SAFETY DATA SHEET

1. Identification

Product identifier          Nordazepam CIV

Other means of identification
Catalog number            1468400
CAS number               1088-11-5
Synonyms                 Nordiazepam * Desmethyldiazepam
Chemical name            7-Chloro-1, 3-dihydro-5-phenyl-2H-1,4-benzodiazepin-2-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
Telephone              RS Technical Services 301-816-8129
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        Reproductive toxicity Category 2
                      Specific target organ toxicity, single exposure Category 3 narcotic effects
Environmental hazards Not classified.
OSHA defined hazards  Not classified.

Label elements

Signal word          Warning
Hazard statement     May cause drowsiness or dizziness. Suspected of damaging fertility or the unborn child.
Precautionary statement
Prevention
Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing dust/fume/gas/mist/vapors/spray. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection.
Response
If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. If exposed or concerned: Get medical advice/attention.
Storage
Store in a well-ventilated place. Keep container tightly closed. 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 Potent pharmacologically active material.
3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nordazepam CIV</td>
<td></td>
<td>1088-11-5</td>
<td>100</td>
</tr>
<tr>
<td>Desmethyldiazepam</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. First-aid measures

**Inhalation**
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a poison center or doctor/physician if you feel unwell.

**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**
If ingestion of a large amount does occur, call a poison control center immediately. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

**Most important symptoms/effects, acute and delayed**
Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

**Indication of immediate medical attention and special treatment needed**
Provide general supportive measures and treat symptomatically. Treatment of benzodiazepine overdose may include the following: Do NOT Induce vomiting. Administer activated charcoal as a slurry. If patient is unconscious, perform gastric lavage with cuffed endotracheal tube. Monitor respiration, pulse, and blood pressure, and maintain an adequate airway. Give intravenous fluids to control blood pressure. After airway, ventilation, and intravenous access have been secured, administer flumazenil, a specific benzodiazepine receptor antagonist, to reverse sedative effects. Do NOT use barbiturates to control excitation.

**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**
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. For waste disposal, see section 13 of the SDS.

**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.
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
No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). 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.

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
Consider double gloves. 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.

Other
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. 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.

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

Thermal hazards
Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations
Pharmacological effects may be seen with occupational exposure. 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.

9. Physical and chemical properties

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

Physical state
Solid.

Form
Powder.

Color
Light yellow. White.

Odor
Practically odorless.

Odor threshold
Not available.

pH
Not available.

Melting point/freezing point
420.8 - 422.6 °F (216 - 217 °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
< 0.0000001 kPa at 25 °C

Vapor density
Not available.

Relative density
Not available.

Solubility(ies)

Solubility (water)
Practically insoluble.
Solubility (other)  Chloroform: Slightly soluble.
Partition coefficient (n-octanol/water)  2.93 = Log P
Auto-ignition temperature  Not available.
Decomposition temperature  Not available.
Viscosity  Not available.
Other information
   Chemical family  Benzodiazepine.
   Molecular formula  C15H11ClN2O
   Molecular weight  270.72 g/mol
   pH in aqueous solution  6

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.
Hazardous decomposition products  NOx, Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure
   Inhalation  May cause drowsiness and dizziness.
   Skin contact  Knowledge about health hazard is incomplete.
   Eye contact  Knowledge about health hazard is incomplete.
   Ingestion  Knowledge about health hazard is incomplete.

Information on toxicological effects
Acute toxicity
<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nordazepam CIV (CAS 1088-11-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>1300 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>670 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>&gt; 5200 mg/kg</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td></td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td></td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Respiratory or skin sensitization</td>
<td></td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td></td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td></td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td></td>
<td>Knowledge about mutagenicity is incomplete.</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ames test (Salmonella typhimurium)</td>
<td></td>
<td>Result: Negative.</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td></td>
<td>Knowledge about carcinogenicity is incomplete.</td>
</tr>
</tbody>
</table>
Suspected of damaging fertility or the unborn child. Most studies do not show a strong association between maternal therapeutic use of benzodiazepines and malformations in the offspring, although the risk of malformations may be increased. Withdrawal effects have been observed in newborns following maternal benzodiazepine use. Adverse reproductive effects were seen in animal studies with a related material.

**Reproductive toxicity**

<table>
<thead>
<tr>
<th>Specific target organ toxicity - single exposure</th>
<th>May cause drowsiness and dizziness.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific target organ toxicity - repeated exposure</td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>Further information</td>
<td>Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.</td>
</tr>
</tbody>
</table>

**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 substance.

- **Bioaccumulative potential**
  Octanol/water partition coefficient log Kow
  2.93, = Log P

- **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.

- **Hazardous waste code**
  The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

- **Waste from residues / unused products**
  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).

- **Contaminated packaging**
  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.

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

- **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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
Yes

Classified hazard categories
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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) (21 CFR 1308.11-15)
Schedule IV - 2838

US state regulations

California Proposition 65

WARNING: This product can expose you to Nordazepam CIV, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Developmental toxin
Nordazepam CIV (CAS 1088-11-5) Listed: October 1, 1992

International Inventories

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

*A "Yes" indicates that all components of this product comply 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

Issue date  07-09-2019
Revision date  07-09-2019
Version #  02
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