

SAFETY DATA SHEET

Preparation Date: 12/28/2018

Revision Number: E1

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name : Capecitabine, USP

Product Number : C2417

Brand : Spectrum Chemical

CAS-No. : 154361-50-9

1.2 Details of the supplier of the safety data sheet

Company : Spectrum Chemical
14422 South San Pedro St.
Gardena, CA 90248

Telephone : +1 310-516-8000

Fax : +1 310-516-9843

1.3 Emergency telephone number

Emergency Phone # : +1-800-424-9300 (CHEMTREC)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Germ cell mutagenicity (Category 2), H341
Carcinogenicity (Category 1B), H350
Reproductive toxicity (Category 1B), H360
Acute aquatic toxicity (Category 3), H402

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word

Danger

Hazard statement(s)

H341 Suspected of causing genetic defects.
H350 May cause cancer.
H360 May damage fertility or the unborn child.
H402 Harmful to aquatic life.

Precautionary statement(s)

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P273 Avoid release to the environment.
P281 Use personal protective equipment as required.

P308 + P313
P405
P501

IF exposed or concerned: Get medical advice/ attention.
Store locked up.
Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Synonyms : 5'-Deoxy-5-fluoro-N-[(pentyloxy)carbonyl]cytidine
Ro-9-1978

Formula : C₁₅H₂₂FN₃O₆
Molecular weight : 359.35 g/mol
CAS-No. : 154361-50-9

Hazardous components

Component	Classification	Concentration
Capecitabine		
	Muta. 2; Carc. 1B; Repr. 1B; Aquatic Acute 3; H341, H350, H360, H402	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NO_x), Hydrogen fluoride

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
For personal protection see section 8.

6.2 Environmental precautions

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

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs.

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature 2 - 8 °C

Keep in a dry place.

Storage class (TRGS 510): Non-combustible, acute toxic Cat.3 / toxic hazardous materials or hazardous materials causing chronic effects

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body Protection

Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

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

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- | | |
|---|--|
| a) Appearance | Form: powder |
| b) Odor | Odorless |
| c) Odor Threshold | No data available |
| d) pH | No data available |
| e) Melting point/freezing point | Melting point/range: 116 - 117 °C (241 - 243 °F) |
| f) Initial boiling point and boiling range | No data available |
| g) Flash point | No data available |
| h) Evaporation rate | No data available |
| i) Flammability (solid, gas) | No data available |
| j) Upper/lower flammability or explosive limits | No data available |
| k) Vapor pressure | No data available |
| l) Vapor density | No data available |
| m) Relative density | No data available |
| n) Water solubility | 26 g/l at 20 °C (68 °F) |
| o) Partition coefficient: n-octanol/water | log Pow: ca.4.5 |
| p) Auto-ignition temperature | No data available |
| q) Decomposition temperature | No data available |
| r) Viscosity | No data available |
| s) Explosive properties | No data available |
| t) Oxidizing properties | No data available |

9.2 Other safety information

Bulk density	ca.450 kg/m ³
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10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Other decomposition products - No data available
In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects****Acute toxicity**

LD50 Oral - Rat - > 2,000 mg/kg

Inhalation: No data available

Dermal: No data available

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

In vitro tests showed mutagenic effects

Carcinogenicity

Possible human carcinogen

Reproductive toxicity

May damage the unborn child.

Reproductive toxicity - Mouse - male - Oral

Paternal Effects: Spermatogenesis (including genetic material, sperm morphology, motility and count).

Reproductive toxicity - Mouse - female - Oral

Effects on Fertility: Mating performance (e.g., # sperm positive females per # females mated; # copulations per # estrus cycles). Effects on Fertility: Female fertility index (e.g., # females pregnant per # sperm positive females; # females pregnant per # females mated).

May damage fertility.

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: Not available

Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

12. ECOLOGICAL INFORMATION**12.1 Toxicity**

Toxicity to fish

LC50 - *Oncorhynchus mykiss* (rainbow trout) - > 867 mg/l - 96 h

NOEC - Oncorhynchus mykiss (rainbow trout) - 867 mg/l - 96 h
Toxicity to daphnia and other aquatic invertebrates EC50 - Daphnia magna (Water flea) - > 850 mg/l - 48 h

Toxicity to algae EbC50 - Selenastrum capricornutum (green algae) - 58 mg/l - 72 h (OECD Test Guideline 201)
ErC50 - Selenastrum capricornutum (green algae) - 200 mg/l - 72 h (OECD Test Guideline 201)
NOEC - Selenastrum capricornutum (green algae) - 14 mg/l - 72 h

12.2 Persistence and degradability

Biodegradability Result: 29 % - Inherently biodegradable.

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Harmful to aquatic life.

Avoid release to the environment.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

15. REGULATORY INFORMATION

SARA 302 Components

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Massachusetts Right To Know Components

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

CAS-No.

Revision Date

Capecitabine

154361-50-9

New Jersey Right To Know Components

CAS-No.

Revision Date

Capecitabine

154361-50-9

California Prop. 65 Components

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

Aquatic Acute	Acute aquatic toxicity
Carc.	Carcinogenicity
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H360	May damage fertility or the unborn child.
H402	Harmful to aquatic life.
Muta.	Germ cell mutagenicity

HMIS Rating

Health hazard:	0
Chronic Health Hazard:	*
Flammability:	0
Physical Hazard	0

NFPA Rating

Health hazard:	0
Fire Hazard:	0
Reactivity Hazard:	0

Further information

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet