

SAFETY DATA SHEETS

According to the UN GHS revision 10

Version: 1.1
Creation Date: July 15, 2024
Revision Date: January 10, 2025

SECTION 1: Identification

1.1 GHS Product identifier

Product name Oxcarbazepine EP Impurity A (Carbamazepine)

1.2 Other means of identification

Product number C4X-11642
Other names Neurotol; Calepsin; Epitol

1.3 Recommended use of the chemical and restrictions on use

Identified uses For laboratory and Industrial use only.
Uses advised against no data available

1.4 Supplier's details

Company CATO Research Chemicals Inc.
Address 3/F,Building B,No.179 BASIGO, Guangpu Rd East,Huangpu Dist,Guangzhou
Telephone +86-20-81960175

1.5 Emergency phone number

Emergency phone number +86-20-81960175
Service hours 'Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

SECTION 2: Hazard identification

2.1 Classification of the substance or mixture

Acute toxicity - Category 4, Oral
Skin sensitization, Category 1
Respiratory sensitization, Category 1

2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word

Danger

Hazard statement(s)

H302 Harmful if swallowed
H317 May cause an allergic skin reaction
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statement(s)

Prevention

P264 Wash ... thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P284 [In case of inadequate ventilation] wear respiratory protection.
P301+P317 IF SWALLOWED: Get medical help.
P330 Rinse mouth.
P302+P352 IF ON SKIN: Wash with plenty of water/...
P333+P317 If skin irritation or rash occurs: Get medical help.
P321 Specific treatment (see ... on this label).
P362+P364 Take off contaminated clothing and wash it before reuse.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342+P316 If experiencing respiratory symptoms: Get emergency medical help immediately.

Storage

none

Disposal

P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

2.3 Other hazards which do not result in classification

no data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
Oxcarbazepine EP Impurity A (Carbamazepine)	Carbamazepine	298-46-4	206-062-7	≈ 99%

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

If inhaled

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

Following ingestion

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

4.2 Most important symptoms/effects, acute and delayed

no data available

4.3 Indication of immediate medical attention and special treatment needed, if necessary

Emergency and supportive measures. Maintain an open airway and assist ventilation if necessary. Administer supplemental oxygen. Treat seizures, coma, hyperthermia, arrhythmias, hyponatremia, and dystonias if they occur. Asymptomatic patients should be observed for a minimum of 6 hours after ingestion and for at least 12 hours if an extended-release preparation was ingested. ...

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media

Use dry chemical, carbon dioxide or alcohol-resistant foam.

5.2 Specific hazards arising from the chemical

no data available

5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing mist, gas or vapours. Avoid contacting with skin and eye. Use personal protective equipment. Wear chemical impermeable gloves. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

6.2 Environmental precautions

Prevent further spillage or leakage if it is safe to do so. Do not let the chemical enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Collect and arrange disposal. Keep the chemical in suitable and closed containers for disposal. Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

7.2 Conditions for safe storage, including any incompatibilities

Carbamazepine tablets, extended-release tablets, and chewable tablets should be stored in tight, light-resistant containers at temperatures not exceeding 30 deg C. Carbamazepine extended-release capsules should be stored in tight, light-resistant containers at 15-25 deg C. Because dissolution characteristics and associated oral bioavailability of carbamazepine tablets may be affected substantially by moisture, patients should be cautioned to keep containers of the tablets tightly closed and in a dry location, away from areas with excessive moisture (e.g., showers, bathrooms, humidifiers). Carbamazepine tablets may lose one-third or more of their oral bioavailability when exposed to excessive moisture. Tablets continuously exposed to 97% relative humidity at room temperature for 2 weeks become hardened and dissolve poorly.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

no data available

Biological limit values

no data available

8.2 Appropriate engineering controls

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

Skin protection

Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

Thermal hazards

no data available

SECTION 9: Physical and chemical properties and safety characteristics

Physical state	Solid
Colour	Crystals from absolute ethanol and benzene
Odour	no data available
Melting point/freezing point	180°C(lit.)
Boiling point or initial boiling point and boiling range	189°C/12mmHg(lit.)
Flammability	no data available
Lower and upper explosion limit/flammability limit	no data available
Flash point	77°C(lit.)
Auto-ignition temperature	no data available
Decomposition temperature	no data available
pH	no data available
Kinematic viscosity	no data available
Solubility	>35.4 [ug/mL]
Partition coefficient n-octanol/water	no data available
Vapour pressure	5.78E-07mmHg at 25°C
Density and/or relative density	1.266g/cm ³
Relative vapour density	no data available
Particle characteristics	no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

no data available

10.2 Chemical stability

To study the photostability of carbamazepine polymorphs, the pure materials on the tablet surface were evaluated without physical damage by means of Fourier-transform infrared reflection-absorption infrared spectrometry (FT-IR-RAS) and colorimetric measurement of the carbamazepine polymorphs I, II, and III, after photodegradation at 2 irradiation intensities under a near-UV fluorescent lamp. The surface

of sample pellets of all crystalline forms turned gradually from white to yellow-orange upon exposure to light, and the discoloration rate of form II was faster than that of forms I and III, indicating that form II was the most unstable of the three. The semilogarithmic plots of the photodegradation profiles of the various polymorphs were straight lines, including the induction period, indicating that degradation of the drug on the surface followed first-order kinetics. The induction periods of all forms were not significantly different. However, the degradation rate constant of form II was 5.1 and 1.5 times larger than those of forms I and III, respectively.

10.3 Possibility of hazardous reactions

no data available

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

no data available

10.6 Hazardous decomposition products

no data available

SECTION 11: Toxicological information

Acute toxicity

- Oral: no data available
- Inhalation: no data available
- Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT-single exposure

no data available

STOT-repeated exposure

no data available

Aspiration hazard

no data available

SECTION 12: Ecological information

12.1 Toxicity

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

12.2 Persistence and degradability

AEROBIC: Removal of carbamazepine in German sewage treatment plants was found to be extremely low at 7%(1). Using a batch suspension of activated sludge maintained under aerobic conditions, an initial decrease in 5.0 ug/L carbamazepine was observed in the first 15 minutes, then reached a constant level of 3.1 ug/L; 37% loss was attributed to adsorption to sludge. No metabolites were identified and no further degradation was observed(2).

12.3 Bioaccumulative potential

An estimated BCF of 15 was calculated in fish for carbamazepine(SRC), using a log Kow of 2.45(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).

12.4 Mobility in soil

The Koc of carbamazepine is estimated as 510(SRC), using a log Kow of 2.45(1) and a regression-derived equation(2). According to a classification scheme(3), this estimated Koc value suggests that carbamazepine is expected to have moderate mobility in soil. In a soil column study using Mahall-Leveen sandy soil from an area northwest of Phoenix, AZ, carbamazepine was detected in the column leachate at a concentration of 0.116 ug/L following addition of the compound at 0.170 ug/L 20 days prior(4).

12.5 Other adverse effects

no data available

SECTION 13: Disposal considerations

13.1 Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

SECTION 14: Transport information

14.1 UN Number

ADR/RID: UN1170 (For reference only, please check.) IMDG: UN1170 (For reference only, please check.) IATA: UN1170 (For reference only, please check.)

14.2 UN Proper Shipping Name

ADR/RID: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) (For reference only, please check.) IMDG: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) (For reference only, please check.) IATA: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) (For reference only, please check.)

14.3 Transport hazard class(es)

ADR/RID: 3 (For reference only, please check.) IMDG: 3 (For reference only, please check.) IATA: 3 (For reference only, please check.)

14.4 Packing group, if applicable

ADR/RID: II (For reference only, please check.) IMDG: II (For reference only, please check.) IATA: II (For reference only, please check.)

14.5 Environmental hazards

ADR/RID: No IMDG: No IATA: No

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to IMO instruments

no data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
Carbamazepine	Carbamazepine	298-46-4	206-062-7
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Not Listed.
China Catalog of Hazardous chemicals 2015			Not Listed.
New Zealand Inventory of Chemicals (NZIoC)			Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Listed.
Vietnam National Chemical Inventory			Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Listed.
Korea Existing Chemicals List (KECL)			Listed.

SECTION 16: Other information

Information on revision

Creation Date July 15, 2024
Revision Date January 10, 2025

Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS - The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>
- HSDB - Hazardous Substances Data Bank, website: <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>
- IARC - International Agency for Research on Cancer, website: <http://www.iarc.fr/>
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>
- ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>
- Germany GESTIS-database on hazard substance, website: <http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
- ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

Any questions regarding this SDS, Please send your inquiry to info@cato-chem.com

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