

SAFETY DATA SHEETS

According to the UN GHS revision 9

Version: 1.2
Creation Date: July 15, 2019
Revision Date: August 08, 2025

SECTION 1: Identification

1.1 GHS Product identifier

Product name Doxycycline EP Impurity E

1.2 Other means of identification

Product number C4X-19315

Other names adamycin; la200; geotilin

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

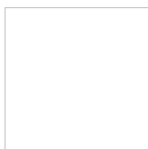
Acute toxicity - Category 4, Oral

Acute toxicity - Category 4, Dermal

Acute toxicity - Category 4, Inhalation

2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word

Warning

Hazard statement(s)

H302 Harmful if swallowed

H312 Harmful in contact with skin

H332 Harmful if inhaled

Precautionary statement(s)

Prevention

P264 Wash ... thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P271 Use only outdoors or in a well-ventilated area.

Response

P301+P317 IF SWALLOWED: Get medical help.

P330 Rinse mouth.

P302+P352 IF ON SKIN: Wash with plenty of water/...

P317 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.

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
Doxycycline EP Impurity E	Oxytetracycline	79-57-2	201-212-8	100%

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

SYMPTOMS: Symptoms of exposure to this compound may include nausea, anorexia, vomiting, diarrhea, glossitis, dysphagia, enterocolitis, inflammatory lesions (with monilial overgrowth) in the anogenital region; edema, benign intracranial hypertension, anaphylaxis, anaphylactoid purpura, pericarditis, exacerbation of systemic lupus erythematosus, hemolytic anemia, neutropenia, thrombocytopenia and eosinophilia. It can cause hypersensitivity reactions, such as rashes, urticaria, dermatitis, atrophic or hypertrophic glossitis, burning of the eyes, cheilosis, pruritus ani or vulvae, vaginitis and fever. Other symptoms of exposure to this type of compound include gastrointestinal disturbances with flatulence, drug fever, rise in blood urea and clinical deterioration in those with renal impairment. This class of compounds may also cause an overgrowth of resistant organisms (such as Candida species and other fungi) in the mouth and intestines, producing angular stomatitis, and rectal and vaginal irritation. It may also cause marked changes in the intestinal flora, resulting in multiplication of resistant organisms and deficiency of B vitamins. Staphylococcal enterocolitis may occur suddenly, often ending fatally. It may cause liver damage, especially in pregnancy. **ACUTE/CHRONIC HAZARDS:** When heated to decomposition this compound emits very toxic fumes of hydrogen chloride and nitrogen oxides. (NTP, 1992)

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

Basic treatment: Establish a patent airway (oropharyngeal or nasopharyngeal airway, if needed). Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if needed. Administer oxygen by nonrebreather mask at 10 to 15 L/min. Monitor for pulmonary edema and treat if necessary. Monitor for shock and treat if necessary. Anticipate seizures and treat if necessary. For eye contamination, flush eyes immediately with water. Irrigate each eye continuously with 0.9% saline (NS) during transport. Do not use emetics. For ingestion, rinse mouth and administer 5 ml/kg up to 200 ml of water for dilution if the patient can swallow, has a strong gag reflex, and does not drool. Cover skin burns with dry sterile dressings after decontamination. Poisons A and B

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media

Fires involving this material can be controlled with a dry chemical, carbon dioxide or Halon extinguisher. (NTP, 1992)

5.2 Specific hazards arising from the chemical

Flash point data for this chemical are not available. It is probably combustible. (NTP, 1992)

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

Oxytetracycline hydrochloride preparations should be stored at a temperature less than 40 deg C, preferably between 15-30 deg C; freezing of oxytetracycline injection should be avoided. Oxytetracycline hydrochloride capsules should be stored in tight, light-resistant containers. Oxytetracycline hydrochloride

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	PHYSICAL DESCRIPTION: Odorless fluffy yellow solid or yellow powder. Bitter taste. (NTP, 1992)
Colour	Light-yellow crystals or needles from aqueous MeOH
Odour	no data available
Melting point/freezing point	183°C
Boiling point or initial boiling point and boiling range	817.08°C at 760 mmHg
Flammability	no data available
Lower and upper explosion limit/flammability limit	no data available
Flash point	447.954°C
Auto-ignition temperature	no data available
Decomposition temperature	no data available
pH	no data available
Kinematic viscosity	no data available
Solubility	47 [ug/mL]
Partition coefficient n-octanol/water	no data available
Vapour pressure	9.7X10-25 mm Hg at 25 deg C (est)
Density and/or relative density	1.634 g/cm3 (20°C)
Relative vapour density	no data available
Particle characteristics	no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

This chemical is hygroscopic. Water soluble. Undergoes slow hydrolysis in the presence of water. Concentrated aqueous solutions at neutral pH hydrolyze on standing.

10.2 Chemical stability

Stable in air, but exposure to strong sunlight causes it to darken. oxytetracycline dihydrate

10.3 Possibility of hazardous reactions

OXYTETRACYCLINE HYDROCHLORIDE is sensitive to light. It may be unstable at temperatures above 77° F. It darkens on exposure to sunlight or to moist air above 194° F. Concentrated aqueous solutions at neutral pH hydrolyze on standing. This chemical undergoes hydrolysis in the presence of water. It may be incompatible with alkalis. (NTP, 1992)

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: LD50 Swiss mice oral 7200 mg/kg hydroxytetracycline monohydrochloride
- 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: LC50 *Lepomis macrochirus* (Bluegill) >100 ppm/96 hr; static /formulated product/[USEPA, Office of Pesticide Programs; Pesticide Ecotoxicity Database (2000) on
- Toxicity to daphnia and other aquatic invertebrates: EC50 *Daphnia magna* (Water flea; intoxication, immobilization) >102 ppm/48 hr; static /formulated product/[USEPA, Office of Pesticide Programs; Pesticide Ecotoxicity Database (2000) on
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

12.2 Persistence and degradability

AEROBIC: Oxytetracycline in a soil and manure sample underwent 0% degradation after 180 days(1). Fifty percent degradation of oxytetracycline took place in an aerobic sediment slurry after 43.8 days(1). Oxytetracycline in soil was degraded to 17 and 39% of the initial concentrations of 60 and 600 mg, respectively, after 35 days and to 3 and 29% of the initial concentrations of 120 and 1200 mg/kg, respectively, after 100 days during manometric respirometry tests(2).

12.3 Bioaccumulative potential

An estimated BCF of 0.12 was calculated for oxytetracycline(SRC), using a log Kow of -0.90(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

Koc values measured for oxytetracycline were 42,506 in Askov sandy loam soil (1.6% organic carbon), 93,317 in Flakkebjerg sandy loam soil (1.1% organic carbon), 27,792 in Borris loamy sand (1.5% organic carbon), and 47,881 in Lundgaard sandy soil (1.4% organic carbon) (1,2,3,4). The Koc of oxytetracycline measured in manure (49% organic carbon) was 195(4,5). According to a classification scheme(6), this range of Koc values suggests that oxytetracycline is expected to have moderate to no mobility in soil. Based on a measured pKa value of 9.5 (tertiary amine)(5), oxytetracycline is expected to exist primarily as a cation in the environment and cations generally have lower mobility in soil than their neutral counterparts(7).

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: no data available

IMDG: no data available

IATA: no data available

14.2 UN Proper Shipping Name

ADR/RID: no data available

IMDG: no data available

IATA: no data available

14.3 Transport hazard class(es)

ADR/RID: no data available

IMDG: no data available

IATA: no data available

14.4 Packing group, if applicable

ADR/RID: no data available

IMDG: no data available

IATA: no data available

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
Oxytetracycline	Oxytetracycline	79-57-2	201-212-8
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			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, 2019
Revision Date August 08, 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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