# SAFETY DATA SHEET

**Brivaracetam Oral Solution**

## 1. IDENTIFICATION

**Product identifier: Brivaracetam Oral Solution**
**Product Codes: 0121-1074-10**

| | |
|---|---|
| **Supplier Name and Address:** | PAI Pharma<br>1700 Perimeter Road<br>Greenville, SC 29605 |
| **Telephone number**: | (864) 277-7282 |
| **Emergency phone number**: | CHEMTREC 800-424-9300 |

**Recommended use:** Human drug
**Restrictions on use:** Prescription use only

## 2. HAZARD(S) IDENTIFICATION

**Classification:**

| Physical | Health |
|---|---|
| Not hazardous | Not hazardous |

**Not hazardous in accordance with the GHS and OSHA Hazcom 2024.**

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical name | CAS No. | Amount |
|---|---|---|
| Brivaracetam | 357336-20-0 | 1-5% |
| D-glucitol | 50-70-4 | Proprietary |
| Glycerol | 56-81-5 | Proprietary |
| Water | 7732-18-5 | Proprietary |
| Sucralose | 56038-13-2 | Proprietary |
| Raspberry Ketone | 5471-51-2 | Proprietary |
| Cellulose, carboxymethyl ether, sodium salt | 9004-32-4 | Proprietary |
| Trisodium citrate dihydrate | 6132-04-3 | Proprietary |
| Methyl paraben | 99-76-3 | Proprietary |
| Citric acid | 77-92-9 | 0.1-1% |

**The exact percentage (concentration) of composition has been withheld as a trade secret.**

## 4. FIRST-AID MEASURES

**Inhalation:** Remove people to fresh air. If irritation or other symptoms occur, get medical attention.
**Skin contact:** Remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.
**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists**.**
**Ingestion:** In the case of unintentional ingestion or overdosage, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

**Most important symptoms/effects, acute and delayed:** May cause mild eye and skin irritation. Swallowing may cause effects as seen in clinical use including drowsiness, tiredness, dizziness, mood and behavior changes, nausea and vomiting.

**Indication of immediate medical attention and special treatment, if necessary:** Medical attention is recommended for unintended ingestion or overdosage.

## 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use any media that is suitable for the surrounding fire.

**Specific hazards arising from the chemical:** Product is not classified as flammable or combustible but will burn in a fire after the water has evaporated.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Contain and **c**ollect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

## 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure guidelines:**

| | |
|---|---|
| Brivaracetam | None Established |
| D-glucitol | None Established |
| Glycerol | 5 mg/m3 (respirable) 15 mg/m3 (total) TWA OSHA PEL |
| Water | None Established |
| Sucralose | None Established |
| Raspberry Ketone | None Established |
| Cellulose, carboxymethyl ether, sodium salt | None Established |
| Trisodium citrate dihydrate | None Established |
| Methyl paraben | None Established |
| Citric acid | None Established |

**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

**Individual protection measures:**
**Respiratory protection:** None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.
**Skin protection:** None required for normal use. Impervious gloves recommended for manufacturing operations.
**Eye protection:** None required for normal use. Chemical safety goggles recommended for manufacturing operations.
**Other:** None known.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| **Physical State:** Liquid | **pH:** Not determined |
| **Odor:** Raspberry | **Color:** Colorless to yellowish |
| **Melting point/freezing point:** Not determined | **Boiling Point:** Not determined |
| **Flash point:** Not applicable | **Particle Characteristics:** Not applicable for liquids |
| **Flammability:** Not flammable | **VOC:** Not determined |
| **Flammable limits: LEL:** None | **UEL:** None |
| **Vapor pressure:** Same as water | **Relative vapor density:** Same as water |
| **Relative density**: Not available | **Solubility(ies):** Partially soluble |
| **Partition coefficient: n-octanol/water:** Not available | **Auto-ignition temperature:** Not available |
| **Decomposition temperature:** Not available | **Kinematic Viscosity:** Not determined |

## 10. STABILITY AND REACTIVITY

**Reactivity:** Not reactive under normal conditions of use.
**Chemical stability**: Stable.
**Possibility of hazardous reactions:** None known.
**Conditions to avoid:** None known.
**Incompatible materials:** Avoid oxidizing agents.
**Hazardous decomposition products:** Thermal decomposition may yield carbon oxides.

## 11. TOXICOLOGICAL INFORMATION

**Acute effects of exposure:**
**Inhalation:** Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and possibly symptoms similar to ingestion
**Ingestion:** Swallowing may cause effects as seen in clinical use including drowsiness, tiredness, dizziness, mood and behavior changes, nausea and vomiting.
**Skin contact:** May cause mild irritation.
**Eye contact**: May cause mild irritation with redness and tearing.
**Chronic Effects:** None known.
**Sensitization:** Components are not known to be sensitizers.
**Germ Cell Mutagenicity:** Components are not classified as germ cell mutagens. Brivaracetam was negative for genotoxicity in *in vitro* (Ames, mouse lymphoma, and CHO chromosomal aberration) and in vivo (rat bone marrow micronucleus) assays.
**Reproductive Toxicity:** Components are not classified as reproductive toxins. Oral administration of brivaracetam (0, 150, 300, or 600 mg/kg/day) to pregnant rats during the period of organogenesis did not produce any significant maternal or embryofetal toxicity. Oral administration of brivaracetam (0, 30, 60, 120, or 240 mg/kg/day) to pregnant rabbits during the period of organogenesis resulted in embryofetal mortality and decreased fetal body weights at the highest dose tested, which was also maternally toxic. When brivaracetam (0, 150, 300, or 600 mg/kg/day) was orally administered to rats throughout pregnancy and lactation, decreased growth, delayed sexual maturation (female), and long-term neurobehavioral changes were observed in the offspring at the highest dose.
**Carcinogenicity:** None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA. In a carcinogenicity study in mice, oral administration of brivaracetam (0, 400, 550, or 700 mg/kg/day) for 104 weeks increased the incidence of liver tumors (hepatocellular adenoma and carcinoma) in male mice at the two highest doses tested. Oral administration (0, 150, 230, 450, or 700 mg/kg/day) to rats for 104 weeks resulted in an increased incidence of thymus tumors (benign thymoma) in female rats at the highest dose tested. The relevance of this data to humans has not been established.

**Acute Toxicity Values**: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg
Brivaracetam: Oral rat LD50 300-2000 mg/kg; Dermal rabbit LD50 >2000 mg/kg; LC50 rat >5.0 mg/L (estimated)

## 12. ECOLOGICAL INFORMATION

Environmental properties of the mixture have not been evaluated. Releases to the environment should be avoided.
**Ecotoxicity values:** No data available.
**Persistence and degradability:** No data available.
**Bioaccumulative potential:** No data available.
**Mobility in soil:** No data is available.
**Other adverse effects:** None known.

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

## 14. TRANSPORT INFORMATION

| | UN Number | Proper shipping name | Hazard Class | Packing Group | Environmental Hazard |
|---|---|---|---|---|---|
| **DOT** | | Not Regulated | | | |
| **TDG** | | Not Regulated | | | |
| **IMDG** | | Not Regulated | | | |
| **IATA** | | Not Regulated | | | |

**Transport in bulk according to IMO instruments:** Not applicable – product is transported only in packaged form.

**Special precautions:** None known.

## 15. REGULATORY INFORMATION

**Safety, health, and environmental regulations specific for the product in question.**

**CERCLA:** This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

**SARA Hazard Category (311/312):** Not Hazardous

**EPA SARA 313:** This product contains the following chemicals regulated under SARA Title III, section 313:
None

**EPA TSCA Inventory:** This product is a drug and not subject to TSCA**.**

**California Proposition 65:** This product is not known to contain regulated chemicals.

**CANADA:**
**Canadian CEPA:** This product is a drug and not subject to CEPA regulations.

## 16. OTHER INFORMATION

**Issue Date:** 01/26/2026
**Revision Number:** 01
**Revision Date:** New SDS
**SDS Revision History:** New SDS

**Disclaimer :** The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.