

## 1. Identification

<b>Product identifier</b>	<b>Amoxapine</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1031401	
<b>Chemical name</b>	Dibenz[b,f][1,4]oxazepine, 2-chloro-11-(1-piperazinyl)-	
<b>Recommended use</b>	Specified quality tests and assay use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
<b>Telephone</b>	RS Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
<b>OSHA hazard(s)</b>	Not classified.	

### Label elements



<b>Signal word</b>	Warning
<b>Hazard statement</b>	Harmful if swallowed. May cause drowsiness or dizziness.
<b>Precautionary statement</b>	
<b>Prevention</b>	Wash thoroughly after handling. Use only outdoors or in a well-ventilated area.
<b>Response</b>	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.
<b>Storage</b>	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	Not classified.

## 3. Composition/information on ingredients

### Substance

#### Hazardous components

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

## 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
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<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Narcotic effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Treatment of overdose should be symptomatic and supportive and may including the following: Perform gastric lavage to decrease absorption. Administer activated charcoal slurry repeatedly, followed by stimulant cathartic to enhance elimination. Monitor and maintain respiratory function, body temperature, and cardiovascular function (ECG) for not less than 5 days. Kidney impairment may develop 3 to 5 days after substantial overdose. For congestive heart failure - Digitalize cautiously. For cardiac arrhythmias - control with lidocaine or by alkalizing blood to pH 7.4 to 7.5 with intravenous sodium bicarbonate. If ineffective, consider slow intravenous infusion of phenytoin. Propranolol is also effective, but should be used with caution. Quinidine and procainamide should NOT be used. For convulsions - administer anticonvulsant such as diazepam, paraldehyde, phenytoin, or an inhalation anesthetic. Physostigmine is contraindicated in amoxapine overdose because it may increase seizure activity. Seizures may be especially severe and may not respond to treatment; amoxapine overdose may lead to acute tubular necrosis and rhabdomyolysis. Use standard measures to manage circulatory shock and metabolic acidosis. Hemodialysis, peritoneal dialysis, exchange transfusions, and forced diuresis are not expected to be successful in treating tricyclic antidepressant overdose. [USP DI 2003]

**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

<b>Suitable extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire-fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
<b>Methods and materials for containment and cleaning up</b>	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

## 7. Handling and storage

<b>Precautions for safe handling</b>	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.
<b>Conditions for safe storage, including any incompatibilities</b>	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

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	No exposure standards allocated.

<b>Appropriate engineering controls</b>	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
<b>Skin protection</b>	
<b>Hand protection</b>	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
<b>Other</b>	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
<b>Respiratory protection</b>	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

<b>Appearance</b>	White to yellowish-white crystalline powder.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	347 - 357.8 °F (175 - 181 °C)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	< 0.0000001 kPa at 25 °C
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility in water</b>	Practically insoluble.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Dibenzoxazepine derivative.
<b>Molecular formula</b>	C17H16ClN3O
<b>Molecular weight</b>	313.78

**Solubility (other)**

Freely soluble in chloroform; soluble in tetrahydrofuran; sparingly soluble in methyl alcohol and in toluene; slightly soluble in acetone.

**10. Stability and reactivity****Reactivity**

No reactivity hazards known.

**Chemical stability**

Material is stable under normal conditions.

**Possibility of hazardous reactions**

No dangerous reaction known under conditions of normal use.

**Conditions to avoid**

None known.

**Incompatible materials**

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****Ingestion**

Harmful if swallowed.

**Inhalation**

Due to lack of data the classification is not possible.

**Skin contact**

Due to lack of data the classification is not possible.

**Eye contact**

Due to lack of data the classification is not possible.

**Symptoms related to the physical, chemical, and toxicological characteristics**

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.

**Delayed and immediate effects of exposure**

Tricyclic antidepressants: Cardiac dysrhythmias. Severe hypotension. Serotonin syndrome. CNS depression. Coma. Death.

**Cross sensitivity**

Persons sensitive to other tricyclic antidepressants, carbamazepine, maprotiline, or trazodone may be sensitive to this material also.

**Medical conditions aggravated by exposure**

Tricyclic antidepressants: Cardiovascular disorders. Narrow-angle glaucoma. Active alcoholism. Asthma. Bipolar disorder. Blood disorders. Gastrointestinal disorders. Hyperthyroidism. Enlarged prostate gland. Schizophrenia. Seizure disorder. Urinary retention. Impaired liver function. Impaired kidney function.

**Acute toxicity**

Harmful if swallowed.

**Product****Species****Test Results**

Amoxapine (CAS 14028-44-5)

*Oral*

LD50

Mouse

104 mg/kg

Rat

313 mg/kg

**Skin corrosion/irritation**

Due to lack of data the classification is not possible.

**Serious eye damage/eye irritation**

Due to lack of data the classification is not possible.

**Respiratory sensitization**

Due to lack of data the classification is not possible.

**Skin sensitization**

Due to lack of data the classification is not possible.

**Germ cell mutagenicity**

Due to lack of data the classification is not possible.

**Carcinogenicity**

Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

**Reproductive toxicity**

Due to lack of data the classification is not possible. In animal studies, high doses of this material caused fetotoxicity.

**Specific target organ toxicity - single exposure**

Narcotic effects.

**Specific target organ toxicity - repeated exposure**

Due to lack of data the classification is not possible.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

**12. Ecological information****Ecotoxicity**

No ecotoxicity data noted for the ingredient(s).

**Persistence and degradability**

No data is available on the degradability of this product.

**Bioaccumulative potential**

Not available.

**Mobility in soil**

Not available.

**Other adverse effects** Not available.

### 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** Not available.

**Hazardous waste code** Not available.

**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** 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 a hazardous material by DOT.

#### IATA

Not regulated as a dangerous good.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** No information available.

### 15. Regulatory information

**US federal regulations** CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

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

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

**SARA 302 Extremely hazardous substance** No

**SARA 311/312 Hazardous chemical** No

#### Other federal regulations

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

**Food and Drug Administration (FDA)** Not regulated.

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

#### 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
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)

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

**Issue date** 04-06-2010

**Revision date** 02-07-2014

**Version #** 02

**Further information** Not available.

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**Revision Information** This document has undergone significant changes and should be reviewed in its entirety.