MATERIAL SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME:	**Fluorouracil Topical Solution USP, 2%**	**PRODUCT No.:**	**51672-4062**
CAS #:	**51-21-8**	**FORMULA:**	
SUBSTANCE CLASS:	**Antineoplastic**	**M.W.:**	**130.08**

SECTION 2: PHYSICAL/CHEMICAL DATA

BOILING POINT:	N/A
PHYSICAL STATE (liquid/solid/gas):	Liquid
SPECIFIC GRAVITY (H_2O=1):	N/A
EVAPORATION RATE (Butyl Acetate=1):	N/A
SOLUBILITY:	N/A
APPEARANCE:	Colorless
ODOR DESCRIPTION:	N/A

SECTION 3: FIRE AND EXPLOSION HAZARD DATA

FLASH POINT:	N/A
EXTINGUISHING MEDIA:	Water, Carbon Dioxide, Dry Chemical, Foam.
SPECIAL FIRE FIGHTING PROCEDURES:	Wear NIOSH/MSHA approved positive pressure, self contained breathing apparatus and full protective turn out gear. Use caution in approaching fire. Use water to keep fire exposed containers cool.
UNUSUAL FIRE AND EXPLOSION HAZARDS:	Toxic emissions may be given off in a fire. See Decomposition products in Section 4 – Stability and Reactivity
HAZARDOUS COMBUSTION PRODUCTS:	N/A

SECTION 4: STABILITY AND REACTIVITY DATA

CHEMICAL STABILITY:	Normally stable even under fire exposure conditions and not water reactive.
CONDITIONS TO AVOID:	None Known.
HAZARDOUS DECOMPOSITION PRODUCTS:	Carbon monoxide, carbon dioxide, hydrogen fluoride, oxides of nitrogen.
HAZARDOUS POLYMERIZATION:	No.
MATERIALS TO AVOID:	Strong bases, Oxidizing agents.

SECTION 5: HEALTH HAZARD DATA

EMERGENCY OVERVIEW

May cause birth defects based on animal data.
May cause reproductive system effects.
May affect fertility (including sperm production, ovulation, motility and impotence) based on animal data. Harmful if swallowed.

EMERGENCY OVERVIEW (con't)	This material has not been tested as a whole; therefore, information described below is based on one or more of its ingredients. May cause drying and/or irritation of the mucous membrane. Causes severe eye irritation. May cause central nervous system effects such as headache, dizziness, drowsiness, fatigue, and lack of muscular coordination. May cause allergic reactions. May cause photoallergenicity (sensitivity to light). May cause cardiovascular effects such as increase or decrease in blood pressure, irregular heartbeat, chest pain, and cardiac arrest. May cause gastrointestinal effects such as nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite. May cause blood system changes.

POTENTIAL HEALTH HAZARDS

Relevant Routes of Exposure:	Skin Contact, Ingestion, Eye Contact.
Target Organs:	Hematopoietic/Blood System, Dermal System, Ocular System, Male Reproductive System/Prostate, Female Reproductive System, Cardiovascular System, Gastrointestinal System, Central Nervous System.
Eye:	May cause eye irritation.
Skin:	May cause skin irritation.
Ingestion:	Harmful if swallowed.
Inhalation:	Remove to fresh air. If discomfort occurs or persists, get medical attention.
Chronic Effects:	May cause lack of muscle coordination. May cause muscle weakness and pain. May decrease bone marrow cell production. May cause hyperpigmentation of the skin.
Carcinogenicity:	Formulation not listed by NTP, IARC or OSHA 5-Fluorouracil IARC Gr3 not classifiable
Reproductive Toxicity:	5-Fluorouracil May cause birth defects based on animal data. May cause reproductive system effects. May affect fertility (including sperm production, ovulation, motility and impotence) based on animal data.
Conditions Aggravated:	Hypersensitivity to this material. Bone marrow depression. Liver conditions and/or impaired liver function. Kidney conditions and/or impaired renal function. Serious infections.

SECTION 6: SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:
Review Section 3 – Hazards Identification, and Section 8-Exposure Controls/Personal Protection before proceeding with the clean up. Shut off the source of the spill or leak if it is safe to do so. Absorb small spills with absorbent material. Dike large spills and pump into metal drums or absorb with absorbent material. Put saturated absorbent material into a suitable labeled open head drum. Secure the drum cover and move the container to a safe holding area. Wash spill area thoroughly with soapy water.

WASTE DISPOSAL METHOD:
Decontaminate equipment. Dispose of protective clothing with the spilled material. Dispose of in accordance with recommendations in Section 13 – Disposal Considerations.

REPORTING REQUIREMENTS:
The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials. State and local regulations vary and may impose additional reporting requirements.

SECTION 7: HANDLING AND STORAGE

HANDLING:	Do not get in eyes, on skin or on clothing. Do not breathe vapor or mist. Use with adequate ventilation. When handling, use proper personal protective equipment specified in Section 8. Wash thoroughly after handling. Keep container tightly closed when not in use. Store in a dry area at room temperature.
STORAGE:	Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F)

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS:	
Ventilation	General room ventilation is adequate unless the process generates mist or vapor.
PERSONAL PROTECTION:	
Respirator Type(s)	None recommended.
Conditions for Use	Under normal conditions of use, respiratory protection is not expected to be necessary. OSHA considers effective engineering controls to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. Whenever respiratory protection is used, a complete respirator program should be developed in accordance with OSHA Subpart I (29CFR1910.134) requirements.
Eye Protection	Safety Glasses Required, Safety Goggles Recommended.
Skin Protection	None required under normal and foreseeable conditions of use. Consult the protective clothing manufacturer, supplier and/or industrial hygienist.
Glove Materials	Any plastic or rubber gloves.
WORK PRACTICES:	
Administrative Controls	Post the work area and limit access to authorized personnel only.
Additional Protective Measures	Work clothing should be removed in a changeroom on site and laundered professionally. Launder contaminated clothing separately. Employees should shower and change into street clothes before leaving the facility. Provide safety showers and eyewash stations in the work area.
EXPOSURE LIMITS	There are no exposure limits specified either for this material or for any of its ingredients.

SECTION 9: TOXICOLOGICAL INFORMATION

5-Fluorouracil

Acute Skin, Single Dose, Rabbit: 1250 mg/kg

Summary: Acute dermal LD_{50} (rabbit) of 1250 mg/kg body weight classifies this material as moderately toxic dermally under the study conditions utilized.

Irritation Eye, Rabbit

Summary: An ocular irritation study with New Zealand white rabbits produced scores of 8.3, 5.3, 2.3, 2.3 and 1.0 at 1, 2, 3, 4 and 7 days post-instillation, respectively, indicating that this material was mildly irritating to rabbit eyes under the study conditions utilized.

Irritation Skin, Rabbit

Summary: A primary skin irritation score of 0.0 for intact and abraded skin indicates that this material was non-irritating to the skin of rabbits under, the study conditions utilized.

Carcinogenicity Oral, Rat

Summary: No evidence of carcinogenicity was observed in rats after administration of oral and intravenous doses up to 3.0 mg/rat/day for 52 weeks and 33 mg/kg/week, respectively, under the study conditions utilized. However, these studies were inconclusive because of small group sizes, low doses, short durations and incomplete histopathological examinations.

Carcinogenicity Intravenous, Mouse

Summary: No evidence of carcinogenicity was observed in female mice after administration of an intravenous dose of 1 mg for 16 weeks, under the study conditions utilized. However, this study was inconclusive because of small group sizes, low doses, short durations and incomplete histopathological examinations.

Reproductive Intraperitoneal, Rat

Summary: Reproductive effects such as chromosomal aberrations and changes in chromosome organization of spermatogonia in male rats were observed at doses of 125 and 250 mg/kg administered intraperitoneally. In female rats, reproductive effects such as reduced incidence of fertile matings, delayed development of pre- and post-implantation embryos, increased incidence of pre-implantation lethality and induction of chromosomal anomalies in the embryos were observed at doses of 25 and 50 mg/kg administered.

Teratogenicity Intramuscular, Hamster

Summary: Evidence of teratogenicity was observed in hamsters after intramuscular doses up to 9 mg/kg between days 8 and 11 of gestation.

Teratogenicity Intraperitoneal, Mouse

Summary: Evidence of teratogenicity was observed in mice after administration of single intraperitoneal injections up to 40 mg/kg on day 10 or 12 of gestation.

Teratogenicity Intraperitoneal, Rat

Summary: Evidence of teratogenicity was observed in rats after intraperitoneal doses up to 37 mg/kg between days 9 and 12 of gestation.

Teratogenicity Intravenous, Monkey

Summary: Embryotoxicity was observed in monkeys after administration of divided doses of 40 mg/kg

(between days 20 and 24 of gestation, and dosage above 40 mg/kg, caused abortion of aal monkey embryos under the study conditions utilized.

Mutagenicity
Summary: Evidence of mutagenicity was observed in the Ames assay (in tester strains TA 1535, TA 1537 and TA 1538), in the mouse micronucleus assay and in a chromosome aberration assay under the study conditions utilized.

SECTION 10: OTHER INFORMATION

Regulatory Affairs Department
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive
Hawthorne, NY 10532

SECTION 11: TRANSPORTATION INFORMATION

Enforcement Agency:	US Dept. of Transportation
Country/Community:	USA
Proper Ship. Name:	Poisonous Liquid, n.o.s. (5-Fluorouracil)
UN/NA Number:	UN2810
Hazard Class/Div:	6.1
Package Group:	III

Enforcement Agency:	International Air Transport Association
Country/Community:	International
Proper Ship. Name:	Poisonous Liquid, n.o.s. (5-Fluorouracil)
UN/NA Number:	UN2810
Hazard Class/Div:	6.1
Package Group:	III

SECTION 12: REGULATORY INFORMATION

Law/Regulation	Safe Drinking Water and Toxic Enforcement Act of 1986, Proposition 65.
Common Name	Prop 65
Enforcement Agency	California Environmental Protection Agency
Governing Authority	California, USA
Criteria Met	Formulation contains 5-fluorouracil which is known to the state to cause reproductive toxicity.
Law/Regulation	Hazardous Chemical Reporting: Community Right-to-Know 40CFR370
Common Name	SARA Title III Section 312 – Hazardous Chemical Inventory
Enforcement Agency	Environmental Protection Agency (EPA)
Governing Authority	USA
Criteria Met	Acute

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Recommendations:	This material is suitable for incineration. These recommendations are based on the product as shipped. Use, processing, alteration or contamination may affect these disposal recommendations. State, local or site restrictions affecting the available proper disposal options may vary.
RCRA Waste #:	Not regulated under RCRA
Empty Containers:	Empty containers must be triple rinsed prior to disposal, recycling, or reuse.

SECTION 14: ECOLOGICAL INFORMATION

5-Fluorouracil

No observable Effect Level

Summary: The no observed effect level (NOEL) is 1000 mg/l to rainbow trout which classifies this material as practically non-toxic to fish under the study conditions utilized.

Aerobic Biodegradation (H_2O)

Summary: This material is not biodegradable under the study conditions utilized. It inhibits slightly (14%) the biodegradability of other substances at concentrations of 100 mg/l, under the study conditions utilized.

DISCLAIMER

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. Taro Pharmaceuticals assumes no responsibility for the use of this information.