

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

Product Name: Clobazam Oral Suspension, USP (2.5 mg/ml)
Product Codes(s): Clobazam Oral Suspension, USP (2.5 mg/ml)
Synonym(s): Active ingredient - Clobazam; 7-Chloro-1-methyl-5-phenyl-1H-1,5-benzodiazepine-2,4-(3H,5H)-dione

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Clobazam Oral Suspension, USP is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older.
Restrictions on use: Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

1.3 Details of the supplier and of the safety data sheet

Manufactured By
 VistaPharm, Inc.
 7265 Ulmerton Road
 Largo FL 33771 USA
 +1-727-530-1633

1.4 Emergency telephone number

In the continental USA: +1-727-530-1633

SECTION 2 - HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

Product definition: Mixture
Classification in accordance with 29 CFR 1910 (OSHA HCS) and Regulation (EC) No 1272/2008
 Not a dangerous substance according to OSHA or to European Union Legislation

2.2 Label Elements

Not a dangerous substance according to GHS

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

% by Weight	Ingredient	CAS Number	EC Number	Index Number	EC Classification
0.25	Clobazam	22316-47-8	244-908-7	-----	-----

Inactive ingredients: Water; Maltitol Syrup; Propylene Glycol; Xanthan Gum; Magnesium Aluminum Silicate; Simethicone; Polysorbate 80; Sucralose; Sodium Phosphate Dihydrate; Polyparaben; Propylparaben; Cherry Flavoring
 There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

SECTION 4 - FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation: If product mist causes respiratory irritation or distress, move the exposed person to fresh air immediately. If breathing is difficult or irregular, administer oxygen; if respiratory arrest occurs, start artificial respiration by trained personnel. Get immediate medical attention. If unconscious place in the recovery position and get immediate medical attention. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. Symptoms may be delayed. Ensure that medical personnel are aware of the material involved. If respiratory irritation persists or if other symptoms develop, seek medical attention.

Eyes: Immediately flush eyes with large amounts of water for 15 minutes, occasionally lifting the upper and lower eyelids. Remove contact lenses after the first 2 minutes and continue rinsing. If irritation persists seek medical attention, preferably from an ophthalmologist.

Skin: Rinse skin with water while removing contaminated clothing. Wash affected area with soap and water. Wash contaminated clothing and shoes thoroughly before reuse. In the event of any complaints or symptoms, avoid further exposure and seek medical attention.

Ingestion: Rinse mouth with water if the victim is conscious. Remove dentures, if present. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept lower than the waist so that vomit does not enter into the lungs. Never give anything by mouth to an unconscious or convulsing person. Do not leave the victim unattended. If the victim is unconscious, place in the recovery position and get immediate medical attention. Immediately contact a poison control center or doctor. Seek medical attention if adverse health effects persist or are severe.

4.2 Most important symptoms and effects, both acute and delayed

Potential health symptoms and effects
Eyes: May cause eye irritation.

Skin: May cause mild, transient irritation.

Inhalation: Inhalation of mist may cause upper respiratory tract irritation and symptoms similar to ingestion.

Ingestion: Swallowing product will cause central nervous system effects, such as sedation, drowsiness, dizziness, sleepiness, constipation, cough, emotional changes, tiredness, salivation and drooling. Ingestion of large amounts may result in fatal respiratory arrest or coma. Clobazam can be abused resulting in dependence (addiction) and withdrawal symptoms. Refer to the product insert for complete side effect data.

Chronic: May cause damage to the unborn child. May cause harm to breast-fed children. Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

4.3 Indication of any immediate medical attention and special treatment needed

Advice to doctor and hospital personnel

Immediate medical treatment is recommended for unintentional ingestion or overdose. Treatment for an overdose may include gastric lavage and/or administration of activated charcoal, intravenous fluid replenishment, early control of airway and general supportive measures in addition to monitoring level of consciousness and vital signs. Hypotension can be treated by replenishment with plasma substitutes and, if necessary, with sympathomimetic agents.

SECTION 5 - FIRE FIGHTING MEASURES

5.1 Extinguishable media

Suitable methods of extinction: Use extinguishing media suitable for the surrounding fire.

Unsuitable methods of extinction: None known

5.2 Special hazards arising from the substance or mixture

During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent or may be delayed. Obtain medical attention.

5.3 Advice for firefighters

Full protective equipment including self-contained breathing apparatus should be used. If possible, firefighters should control runoff water contaminated with this material and prevent it from being discharged to any waterway, sewer or drain to prevent environmental contamination.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Evacuate non-essential personnel from the area. Wear appropriate protective clothing designated in Section 8. Remove all sources of ignition. Ventilate the area. Spill creates a slip hazard.

6.2 Environmental precautions

Avoid dispersal of spilled material or runoff and prevent contact with soil and entry into drains, sewers and waterways.

6.3 Methods and materials for containment and cleaning up

Cover drains and contain spill. Small spills can be wiped up with absorbent material (e.g. cloth, fleece). Cover larger spills with inert absorbent. Do not use combustible material such as sawdust. Collect material and place into an approved, labeled container for proper disposal. Observe possible material restrictions (Sections 7.2 and 10.5). Dispose of material via a licensed pharmaceutical waste contractor and in accordance with FDA and DEA regulations. Clean contaminated area with soap and water.

6.4 Reference to other sections

For symptoms of overexposure and first aid treatment, see Section 4.

SECTION 7 - HANDLING AND STORAGE

7.1 Precautions for safe handling

Observe label precautions. Wear all appropriate protective equipment specified in Section 8. Do not get in eyes or on skin or clothing. If normal use presents a respiratory hazard, use only adequate ventilation or wear an appropriate respirator.

Advice on protection against fire and explosion

Not expected to be a fire or explosion hazard.

7.2 Conditions for safe storage, including any incompatibilities

Store at 20 - 25 °C (68 - 77 °F) in a dry, well-ventilated area away from incompatible materials (see Section 10.5), food and drink. Keep container tightly closed when not in use. Protect containers from physical damage. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Containers of this material are hazardous when empty as they contain product residues. Use appropriate containment to avoid environmental contamination. Ventilate closed areas. Keep locked up and out of reach of children.

7.3 Specific end uses

Apart from the uses mentioned in Section 1.2, no other specific uses are stipulated.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure values.

8.2 Exposure controls

Engineering Measures: Use adequate ventilation. Local exhaust is preferable. Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Individual protection measures: Not normally required. Wear protective clothing to prevent repeated or prolonged contact with product. Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled.

Hygiene measures: Facilities storing or using this material should be equipped with an eyewash station and safety shower. Change contaminated clothing. Wash hands and forearms thoroughly after use, before eating, drinking, smoking or using the lavatory.

Eye/face protection: None normally required. If there is a danger of splashing wear safety glasses with unperforated side shields during use.

Hand Protection: Not normally needed. For prolonged or repeated skin contact wear gloves recommended by supplier for protection against materials in Section 3. Breakthrough time of selected gloves must be greater than the intended use period.

Other protective equipment: Not normally needed. Wear protective clothing and protective boots if the situation requires.

Respiratory Protection: No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to vapor/fume at levels exceeding the exposure limits.

Environmental exposure controls: Do not empty into drains.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Off-white suspension
Odor	Characteristic
Odor Threshold	No data available
Molecular Weight	300.74 g/mol (Clobazam)
Chemical Formula	C ₁₆ H ₁₃ ClN ₂ O ₂ (Clobazam)
pH	No data available
Freezing/Melting Point, Range	No data available
Initial Boiling Point	No data available
Evaporation Rate	No data available
Flammability (solid, gas)	Not applicable
Flash Point	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Lower Explosive Limit (LEL)	No data available
Upper Explosive Limit (UEL)	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	No data available
Viscosity	No data available
Solubility in Water	Dispersible
Partition Coefficient: n-octanol/water	No data available
Volatiles by Weight @ 21° C	No data available

9.2 Other data

No relevant additional information available

SECTION 10 - STABILITY AND REACTIVITY

10.1 Reactivity

No special reactivity has been reported.

10.2 Chemical stability

Product is stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid temperature extremes. Avoid contact with incompatible materials.

10.5 Incompatible materials

Oxidizing agents

10.6 Hazardous decomposition products

Thermal decomposition products include oxides of carbon, oxides of nitrogen and chlorine compounds including hydrogen chloride gas.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute Oral Toxicity

Albuterol Sulfate - LD₅₀, Rat: >6,000 mg/kg

Product - LD₅₀, Rat: 200,000 mg/kg, *calculated*

Acute inhalation toxicity

Expected to have low acute inhalation toxicity

Acute dermal toxicity

Expected to have low acute dermal toxicity

Skin irritation

May cause mild, transient skin irritation.

Eye irritation

May cause eye irritation

Sensitization

No data available

Genotoxicity

No data available

Mutagenicity

Negative based on *in vitro* testing (bacteria reverse mutation, mammalian clastogenicity) and *in vivo* (mouse micronucleus) assays.

Specific organ toxicity - single exposure

No data available

Specific organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Further information

May be harmful to the unborn child. Laboratory tests have shown teratogenic effects, including an increased incidence of fetal abnormalities following oral administration of clobazam to pregnant animals at doses similar to those used clinically. Data for other benzodiazepines suggest the possibility of adverse effects in animals and humans. Long-term effects on neurobehavioral and immunological function have been reported in rodents following prenatal exposure to benzodiazepines. Effects on the musculoskeletal system, testes, epididymis and sperm ducts have been reported as well as stillbirths.

Limited data is available regarding the risk of teratogenicity in humans associated with benzodiazepines, including clobazam, to assess the effect of benzodiazepine exposure during pregnancy on neurodevelopment. However, the administration of benzodiazepines immediately prior to or childbirth can result in a syndrome of hypothermia, hypotonia, respiratory depression and difficulty feeding. In addition, infants born to mothers who have taken benzodiazepines during the later stages of pregnancy can develop dependence, and subsequently withdrawal, during the postnatal withdrawal, during the postnatal period.

May cause harm to breast-fed children. Clobazam is excreted in human milk and has the potential for serious adverse reactions in nursing infants.

Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

No component of this product is present at levels greater than or equal to the 0.1% threshold (de minimis) is identified as a probable, possible, potential or confirmed carcinogen by ACGIH, IARC, NTP or OSHA.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12 - ECOLOGICAL INFORMATION**12.1 Toxicity**

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.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulation potential

This product is not expected to bioaccumulate.

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects**Additional ecological information**

Do not allow material to enter into surface waters, wastewater or soil.

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

SECTION 13 - DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Methods of disposal: The generation of waste should be avoided or minimized whenever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way via a licensed pharmaceutical waste contractor and in accordance with FDA and DEA regulations. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

Hazardous waste: The classification of this product may meet the criteria for a hazardous waste.

SECTION 14 - TRANSPORT INFORMATION

Note: Transportation information provided is for reference only. Customer is urged to consult 49 CFR 100 - 177, IMDG, IATA, EC, United Nations TDG and WHMIS (Canada) TDG information manuals for detailed regulations and exceptions covering specific container sizes, packaging materials and methods of shipping.

NOT REGULATED FOR TRANSPORT

15.1 Safety, health and environmental regulations/legislation specific for substance or mixture**U. S. Federal Regulations**

OSHA Hazard Communication Standard: This material is not classified as hazardous in accordance with OSHA 29 CFR 1910.1200.

TSCA Status: Clobazam (CAS #22316-47-9) is not on the Toxic Substance Control Act (TSCA) Inventory as it is intended for use in applications regulated by the Food and Drug Administration in the United States. It can only be used for TSCS exempt purposes such as R&D or drug use. It is not subject to TSCA 12(b) Export Notification.

DEA Schedule IV (29 CFR 1308.14): Clobazam (CAS #22316-47-8) is a controlled substance.

Superfund Amendments and Reauthorization Act (SARA)

SARA Section 311/312 Hazard Categories: None known

SARA 313 Information: None of the chemicals in this product exceed the threshold (de minimis) reporting levels established by Section 313 of the Emergency Planning and Community Right-to Know Act of 1986.

SARA 302/304 Extremely Hazardous Substance: No components of the product are subject to the reporting requirements of these sections of Title III of SARA.

SARA 302/304 Emergency Planning & Notification: No components of the product are subject to the reporting requirements of these sections of Title III of SARA.

Comprehensive Response Compensation and Liability Act (CERCLA): No components of the product exceed the threshold (de minimis) reporting levels for hazardous wastes established by CERCLA.

Clean Air Act (CAA)

This product does not contain any chemicals listed as a Hazardous Air Pollutant (HAP) designated in CAA Section 112 (b).

This product does not contain any Class 1 Ozone depleters.

This product does not contain any Class 2 Ozone depleters.

Clean Water Act (CWA)

None of the chemicals in this product are listed as Hazardous Substances under the CWA.

None of the chemicals in this product are listed as Priority Pollutants under the CWA.

None of the chemicals in this product are listed as Toxic Pollutants under the CWA.

U.S. State Regulations**California Prop 65, Safe Drinking Water and Toxic Enforcement Act of 1986**

This product contains no chemical(s) known to the State of California to cause cancer, birth defects or other reproductive harm.

Other U.S. State Inventories

The components of this product are not listed on any State Hazardous Substance Inventories, Right-to-Know lists or Air Quality/Air Pollutants Inventories.

Canada

WHMIS Hazard Symbol and Classification: Uncontrolled product according to WHMIS classification criteria

Canadian National Pollutant Release Inventory (NPRI): None of the components of this product are not listed on the NPRI.

European Economic Community**Labeling (67/548/EEC or 1999/45/EC)**

Not a dangerous substance according to European Union Legislation.

WGK, Germany (Water danger/protection): No data available

Global Chemical Inventory Lists

Country	Inventory Name	Inventory Listing*
Canada:	Domestic Substance List (DSL)	Yes
Canada:	Non-Domestic Substance List (NDSL)	No
Europe:	Inventory of New and Existing Chemicals (EINECS)	Yes
United States:	Toxic Substance Control Act (TSCA)	Yes
Australia:	Australian Inventory of Chemical Substances (AICS)	Yes
New Zealand:	New Zealand Inventory of Chemicals (NZIoC)	Yes
China:	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Japan:	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea:	Existing Chemicals List (ECL)	Yes
Philippines:	Philippines Inventory of Chemicals and Chemical Substances (PICCS)	Yes

*Yes - All components of this product are in compliance with the inventory requirements administered by the governing country.

No - One or more components of this product are not on the inventory or are exempt from listing.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16 - OTHER INFORMATION

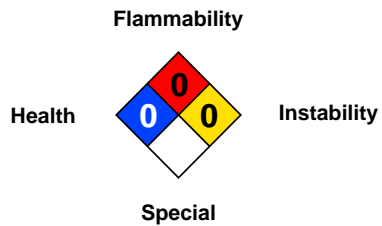
Hazardous Material Information System (HMIS)

Health	<input type="checkbox"/> 0
Flammability	<input type="checkbox"/> 0
Physical Hazard	<input type="checkbox"/> 0
Personal Protection	<input type="checkbox"/>

HMIS & NFPA Hazard Rating Legend

* = Chronic Health Hazard	2 = MODERATE
0 = INSIGNIFICANT	3 = HIGH
1 = SLIGHT	4 = EXTREME

National Fire Protection Association (NFPA)



NFPA Hazard Rating Legend

- 0 = INSIGNIFICANT
- 1 = SLIGHT
- 2 = MODERATE
- 3 = HIGH
- 4 = EXTREME

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