




## SAFETY DATA SHEET

### Section 1. IDENTIFICATION

<b>Product identifier used on the label</b>	LONSURF Tablet (15 mg trifluridine/6.14 mg tipiracil) LONSURF Tablet (20 mg trifluridine/8.19 mg tipiracil)
<b>Other means of identification</b>	FTD: Trifluridine; TPI: Tipiracil hydrochloride
<b>Recommended use</b>	LONSURF is a combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, indicated for the treatment of patients with metastatic colorectal cancer.
<b>Restrictions on use</b>	No information
<b>Manufacturer/distributor</b>	
Manufactured by:	Taiho Pharmaceutical Co., Ltd.
Manufactured for:	Taiho Oncology, Inc.
<b>Phone number</b>	1-844-878-2446
<b>Emergency phone number</b>	1-800-535-5053 - US and Canada 1-352-323-3500 - International

### Section 2. HAZARD(S) IDENTIFICATION

<b>Physical Hazards</b>	Not classified
<b>Health Hazards</b>	
Skin corrosion/irritation:	Category 2
Serious eye damage/eye irritation:	Category 2
Reproductive toxicity:	Category 2
Specific target organ toxicity repeated or prolonged exposure:	Category 2 (Gastrointestinal and bone marrow)
<b>Environmental Hazards</b>	Not classified
<b>Other Hazards</b>	No information
<b>Symbol(s)</b>	
<b>Signal word</b>	<b>Warning</b>
<b>Hazard Statement(s)</b>	Causes skin irritation Causes serious eye irritation Suspected of damaging fertility or the unborn child May cause damage to gastrointestinal and bone marrow through prolonged or repeated exposure



<b>Precautionary Statement(s)</b>	
[Prevention]	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.
[Emergency response]	If on skin: Wash with plenty of water. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell. If skin irritation occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.
[Storage]	Store locked up.
[Disposal]	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Description of any hazards not otherwise classified</b>	No information
<b>Ingredient with unknown acute toxicity in the mixture</b>	Not applicable

### Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Composition (contents of the product):

Chemical name	CAS No.	Concentration/concentration ranges (wt %)
2'-deoxy-5-(trifluoromethyl)uridine (FTD)	70-00-8	12.22
5-chloro-6-[(2-iminopyrrolidin-1-yl)methyl]pyrimidine-2,4-(1 <i>H</i> , 3 <i>H</i> )-dione monohydrochloride (TPI)	183204-72-0	5.76
Others	-	82.02



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**Section 4. FIRST-AID MEASURES**

<b>Necessary first-aid measures by relevant routes of exposure</b>	
IF INHALED	Gargle with water. Move individual to fresh air. Begin artificial respiration, if not breathing. Get medical attention.
IF ON SKIN	Wash with copious amounts of water. Get medical attention if irritation develops.
IF IN EYES	Flush with copious amounts of water. Get medical attention if irritation develops.
IF SWALLOWED	If a large amount is ingested, give some water first (a glass or two) and put fingers down the throat to induce vomiting. Wash out mouth with water. Make sure to seek medical advice even if no immediate symptom is noticed.
<b>Most important symptoms/effects, acute and delayed</b>	Causes skin irritation Causes serious eye irritation Suspected of damaging fertility or the unborn child May cause damage to gastrointestinal and bone marrow through prolonged or repeated exposure
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	No information

**Section 5. FIRE-FIGHTING MEASURES**

<b>Suitable extinguishing media</b>	Water or carbon dioxide, dry chemical powder or appropriate foam.
<b>Unsuitable extinguishing media</b>	No information
<b>Specific hazards arising from the chemical</b>	Emits toxic fumes (carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen fluoride, hydrogen chloride) under fire conditions.
<b>Special protective equipment and precautions for fire-fighters</b>	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

**Section 6. ACCIDENTAL RELEASE MEASURES**

<b>Personal precautions, protective equipment, and emergency procedures</b>	Ensure adequate ventilation if tablets are crushed, avoid inhalation of dust, wear protective personal clothing and equipment.
<b>Methods and materials for containment and cleaning up</b>	Sweep up and place in a bag (polyethylene or others), being careful not to damage tablets. If tablets are crushed, wear appropriate protective equipment and follow the procedure listed below.



	<p>Collect crushed tablets, being careful not to raise dust. Place in a bag (polyethylene or others).</p> <p>Vacuum contaminated area. Wash the area with water.</p>
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## Section 7. HANDLING AND STORAGE

### Precautions for safe handling:

<b>Protective measures</b>	<p>When handling in tablet state, be careful not to damage tablets.</p> <p>May be harmful if swallowed, inhaled, or absorbed through the skin.</p> <p>When handling powdered tablet, avoid skin contact.</p> <p>Do not inhale or get in eyes.</p>
<b>Advice on general occupational hygiene</b>	<p>Wash hands thoroughly after handling.</p> <p>No eating, drinking, or smoking in area.</p>

### Conditions for safe storage, including any incompatibilities:

<b>Technical measures</b>	<p>Keep container closed.</p> <p>Use adequate ventilation.</p>
<b>Incompatible materials</b>	Strong oxidizing agents
<b>Conditions for safe storage</b>	Controlled room temperature
<b>Packing material</b>	No information

## Section 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>FTD</b> TAIHO Occupational Exposure Limits (OEL)	1~10 µg/m <sup>3</sup>
<b>Appropriate engineering controls</b>	Use local dust collector when handling powdered tablet.
<b>Individual protection measures, such as personal protective equipment</b>	
Respiratory protection	<p>Wear dustproof mask when handling powdered tablet.</p> <p>Use local dust collector when handling powdered tablet.</p>
Hand protection	Wear protective gloves in accordance with the operation.
Eye protection	Wear protective eye glasses or safety goggles when handling powdered tablet.
Skin and body protection	Wear white robes for analytical work. Wear dust free garment for manufacturing work.



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## Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.)	LONSURF Tablet (15mg trifluridine/6.14 mg tipiracil): White, biconvex, round, film-coated tablet, imprinted with '15' on one side, and '102' and '15 mg' on the other side, in gray ink. LONSURF Tablet (20 mg trifluridine/8.19 mg tipiracil): Pale red, biconvex, round, film-coated tablet, imprinted with '20' on one side, and '102' and '20 mg' on the other side, in gray ink.
Odor	No information
Odor threshold	No information
pH	No information
Melting point/freezing point	No information
Initial boiling point and boiling range	No information
Flash point	No information
Evaporation rate	No information
Flammability (solid, gas)	No information
Upper/lower flammability or explosive limits	No information
Vapor pressure	No information
Vapor density	No information
Relative density	No information
Solubility (ies)	No information
Partition coefficient: <i>n</i> -octanol/water	No information
Auto-ignition temperature	No information
Decomposition temperature	No information
Viscosity	No information
Other information	No information

## Section 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	Stable under normal handling conditions.
<b>Chemical stability</b>	Stable under normal handling conditions.
<b>Possibility of hazardous reactions</b>	No hazardous reaction expected with normal handling.
<b>Conditions to avoid</b>	No information
<b>Incompatible materials</b>	Strong oxidizing agents
<b>Hazardous decomposition products</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen fluoride and hydrogen chloride

## Section 11. TOXICOLOGICAL INFORMATION

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	
Acute toxicity (oral):	Rat: Approximate Lethal Dose



	LONSURF: 2,000 mg/kg as FTD (♂♀) Dog: Approximate Lethal Dose LONSURF: 2,000 mg/kg (♂), >2,000 mg/kg (♀)		
Acute toxicity (dermal):	No information		
Acute toxicity (inhalation: gases):	No information		
Acute toxicity (inhalation: vapors):	No information		
Acute toxicity (inhalation: dust/mist):	No information		
Skin corrosion/irritation:	Irritant with in vitro test (FTD, TPI)		
Serious eye damage/irritation:	Irritant with in vitro test (FTD, TPI)		
Respiratory sensitization:	No information		
Skin sensitization:	No information		
Germ cell mutagenicity:	Clastogenicity: LONSURF, FTD: positive; TPI: negative		
Carcinogenicity:	No information		
Reproductive toxicity:	Observed effects on fertility and early embryonic development (Female Rat) Teratogenicity : Teratogenic (Rat)		
Specific target organ toxicity single exposure:	Gastrointestinal toxicity		
Specific target organ toxicity repeated exposure:	Gastrointestinal and bone marrow-toxicity NOAEL(Oral):		
	LONSURF (equivalent of FTD)	Rat	4 week study, 50 mg/kg, 13 week study, 15 mg/kg
		Monkey	4 week study, 6.25 mg/kg 13 week study, 1.25 mg/kg
		Dog	2 week study, < 17 mg/kg
Aspiration hazard:	No information		
Other toxicological information:	Dental toxicity including whitening, breakage, and malocclusion were observed in rat incisors persistently growing for entire lifetime.		
<b>Delayed and immediate effects and also chronic effects from short- and long-term exposure</b>	Causes skin irritation Causes serious eye irritation Suspected of damaging fertility or the unborn child May cause damage to gastrointestinal and bone marrow through prolonged or repeated exposure		
<b>Numerical measures of toxicity (such as acute toxicity estimates)</b>	Not applicable.		
<b>Whether the chemical is listed in the NTP Report on Carcinogens or has been found to be a potential carcinogen in the IARC Monographs, or by OSHA</b>	IARC: Not listed as Group1, Group2A or Group 2B NTP Report: Not listed OSHA: Not listed		



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## Section 12. ECOLOGICAL INFORMATION

<b>Ecotoxicity</b>	No information
<b>Persistence and degradability</b>	No information
<b>Bioaccumulative potential</b>	No information
<b>Mobility in soil</b>	No information
<b>Other adverse effects</b>	No information

## Section 13. DISPOSAL CONSIDERATIONS

<b>Waste treatment methods</b>	Wash with a detergent solution. Rinse with water. Air dry or wipe dry. Incineration is recommended.
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## Section 14. TRANSPORT INFORMATION

<b>UN number</b>	Not applicable
<b>UN proper shipping name</b>	Not applicable
<b>Transport hazard class(es)</b>	Not applicable
<b>Packing group</b>	Not applicable
<b>Environmental hazards</b>	Not applicable
<b>Transport in bulk according to Annex II of MARPOL 73/78 and IBC code</b>	Not applicable
<b>Special precautions for user</b>	When transporting, avoid direct sunlight. Confirm no leakage to containers. When loading, prevent containers from falling, dropping off, or damaging. Take preventive measures to avoid collapse.

## Section 15. REGULATORY INFORMATION

<b>OSHA</b>	Hazardous chemical
<b>TSCA inventory</b>	Not listed
<b>TSCA SNUR</b>	Not listed
<b>SARA Title III</b>	Section 302 (Extremely Hazardous Substances): Not listed Section 304 (Hazardous Substances): Not listed Section 313 (TRI Chemicals): Not listed
<b>Clean Air Act</b>	This product does not contain any substances regulated as hazardous air pollutants under Section 112 of the Clean Air Act.
<b>Clean Water Act</b>	This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act.



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## **Section 16. OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION**

### **Update history:**

Version: 1.0  
Date of issue: 17 December 2015

### **References:**

Information of TAIHO PHARMACEUTICAL CO., LTD.  
ACGIH, American Conference of Governmental Industrial Hygienists (2015) TLVs and BEIs.

### **[Disclaimer]**

This SDS has been prepared based on the best available information; however, it may not be sufficient in some cases. It is the user's responsibility to modify or update any contents in this SDS regarding information on hazardous properties and/or instruction for safe handling of the product when they become available. Precautionary measures in this SDS are only applicable for normal handling conditions and it is necessary to take appropriate additional measures to ensure safe handling, which depends on specific use conditions or situations.