SAFETY DATA SHEET

1. Identification

Product identifier **Oxcarbazepine**

Other means of identification

Catalog number 1483152

Chemical name 5H-Dibenz[b,f]azepine-5-carboxamide, 10,11-dihydro-10-oxo-

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

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

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

Acute toxicity, oral	Category 4
Sensitization, skin	Category 1
Reproductive toxicity	Category 1

OSHA hazard(s) Not classified.

Label elements

Signal word Danger

Hazard statement Harmful if swallowed. May cause an allergic skin reaction. May damage 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. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection.

Response If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If exposed or concerned: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Oxcarbazepine		28721-07-5	100

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.

Most important symptoms/effects, acute and delayed May cause allergic skin reaction.

Indication of immediate medical attention and special treatment needed Treatment of overdose should be symptomatic and supportive. Administer activated charcoal with sorbitol to decrease absorption. Perform gastric lavage. Do not induce vomiting. For hypotension, infuse 10- 20 mL/kg isotonic fluid. Administer dopamine or norepinephrine if hypotension persists. For seizures, administer a benzodiazepine intravenously, followed by phenobarbital or propofol if the seizures recur. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, hypoxia. For rhabdomyolysis, administer 0.9% saline. Monitor input and output, electrolytes, CK, and renal function. Administer diuretics if needed to maintain urine output. Urinary alkalinization is NOT recommended. Monitor ECG. Hemodialysis may be of benefit. (AHFS) (Meditext) (PDR)

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 Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

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.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures 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.

Methods and materials for containment and cleaning up 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

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.

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

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines No exposure standards allocated.

Appropriate engineering controls	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.

Individual protection measures, such as personal protective equipment

Eye/face protection	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.
Skin protection	
Hand protection	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.
Other	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.
Respiratory protection	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).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	Light orange to creamish-white or off-white powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
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 density	Not available.
Relative density	Not available.
Solubility in water	Practically insoluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Tricyclic iminostilbene derivative.
Molecular formula	C15H12N2O2
Molecular weight	252.27
Solubility (other)	Soluble in acetic acid; sparingly soluble in chloroform; slightly soluble in dichloromethane, in acetone, and in methanol; very slightly soluble in ethanol; insoluble in ether.

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	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

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	May cause an allergic skin reaction.
Eye contact	Due to lack of data the classification is not possible.
Symptoms related to the physical, chemical, and toxicological characteristics	Suicidal thoughts. Dizziness. Fatigue. Weakness. Tremor. Unsteady gait. Nausea. Vomiting. Indigestion. Abdominal pain. Changes in vision. Unusual eye movements. Skin rash. Itching. Headache. Confusion. Slow heartbeat. Seizures. Unconsciousness.
Delayed and immediate effects of exposure	Hyponatremia.
Cross sensitivity	Persons sensitive to carbamazepine may be sensitive to this material also.
Medical conditions aggravated by exposure	Active alcoholism. Hyponatremia. Cardiac conduction disorders.
Acute toxicity	Harmful if swallowed.

Product	**Species**	**Test Results**
Oxcarbazepine (CAS 28721-07-5)		
Acute		
Oral		
LD50		1240, (Unspecified mammal)

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	May cause an allergic skin reaction.
Sensitization	There have been reports of anaphylactic reactions following therapeutic use of this material. Multiorgan hypersensitivity reactions which may be delayed have been reported rarely with therapeutic use of this material.
Germ cell mutagenicity	Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity

In vitro Ames test without activation
Result: Positive in one of five bacterial strains.
In vitro assay in Chinese hamster ovary cells without activatio
Result: Increased chromosome aberrations and polyploidy.
In vitro assay in V79 Chinese hamster cells
Result: Negative.
In vivo mouse bone marrow micronucleus test
Result: Negative.

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.

250 mg/kg/day Carcinogenicity
Result: Increased benign testicular interstitial cell tumors in males.
Species: Rat
>= 25 mg/kg/day Carcinogenicity
Result: Increased hepatocellular carcinomas in females.
Species: Rat
>= 70 mg/kg/day oral dose Carcinogenicity
Result: Increased hepatocellular adenomas.
Species: Mouse

Reproductive toxicity May damage fertility or the unborn child.
This material is closely related to carbamazepine, which causes birth defects in humans. Human epidemiological studies have not identified abnormalities caused by therapeutic use of this material during pregnancy.

Reproductivity

1000 mg/kg oral dose Reproductivity and development test, Administered during gestation.
Result: Embryofetal death; decreased fetal weight.
Species: Rat

1100 mg/kg/day oral dose Reproductivity and development test, Administered during gestation.
Result: Increased malformations.
Species: Mouse

150 oral dose Reproductivity and development test, Administered during gestation.
Result: Reduction in body weight and altered behavior in offspring.
Species: Rat

300 mg/kg oral dose Reproductivity and development test, Administered during gestation.
Result: Increased birth defects.
Species: Rat

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

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 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).

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 - Yes 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 California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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	No
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	11-10-2008
Revision date	09-10-2014
Version #	03
Further information	Not available.
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Revision Information	This document has undergone significant changes and should be reviewed in its entirety.