

# SAFETY DATA SHEET – Floxuridine for Injection, USP

## Section 1. Identification

<b>GHS product identifier:</b>	Floxuridine for Injection, USP
<b>Product code:</b>	NDC 81643-9270-1
<b>Product type:</b>	Lyophilized powder
<b>Container information:</b>	5 mL
<b>Identified uses:</b>	Floxuridine for Injection, USP is effective in the palliative management of gastrointestinal adenocarcinoma metastatic to the liver, when given by continuous regional intra-arterial infusion in carefully selected patients who are considered incurable by surgery or other means. Patients with known disease extending beyond an area capable of infusion via a single artery should, except in unusual circumstances, be considered for systemic therapy with other chemotherapeutic agents.
<b>Manufacturer:</b>	THYMOORGAN PHARMAZIE GmbH Schiffgraben 23, 38690 Goslar, Germany
<b>Supplier's details:</b>	Cerona Therapeutics, Inc 65 William Street Suite 200, Wellesley, MA 02481 USA
<b>Emergency telephone number:</b>	CHEMTREC, U.S., Toll Free: 1-800-424-9300, 24 hours/7 days

## Section 2. Hazards identification

<b>OSHA/HCS status:</b>	This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
<b>Classification of the substance or mixture:</b>	ACUTE TOXICITY (oral) - Category 3

### GHS label elements

#### Hazard pictograms:



<b>Signal word:</b>	DANGER
<b>Hazard statements:</b>	H301 – Toxic if swallowed. H431 – Suspected of causing genetic defects
<b>Precautionary statements:</b>	
<b>Prevention:</b>	P203 – Obtain, read and follow all safety instructions before use. P270 – Do not eat, drink or smoke when using this product. P264 – Wash hands thoroughly after handling.
<b>Response:</b>	P301+P316+P330 – IF SWALLOWED: Get emergency medical help immediately. Rinse mouth. P318 – if exposed or concerned, get medical advice.
<b>Storage</b>	Not applicable.

**Disposal:** P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.  
**Hazards not otherwise classified:** None known.

### Section 3. Composition/information on ingredients

**Substance/mixture:** Substance  
**Common name and synonyms:** Floxuridine, 2'-Deoxy-5-fluorouridine, FuDR  
**Other means of identification:** Chemical formula: C<sub>9</sub>H<sub>11</sub>FN<sub>2</sub>O<sub>5</sub>

<b>Ingredient Name</b>	<b>%</b>	<b>CAS Number</b>
Floxuridine	<=100%	50-91-9

See Package Insert for further information.

### Section 4. First aid measures

**Eye contact:** First check the victim for contact lenses and remove if present. Flush victim's eyes with water or normal saline solution for 20 to 30 minutes while simultaneously calling a hospital or poison control center. Do not put any ointments, oils, or medication in the victim's eyes without specific instructions from a physician. IMMEDIATELY transport the victim after flushing eyes to a hospital even if no symptoms (such as redness or irritation) develop.

**Inhalation:** IMMEDIATELY leave the contaminated area; take deep breaths of fresh air. If symptoms (such as wheezing, coughing, shortness of breath, or burning in the mouth, throat, or chest) develop, call a physician and be prepared to transport the victim to a hospital. Provide proper respiratory protection to rescuers entering an unknown atmosphere. Whenever possible, Self-Contained Breathing Apparatus (SCBA) should be used; if not available, use a level of protection greater than or equal to that advised under Protective Clothing.

**Skin contact:** IMMEDIATELY flood affected skin with water while removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water. If symptoms such as redness or irritation develop, IMMEDIATELY call a physician and be prepared to transport the victim to a hospital for treatment.

**Ingestion:** DO NOT INDUCE VOMITING. If the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical and IMMEDIATELY call a hospital or poison control center. Be prepared to transport the victim to a hospital if advised by a physician. If the victim is convulsing or unconscious, do not give anything by mouth, ensure that the victim's airway is open and lay the victim on his/her side with the head lower than the body. IMMEDIATELY transport the victim to a hospital.

#### Most important symptoms/effects, acute and delayed

##### **Potential acute health effects**

<b>Eye contact:</b>	No data available
<b>Inhalation:</b>	No data available
<b>Skin contact:</b>	No data available
<b>Ingestion:</b>	Harmful if swallowed

##### **Over-exposure signs/symptoms**

<b>Eye contact:</b>	No data available
<b>Inhalation:</b>	No data available
<b>Skin contact:</b>	No data available

**Ingestion:** Harmful if swallowed

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

**Notes to physician:** In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

**Specific treatments:** No specific treatment

**Section 5. Fire-fighting measures**

**Extinguishing media**

**Suitable extinguishing media:** Use an extinguishing agent suitable for the surrounding fire

**Unsuitable extinguishing media:** None known

**Hazardous thermal decomposition products:** Decomposition products may include the following materials: carbon dioxide, carbon monoxide, nitrogen oxides (NOx), halogenated compounds

**Special protective actions and equipment for fire-fighters:**

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

**Section 6. Accidental release measures**

**Personal precautions, protective equipment and emergency procedures:**

Keep unnecessary and unprotected personnel from entering. Do not touch or walk-through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment. Refer to Section 8 for personal protection information.

**Environmental precautions:**

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

**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. See Section 1 for emergency contact information and Section 13 for waste disposal

**Section 7 Handling and storage**

**Precautions for safe handling**

**Storage Conditions:** Store at controlled room temperature of 20 to 25°C (68 to 77°F)

**Protective measures:** Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Keep in the original container, keep tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

**Advice on general occupational hygiene:** Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.

**Conditions for safe storage,**

**including any incompatibilities:**

Store in accordance with local regulations and storage conditions. Keep away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

## Section 8 Exposure controls/personal protection

### Occupational exposure limits

**Exposure limits:**

None established

**Appropriate engineering controls:**

Good general ventilation should be sufficient to control worker exposure

**Environmental exposure controls:**

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

### Individual protection measures

**Hygiene measures:**

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

**Eye/face protection:**

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

**Skin/Hand protection:**

Wear chemical-resistant, impervious gloves at all times when handling. Appropriate footwear and any additional skin protection measures should be selected before handling this product.

**Respiratory protection:**

No personal respiratory protective equipment is normally required when this product is used/administrated by a licensed healthcare clinician or practitioner under normal use. The need for respiratory protection will vary according to meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

## Section 9. Physical and chemical properties

### Appearance

**Physical state:**

Lyophilized Powder

**Color:**

White to off-white

**Odor:**

Not available

**Odor threshold:**

Not available

**pH:**

Not available

**Melting point:**

Not available

**Freezing point**

Not available

**Boiling point, boiling range**

Not available

**Flash point:**

Not applicable

**Evaporation rate:**

Not available

**Flammability (solid, gas):**

Not applicable

**Lower and upper explosive (flammable) limits:**

Not applicable

**Vapor pressure**

Not available

**Vapor density**

Not available

**Relative density**

Not available

**Solubility**

Soluble in water

Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not applicable
Decomposition temperature:	Not available
Viscosity	Not available

## Section 10. Stability and reactivity

<b>Reactivity:</b>	No specific test data related to reactivity are available
<b>Chemical stability:</b>	Stable under recommended storage conditions
<b>Possibility of hazardous reactions:</b>	Under recommended conditions of storage and use, hazardous reactions will not occur
<b>Conditions to avoid:</b>	Avoid heat and moisture
<b>Incompatible materials:</b>	Reactive or incompatible with the following: strong acids, strong alkalis, strong oxidizers, strong reducers
<b>Hazardous decomposition products:</b>	Under recommended conditions of storage and use, hazardous decomposition is not expected to occur
<b>Hazardous polymerization products:</b>	Hazardous polymerization is not expected to occur

## Section 11. Toxicological Information

**Likely routes of exposure:** Eye contact. Inhalation. Skin contact. Ingestion.

### Potential immediate health effects

<b>Eye contact:</b>	No data available
<b>Inhalation:</b>	No data available
<b>Skin contact:</b>	No data available
<b>Ingestion:</b>	Harmful if swallowed

### Potential delayed health effects

<b>Eye contact:</b>	No data available
<b>Inhalation:</b>	No data available
<b>Skin contact:</b>	No data available
<b>Ingestion:</b>	Harmful if swallowed

### Potential chronic health effects from short- or long- term exposure

<b>General:</b>	No data available
<b>Carcinogenicity:</b>	No data available
<b>Mutagenicity:</b>	No data available
<b>Teratogenicity:</b>	Floxuridine is a Pregnancy Category D pharmaceutical
<b>Developmental effects:</b>	No data available
<b>Fertility effects:</b>	No data available

### Symptoms related to chemical exposure

<b>Eye contact:</b>	No data available
<b>Inhalation:</b>	No data available
<b>Skin contact:</b>	No data available
<b>Ingestion:</b>	Harmful if swallowed

### Toxicological effects

<b>Acute toxicity:</b>	LD <sub>50</sub> Oral (Rat): 215 mg/kg LD <sub>50</sub> Intravenous (Mouse): 880 mg/kg LD <sub>50</sub> Intravenous (Rat): 670 mg/kg LD <sub>50</sub> Intravenous (Rabbit): 94 mg/kg LD <sub>50</sub> Intravenous (Dog): 157 mg/kg
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**Irritation/Corrosion:** No data available

<b>Sensitization:</b>	No data available
<b>Mutagenicity:</b>	Oncogenic transformation of fibroblasts from mouse embryo has been induced <i>in vitro</i> by floxuridine, but the relationship between oncogenicity and mutagenicity is not clear. Floxuridine has also been shown to be mutagenic in human leukocytes <i>in vitro</i> and in the <i>Drosophila</i> test system. In addition, 5-fluorouracil, to which floxuridine is catabolized when given by intra-arterial injection, has been shown to be mutagenic in <i>in vitro</i> tests.
<b>Carcinogenicity:</b>	Long-term studies in animals to evaluate the carcinogenic potential of floxuridine have not been conducted. On the basis of the available data, no evaluation can be made of the carcinogenic risk of floxuridine to humans.
<b>Reproductive toxicity:</b>	The effects of floxuridine on fertility and general reproductive performance have not been studied in animals. However, because floxuridine is catabolized to 5-fluorouracil, it should be noted the 5-fluorouracil has been shown to induce chromosomal aberrations and changes in chromosome organization of spermatogonia in rats at doses of 125 or 250 mg/kg, administered intraperitoneally. Spermatogonial differentiation was also inhibited by fluorouracil, resulting in transient infertility. In female rats, fluorouracil, administered intraperitoneally at doses of 25 or 50 mg/kg during the preovulatory phase of oogenesis, significantly reduced the incidence of fertile matings, delayed the development of pre- and post-implantation embryos, increased the incidence of preimplantation lethality and induced chromosomal anomalies in these embryos. Compounds such as floxuridine, which interfere with DNA, RNA and protein synthesis, might be expected to have adverse effects on gametogenesis.
<b>Teratogenicity:</b>	Floxuridine has been shown to be teratogenic in the chick embryo, mouse (at doses of 2.5 to 100 mg/kg) and rat (at doses of 75 to 150 mg/kg). Malformations included cleft palates, skeletal defects and deformed appendages, paws and tails. The dosages which were teratogenic in animals were 4.2 to 125 times the recommended human therapeutic dose. There are no adequate and well-controlled studies with floxuridine in pregnant women. While there is no evidence of teratogenicity in humans due to floxuridine, it should be kept in mind that other drugs which inhibit DNA synthesis (e.g., methotrexate and aminopterin) have been reported to be teratogenic in humans. Floxuridine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
<b>Specific target organ toxicity (single exposure):</b>	No data available.
<b>Specific target organ toxicity (repeated exposure):</b>	No data available.
<b>Aspiration hazard:</b>	No data available.
<b><u>Numerical measures of toxicity</u></b>	
<b>Acute toxicity estimates:</b>	Oral ATE value = 1365.1 mg/kg

## Section 12. Ecological Information

<b>Toxicity:</b>	No data available.
<b>Persistence and degradability:</b>	No data available
<b>Bioaccumulative potential:</b>	LogP <sub>ow</sub> = -1.16 Potential: Low
<b><u>Mobility in soil</u></b>	
<b>Soil/water partition coefficient (K<sub>oc</sub>):</b>	Not available

**Other adverse effects:** No known significant effects or critical hazards

### Section 13. Disposal considerations

**Disposal methods:** Dispose of in accordance with Local, State, and Federal regulations.

### Section 14. Transport information

**DOT Shipping Name:** Not regulated

**DOT UN Number:** Not regulated

**Precautions for transport:** Transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

### Section 15. Regulatory information

**FDA:** Floxuridine is an approved prescription medication.

#### **U.S. Federal regulations**

**TSCA 8(a) CDR Exempt/Partial exemption:** Not determined

**United States inventory (TSCA 8b):** Not determined

#### **SARA 302/304**

**Composition/information on ingredients** No products were found

**SARA 304 RQ:** Not applicable

#### **SARA 311/312**

**Classification:** ACUTE TOXICITY (oral) - Category 3

#### **SARA 313:**

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

#### **State Regulations**

Massachusetts Right to Known Not listed

New York Not listed

New Jersey Right to Know Floxuridine, CAS 50-91-9

Pennsylvania Right To Know Floxuridine, CAS 50-91-9

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

### Section 16. Other information

Document Number TLB-80003  
Date of Initial Release 17 June 2022  
Current Revision Revision A  
Date of Current Revision 17 June 2022

SDS conforms to HCS 2012 – USA

DISCLAIMER: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Cerona Therapeutics and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.