/information on ingredients

Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabapentin Related Compound A</td>
<td>3,3-Pentamethylene-4-butyrolactam</td>
<td>64744-50-9</td>
<td>100</td>
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</tbody>
</table>
4. First-aid measures

**Inhalation**
Move to fresh air. Call a physician if symptoms develop or persist.

**Skin contact**
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye contact**
Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion**
Rinse mouth thoroughly. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

**Most important symptoms/effects, acute and delayed**
Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects.

**Indication of immediate medical attention and special treatment needed**
Provide general supportive measures and treat symptomatically.

**General information**
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

**Suitable extinguishing media**
Water, Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters**
Wear suitable protective equipment.

**Fire fighting equipment/instructions**
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards**
No unusual fire or explosion hazards noted.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

**Methods and materials for containment and cleaning up**
For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

**Environmental precautions**
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

**Precautions for safe handling**
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Cover all containers for solutions and slurries while being transferred. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). No open handling.

**Conditions for safe storage, including any incompatibilities**
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

**Occupational exposure limits**
No exposure limits noted for ingredient(s).

**Biological limit values**
No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls**
Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). No open handling.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**
Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin protection

Hand protection
Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Consider double gloves.

Other
Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task.

Respiratory protection
Chose respiratory protection appropriate to the task and the level of existing engineering controls. Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup.

Thermal hazards
Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations
Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment. Pharmacological effects may be seen with occupational exposure.

9. Physical and chemical properties

Appearance descriptions are general information and not specific to any USP lot.

Appearance
Solid.

Physical state
Powder.

Form
Off-white.

Color
Odor
Not available.

Odor threshold
Not available.

pH
Not available.

Melting point/freezing point
183.2 - 192.2 °F (84 - 89 °C)

Initial boiling point and boiling range
Not available.

Flash point
Not available.

Evaporation rate
Not available.

Flammability (solid, gas)
Not available.

Upper/lower flammability or explosive limits
Flammability limit - lower (%)
Not available.

Flammability limit - upper (%)
Not available.

Explosive limit - lower (%)
Not available.

Explosive limit - upper (%)
Not available.

Vapor pressure
Not available.

Vapor density
Not available.

Relative density
Not available.

Solubility(ies)
Solubility (water)
Slightly soluble.

Solubility (other)
Chloroform: Soluble.

Methanol: Soluble.

Mineral acid: Soluble.

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

Other information
Molecular formula
C9H15NO

Molecular weight
153.22

10. Stability and reactivity

Reactivity
The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability
Material is stable under normal conditions.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
Contact with incompatible materials.

Incompatible materials
Strong oxidizing agents.
Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

11. Toxicological information

Information on likely routes of exposure

Inhalation
Knowledge about health hazard is incomplete.

Skin contact
Knowledge about health hazard is incomplete.

Eye contact
Knowledge about health hazard is incomplete.

Ingestion
Toxic if swallowed.

Symptoms related to the physical, chemical, and toxicological characteristics
Not available.

Information on toxicological effects

Acute toxicity
Toxic if swallowed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabapentin Related Compound A (CAS 64744-50-9)</td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
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<tr>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>LD50 Mouse</td>
<td>300 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>200 - 500 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Knowledge about health hazard is incomplete.

Serious eye damage/eye irritation
Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization
Knowledge about health hazard is incomplete.

Skin sensitization
Knowledge about health hazard is incomplete.

Germ cell mutagenicity
Knowledge about mutagenicity is incomplete.

Carcinogenicity
Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity
Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens
Not listed.

Reproductive toxicity
Knowledge about health hazard is incomplete.

Specific target organ toxicity - single exposure
Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure
Knowledge about health hazard is incomplete.

Aspiration hazard
Based on available data, the classification criteria are not met.

Further information
Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions
Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations
Dispose in accordance with all applicable regulations.
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

**DOT**
- **UN number**: UN2811
- **UN proper shipping name**: Toxic solid, organic, n.o.s. (2-Azaspiro(4,5)decan-3-one)
- **Class**: 6.1
- **Subsidiary risk**: -
- **Packing group**: III

**IATA**
- **UN number**: UN2811
- **UN proper shipping name**: Toxic solid, inorganic, n.o.s. (2-Azaspiro(4,5)decan-3-one)
- **Class**: 6.1
- **Subsidiary risk**: -
- **Packing group**: III

**Other information**
- **Passenger and cargo aircraft**: Allowed with restrictions.
- **Cargo aircraft only**: Allowed with restrictions.
- Not applicable.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

**DOT; IATA**

General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

**US federal regulations**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

- **TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**
  Not regulated.
- **CERCLA Hazardous Substance List (40 CFR 302.4)**
  Not listed.
- **SARA 304 Emergency release notification**
  Not regulated.
  Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

- **Hazard categories**
  - Immediate Hazard: Yes
  - Delayed Hazard: No
  - Fire Hazard: No
  - Pressure Hazard: No
  - Reactivity Hazard: No

- **SARA 302 Extremely hazardous substance**
  Not listed.

**SARA 311/312 Hazardous chemical**

Yes
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