# SAFETY DATA SHEET

## 1. Identification

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|---|---|
| **Product identifier** | **Amoxapine** |
| **Other means of identification** | |
| **Catalog number** | 1031401 |
| **CAS number** | 14028-44-5 |
| **Chemical name** | 2-Chloro-11-(1-piperazinyl)dibenz[b,f][1,4]oxazepane |
| **Recommended use** | For analytical laboratory 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<br>Rockville<br>MD<br>20852-1790<br>United States | |
| **Telephone** | Customer Service | 301-881-0666 |
| **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 4 |
| | Specific target organ toxicity, single exposure | Category 3 narcotic effects |
| **Environmental hazards** | Not classified. | |
| **OSHA defined hazards** | Not classified. | |

**Label elements**

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|---|---|
| **Signal word** | Warning |
| **Hazard statement** | Harmful if swallowed. May cause drowsiness or dizziness. |
| **Precautionary statement** | |
| **Prevention** | Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. |
| **Response** | If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. |
| **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** | Pharmacologically active material. |

## 3. Composition/information on ingredients

**Substance**

| Chemical name | Common name and synonyms | CAS number | % |
|---|---|---|---|
| Amoxapine | | 14028-44-5 | 100 |

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

## 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** 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** Do NOT induce vomiting. Rinse mouth. Get medical advice/attention if you feel unwell.

**Most important symptoms/effects, acute and delayed** Central nervous system effects. Pharmacologically active material. Occupational exposure may cause physiological effects.

**Indication of immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically. Keep victim warm. Symptoms may be delayed.

**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 materials, 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. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

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|---|---|
| **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** | For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. 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**

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|---|---|
| **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. |
| **Other** | Train employees in proper gowning and degowning practices. Wear lab coat. 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** | Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters 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 USP materials. |

## 9. Physical and chemical properties

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| **Appearance** | Appearance descriptions are general information and not specific to any USP lot. |
| **Physical state** | Solid. |
| **Form** | Powder. |
| **Color** | White. Off-white. |
| **Odor** | Not available. |
| **Odor threshold** | Not available. |
| **pH** | Not available. |
| **Melting point/freezing point** | 347 - 357.8 °F (175 - 181 °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**

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|---|---|
| **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 (77 °F (25 °C)) |
| **Vapor density** | Not available. |
| **Relative density** | Not available. |

**Solubility(ies)**

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|---|---|
| **Solubility (water)** | Practically insoluble. |
| **Solubility (other)** | Acetone: Slightly soluble.<br>Chloroform: Freely soluble.<br>Methyl alcohol: Sparingly soluble.<br>Tetrahydrofuran: Soluble. |

Toluene: Sparingly soluble.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

**Other information**

**Chemical family** Dibenzoxazepine derivative.

**Molecular formula** C17H16ClN3O

**Molecular weight** 313.78

## 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** Avoid temperatures exceeding the decomposition temperature. Contact with incompatible materials.

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition products** Cl-. NOx. 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 or dizziness. Knowledge about health hazard is incomplete.

**Skin contact** Knowledge about health hazard is incomplete.

**Eye contact** Knowledge about health hazard is incomplete.

**Ingestion** Harmful if swallowed. Based on information from therapeutic use, this material may cause: Central nervous system effects.

**Symptoms related to the physical, chemical and toxicological characteristics** May cause drowsiness or dizziness. Tricyclic antidepressants: Dizziness. Drowsiness. Stupor. Restlessness. Vomiting. Troubled breathing. Tiredness. Enlarged pupils. Fever. Headache. Dry mouth. Weakness. Increased appetite. Diarrhea. Excessive sweating. Heartburn. Blurred vision. Eye pain. Confusion. Hallucinations. Difficult urination. Difficulty speaking or swallowing. Nervousness. Loss of balance. Convulsions.

**Information on toxicological effects**

**Acute toxicity** In high concentrations, vapors are anesthetic and may cause headache, fatigue, dizziness and central nervous system effects.

| Product | Species | Test Results |
|---|---|---|
| Amoxapine (CAS 14028-44-5) | | |
| **Oral** | | |
| LD50 | Mouse | 104 mg/kg |
| | Rat | 313 mg/kg |

**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 sensitization hazard is incomplete.

**Skin sensitization** Knowledge about sensitization 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 1910.1001-1053)**

Not listed.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

| | |
|---|---|
| **Reproductive toxicity** | Knowledge about health hazard is incomplete. For tricyclic antidepressants: Withdrawal symptoms such as colic, cyanosis, rapid breathing, and irritability have been observed in infants whose mothers received tricyclic antidepressants prior to delivery. |
| **Specific target organ toxicity - single exposure** | May cause drowsiness or dizziness. |
| **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** | Pharmacologically active material. Occupational exposure may cause physiological effects. |

## 12. Ecological information

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| **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** | 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

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| **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. Empty containers should be taken to an approved waste handling site for recycling or disposal. |

## 14. Transport information

**DOT**

Not regulated as dangerous goods.

**IATA**

Not regulated as dangerous goods.

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|---|---|
| **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.

**Toxic Substances Control Act (TSCA)**

**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 1910.1001-1053)**

Not listed.

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

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**Classified hazard categories** Acute toxicity (any route of exposure)
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.

**US state regulations**

**California Proposition 65**

**WARNING:** This product can expose you to Amoxapine, 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**

Amoxapine (CAS 14028-44-5) Listed: May 15, 1998

**International Inventories**

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|---|---|---|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| 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) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | Yes |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | Yes |
| 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** 04-06-2010

**Revision date** 12-11-2023

**Version #** 04

**Disclaimer** USP materials are sold for analytical laboratory use only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been compiled by USP staff from sources considered to be scientifically reliable but has not been independently verified by USP. USP does not guarantee the accuracy or completeness of the information from these sources included herein nor should the statements contained herein be considered an official expression by USP. USP does not independently create or develop the information included in this safety data sheet. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.