# SAFETY DATA SHEET

## 1. Identification

**Product identifier** Capecitabine Related Compound B

Other means of identification

Catalog number 1090728 3094-09-5 **CAS** number

**Synonyms** Doxifluridine, 5-DFUR **Chemical name** 5'-Deoxy-5-fluorouridine

Specified quality tests and assay use only. Recommended use

Not for use as a drug. Not for administration to humans or animals. **Recommended restrictions** 

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia **Address** 12601 Twinbrook Parkway

> Rockville MD 20852-1790 **United States**

**Telephone RS Technical Services** 301-816-8129

Website www.usp.org E-mail RSTECH@usp.org

**Emergency phone number** CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards** Carcinogenicity Category 1B

> Category 1B Reproductive toxicity

Not classified. **Environmental hazards OSHA** defined hazards Not classified.

Label elements



Signal word

**Hazard statement** May cause cancer. 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. Wear protective gloves/protective clothing/eye protection/face protection.

Response If exposed or concerned: Get medical advice/attention.

Store locked up. Storage

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

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Pharmaceutical related compound of unknown potency.

USP SDS US 1/6 1090728 Version #: 04 Revision date: 07-20-2018 Issue date: 11-16-2006

## 3. Composition/information on ingredients

#### **Substance**

Chemical name	Common name and synonyms	CAS number	%	
Capecitabine Related Compound B	Doxifluridine, 5-DFUR	3094-09-5	100	

## 4. First-aid measures

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Inhalation

Call a physician if symptoms develop or persist.

Rinse skin with water/shower. Get medical attention if irritation develops and persists. Skin contact

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

Ingestion Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Gastrointestinal disturbances. Pharmaceutical related compound of unknown potency. It is not

Most important

known if occupational exposure may cause physiological effects. symptoms/effects, acute and delayed

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from **General information** 

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

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

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

Fire fighting

Wear suitable protective equipment.

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.

Use standard firefighting procedures and consider the hazards of other involved materials. Specific methods

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 For waste disposal, see section 13 of the SDS. 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.

**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 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. Use of a designated area is recommended for handling of potent materials. 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 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

Occupational exposure limits No exposure limits noted for ingredient(s). **Biological limit values** 

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

controls

Appropriate engineering

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. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated

balance enclosure, glovebox). No open handling.

Individual protection measures, such as personal protective equipment

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Eye/face protection

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

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved Hand protection

or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Consider double gloves.

Base the choice of skin protection on the job activity, potential for skin contact and solvents and Other

reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Train employees in proper gowning and degowning practices. Wear disposable lab

coat, disposable sleeve covers and two pair of gloves as appropriate for the task.

Chose respiratory protection appropriate to the task and the level of existing engineering controls. Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head

cover for spill cleanup.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards.

Procedures for any other uses or quantities should be determined after an appropriate

assessment. Pharmacological effects may be seen with occupational exposure.

## 9. Physical and chemical properties

Appearance descriptions are general information and not specific to any USP lot. **Appearance** 

Physical state Solid. **Form** Powder. White. Color

Not available. Odor **Odor threshold** Not available. pН Not available.

366.8 - 379.4 °F (186 - 193 °C) Melting point/freezing point

Initial boiling point and boiling

range

Not available.

Not available. Flash point Not available. **Evaporation rate** Not available. Flammability (solid, gas) 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.

< 0.0000001 kPa at 25 °C Vapor pressure

Vapor density Not available. Not available. Relative density

Solubility(ies)

Not available. Solubility (water) Not available. **Auto-ignition temperature Decomposition temperature** Not available. Not available. Viscosity

USP SDS US

Other information

**Chemical family** Pyrimidine analog. **Molecular formula** C9H11FN2O5

Molecular weight 246.2

## 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 Contact with incompatible materials.

Incompatible materials Strong acids.

Hazardous decomposition

products

F-. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

# 11. Toxicological information

## Information on likely routes of exposure

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.Eye contactKnowledge about health hazard is incomplete.IngestionKnowledge about health hazard is incomplete.

Symptoms related to the physical, chemical, and

toxicological characteristics

Related material: Fatigue. Gastrointestinal disturbances. Weight loss. Dizziness. Headache. Yellow eyes and/or skin. Blisters. Numbness, pain, tingling, or weakness in hands or feet.

Swelling of extremities. Painful or difficult urination. Fever. Chills. Cough. Hoarseness. Lower back or side pain. Mouth sores. Loss of appetite. Constipation. Fainting. Dry mouth. Increase in heart rate. Rapid breathing. Thirst. Heartburn. Red eyes. Eye pain. Insomnia. Skin rash. Itching. Hair

loss. Bleeding or bruising.

#### Information on toxicological effects

Acute toxicity Not known.

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

irritation

Respiratory or skin sensitization

Respiratory sensitization Knowledge about sensitization hazard is incomplete.

Skin sensitization Knowledge about health hazard is incomplete.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Carcinogenicity May cause cancer.

Antimetabolites have been shown to be carcinogenic in animals and may be associated with an increased risk of development of secondary carcinomas when used as antineoplastics in humans.

### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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

Not listed.

**Reproductive toxicity** May damage fertility or the unborn child.

Antineoplastic therapy can adversely affect male and female fertility through gonadal suppression, resulting in the absence of menstruation or sperm. The effects appear to be related to dose and

length of therapy and may be irreversible.

Specific target organ toxicity -

single exposure

**Aspiration hazard** 

Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

repeated exposure

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

Further information Pharmaceutical related compound of unknown potency. It is not known if occupational exposure

may cause physiological effects.

Material name: Capecitabine Related Compound B

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## 12. Ecological information

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity** 

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 product.

No data available. Bioaccumulative potential 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

**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.

Dispose in accordance with all applicable regulations. Local disposal 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 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 dangerous goods.

**IATA** 

Not regulated as dangerous goods.

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

**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 CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

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 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Immediate Hazard - No **Hazard categories** 

Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Yes

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## 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 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

Australia Australian Inventory of Chemical Substances (AICS) Canada Domestic Substances List (DSL)	No No No No
Canada Domestic Substances List (DSL)	No
Canada Non-Domestic Substances List (NDSL)	No
China Inventory of Existing Chemical Substances in China (IECSC)	110
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	No
Philippines Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

<sup>\*</sup>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

11-16-2006 Issue date 07-20-2018 **Revision date** 

Version # 04

United States & Puerto Rico

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Toxic Substances Control Act (TSCA) Inventory

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herein.

Material name: Capecitabine Related Compound B

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No