

**1. Identification**

**Product identifier** Diazepam Oral Solution, 5mg/5mL CIV  
**NDC Number(s)** 0121-0905-94  
**Recommended use** Management of anxiety disorders and for short term relief of symptoms of anxiety. Should be used at minimum effective dose for the shortest duration of use.  
**Recommended restrictions** Should not be used concomitantly with opioids as the combination may result in profound sedation, respiratory depression, coma and death.

**Manufacturer/Importer/Supplier/Distributor information**

**Company name** Pharmaceutical Associates, Inc  
**Address** 1700 Perimeter Road  
Greenville, SC 29605  
**Telephone** 1-864-277-7282  
**Emergency phone number** CHEMTREC, U.S.: 1-800-424-9300 24/7

**2. Hazard(s) identification**

**Physical hazards** Not classified.  
**Health hazards** Not classified.  
**OSHA defined hazards** Not classified.

**Label elements**

**Hazard symbol** None.  
**Signal word** Warning  
**Hazard statement** 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 statement**

**Prevention** Observe good industrial hygiene practices.  
**Response** Wash hands after handling.  
**Storage** Store away from incompatible materials. Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F). Protect from light.  
**Disposal** Incineration of waste at an approved USEPA incinerator is recommended.

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

**3. Composition/information on ingredients****Substances**

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

Chemical name	Common name and synonyms	CAS number	%
7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one		439-14-5	5 mg/5 mL

**Composition comments** Refer to Physician's Desk Reference for common components present at <1%

**4. First-aid measures**

**Inhalation** Move to fresh air. Call a physician if symptoms develop or persist.  
**Skin contact** Wash off with soap and water. Get medical attention if irritation develops and persists.  
**Eye contact** Rinse with water. Get medical attention if irritation develops and persists.  
**Ingestion** Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.

<b>Most important symptoms/effects, acute and delayed</b>	Side effects most commonly reported were drowsiness, fatigue and ataxia.
<b>Indication of immediate medical attention and special treatment needed</b>	General supportive measures should be employed, along with immediate gastric lavage. Intravenous fluids should be administered and an adequate airway maintained. Hypotension may be combated by the use of norepinephrine or metaraminol. Dialysis is of limited value
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).
<b>Methods and materials for containment and cleaning up</b>	Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended. Controlled substances must be destroyed following DEA guidelines for witnessed destruction of the product beyond reclamation.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.
<b>Conditions for safe storage, including any incompatibilities</b>	Store away from incompatible materials (see Section 10 of the SDS). Dispense in a tight, light-resistant container as defined in the USP/NF. Protect from light. Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F). Discard opened bottle after 90 days.

## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	Ventilation should be matched to conditions.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.
<b>Skin protection</b>	
<b>Hand protection</b>	For consumer use, no unusual precautions are necessary.
<b>Other</b>	None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

**Respiratory protection** None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations** Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

**Appearance** Clear orange liquid.

**Physical state** Liquid.

**Form** Liquid.

**Color** Clear orange.

**Odor** Not available.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** Not available.

**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.

**Relative density temperature** estimated

**Solubility(ies)**

**Solubility (water)** Insoluble

**Partition coefficient (n-octanol/water)** Not available.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

## 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. Exposure to light.

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition products** No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

**Inhalation** Not expected to be hazardous in final pharmaceutical form.  
**Skin contact** Not expected to be hazardous in final pharmaceutical form.  
**Eye contact** Not expected to be hazardous in final pharmaceutical form. Direct contact with eyes may cause temporary irritation.  
**Ingestion** Ingestion may cause irritation and malaise.

**Symptoms related to the physical, chemical and toxicological characteristics** Side effects most commonly reported were drowsiness, fatigue and ataxia

### Information on toxicological effects

**Acute toxicity** May be harmful if swallowed in large quantities.

Components	Species	Test Results
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7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one (CAS 439-14-5)

#### Acute

Oral

LD50	Rat	1240 mg/kg
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**Skin corrosion/irritation** Prolonged skin contact may cause temporary irritation.

**Serious eye damage/eye irritation** Direct contact with eyes may cause temporary irritation.

### Respiratory or skin sensitization

**Respiratory sensitization** Not a respiratory sensitizer.

**Skin sensitization** This product is not expected to cause skin sensitization.

**Germ cell mutagenicity** Studies in rats did not reveal teratological effects on the offspring.

**Carcinogenicity** Long-term studies in animals have not been conducted to evaluate carcinogenic potential

#### IARC Monographs. Overall Evaluation of Carcinogenicity

7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one (CAS 439-14-5) 3 Not classifiable as to carcinogenicity to humans.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

**Reproductive toxicity** An increased risk of congenital malformations associated with the use of minor tranquilizers (diazepam, meprobamate and chlordiazepoxide) during the first trimester of pregnancy has been suggested in several studies. Because use of these drugs is rarely a matter of urgency, their use during this period should almost always be avoided.

**Specific target organ toxicity - single exposure** Not classified.

**Specific target organ toxicity - repeated exposure** Not classified.

**Aspiration hazard** Not classified.

**Further information** See package insert.

## 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous.

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

**Bioaccumulative potential** No data available.

#### Partition coefficient n-octanol / water (log Kow)

7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one (CAS 439-14-5)	2.99
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**Mobility in soil** No data available.

**Other adverse effects** None.

### 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. 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).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

#### DOT

Not regulated as dangerous goods.

#### IATA

Not regulated as dangerous goods.

#### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

### 15. Regulatory information

**US federal regulations** This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

DEA: Diazepam Oral Solution, 5mg/5mL CIV is a DEA scheduled IV controlled substance.

FDA: Diazepam Oral Solution, 5mg/ 5mL CIV is an approved prescription medication.

#### **TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

#### **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

#### **CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

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

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

#### **SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** No

#### **SARA 313 (TRI reporting)**

Not regulated.

#### **Other federal regulations**

##### **Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

##### **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

Drug Enforcement Administration (DEA): This product is a Schedule IV Controlled Substance (21 CFR 1308.14)

## US state regulations

### US. Massachusetts RTK - Substance List

7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one (CAS 439-14-5)

### US. New Jersey Worker and Community Right-to-Know Act

Not listed.

### US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

### US. Rhode Island RTK

Not regulated.

### US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

### US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one (CAS 439-14-5)

## International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

<b>Revision date</b>	24MAR2021
<b>Version #</b>	0
<b>References</b>	1) Diazepam Oral Solution, Package Insert, Pharmaceutical Associates, Inc 2) PDR – Physicians Desk Reference. 3) Ariel Webinsight. Regulatory and ChemExpert Database.

<b>Disclaimer</b>	Pharmaceutical Associates, Inc cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.
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