

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Fluoro-AUS/DP-003

Effective Date: 11th November 2024

FLUOROURACIL INJECTION

250 MG/5 ML, 500 MG/10 M, 1000 MG/20 ML, 2500 MG/50 ML, AND 5000 MG/100 ML

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Fluorouracil Accord Injection
250 mg/5 mL, 500 mg/10 mL, 1000 mg/20 mL, 2500 mg/50 mL,
and 5000 mg/100 mL

Sponsor	Manufacturer-1	Manufacturer-2
Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia Telephone: 1800 222 673 (hours 8:30am – 4:30pm)	Intas Pharmaceuticals Ltd. Plot No. 457, 458 Village-Matoda, Bavla Road, Ta. Sanand, Dist. Ahmedabad-382 210, Gujarat, India	Intas Pharmaceuticals Ltd. Plot No. 5, 6 and 7, Pharmed, Near Matoda Village, Ahmedabad-382 213, Gujarat, India

SECTION 2 – HAZARD(S) IDENTIFICATION

Classification of the Substance or Mixture:

GHS – Classification:

Germ Cell Mutagenicity : Category 1B
Reproductive Toxicity : Category 1B
Acute Toxicity, Aquatic : Category 1
Chronic Toxicity, Aquatic : Category 1

Label Elements:



Signal Word: Danger

Hazard Statements:

H340 - May cause genetic defects
H360FD - May damage fertility. May damage the unborn child
H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements:

P201 - Obtain special instructions before use.

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- 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 - If exposed or concerned: Get medical advice/attention.
- P405 - Store locked up.
- P501 - Dispose of contents/container in accordance with local, state, federal and provincial regulations.

Other Hazards: An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Active: Fluorouracil.

Inactive: Sodium hydroxide, Hydrochloric acid, and Water for Injection.

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Fluorouracil	51-21-8	200-085-6	Acute Tox.3 (H301) Repr.1B (H360FD) Muta.1B (H340) Aquatic Acute.1 (H400) Aquatic Chronic.1 (H410)	5
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr.1A (H314)	**
Hydrochloric acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	**
Water for Injection	7732-18-5	231-791-2	Not Listed	*

Additional Information: * Proprietary, ** to adjust pH,

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

SECTION 4 - FIRST AID MEASURES

Description of Necessary First Aid Measures:

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Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known.

Medical Attention and Special Treatment: None.

SECTION 5 - FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Extinguish fires with CO₂, dry chemical, alcohol-resistant foam, or water spray.

Special Hazards Arising from the Substance or Mixture: Fine particles (such as dust and mists) may fuel fires/explosions.

Special Protective Equipment and Precautions for Fire-Fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

SECTION 7 - HANDLING AND STORAGE

Precautions for Safe Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product used as Antineoplastic.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters – Exposure Standards, Biological Monitoring:

Fluorouracil:

Poland : 0.0035 mg/m³

Hydrochloric acid:

ACGIH Ceiling Threshold Limit : 2 ppm

Australia PEAK : 5 ppm

Sodium hydroxide:

ACGIH OEL (Ceiling) : 2 mg/m³

ACGIH TLV (Ceiling) : 2 mg/m³

Austria : 2 mg/m³

Bulgaria : 2.0 mg/m³

Czech Republic : 1 mg/m³

Ceiling: 2 mg/m³

Denmark : Ceiling: 2 mg/m³

Estonia : 1 mg/m³

STEL: 2 mg/m³

Finland : Ceiling: 2 mg/m³

France : 2 mg/m³

Hungary : 1 mg/m³

STEL: 2 mg/m³

Ireland : STEL: 2 mg/m³

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Latvia	: 0.5 mg/m ³
Poland	: 0.5 mg/m ³ STEL: 1 mg/m ³
Romania	: 1 mg/m ³ STEL: 3 mg/m ³
Slovakia	: 2 mg/m ³
Spain	: STEL: 2 mg/m ³
Switzerland	2 mg/m ³ STEL: 2 mg/m ³
OSHA PEL	: 2 mg/m ³ (vacated) Ceiling: 2 mg/m ³
United Kingdom	: STEL: 2 mg/m ³

Appropriate Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Solution
Colour	:	Colourless
Odour	:	No data available
Odour Threshold	:	No data available
Solvent Solubility	:	No data available

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Water Solubility	:	No data available
pH	:	No data available
Melting/Freezing Point (°C)	:	No data available
Boiling Point and boiling range (°C)	:	No data available
Partition Coefficient	:	No data available
Decomposition Temperature (°C)	:	No data available
Evaporation Rate (Gram/s)	:	No data available
Vapour Pressure (kPa)	:	No data available
Vapour Density (g/ml)	:	No data available
Relative Density	:	No data available
Viscosity	:	No data available
Auto-ignition Temperature (Solid) (°C)	:	No data available
Flammability (Solids)	:	No data available
Flash Point (Liquid) (°C)	:	No data available
Upper Flammability or Explosive Limits (Liquid) (% by Vol.)	:	No data available
Lower Flammability or Explosive Limits (Liquid) (% by Vol.)	:	No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials and Possible Hazardous Reactions: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: No data available.

SECTION 11 – TOXICOLOGICAL INFORMATION

The information included in this section describes the potential hazards of the active ingredient.

Information on Toxicological Effects:

Short Term: May be absorbed through the skin and cause systemic effects. Active ingredient may be harmful if swallowed.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs.

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Known Clinical Effects: Adverse effects associated with therapeutic use include gastrointestinal disturbances such as nausea, dyspepsia, and vomiting and gastrointestinal irritation. Effects on blood and blood forming organs have also occurred.

Acute Toxicity:

Fluorouracil:

Species	Route	End Point	Dose
Rat	Oral	LD 50	230 mg/kg
Rat	Para-periosteal	LD 50	383 mg/kg
Mouse	Oral	LD 50	247 mg/kg
Mouse	Intravenous	LD 50	247 mg/kg

Sodium hydroxide:

Species	Route	End Point	Dose
Mouse	IP	LD 50	40 mg/kg

Hydrochloric acid:

Species	Route	End Point	Dose
Rat	Oral	LD 50	238-277 mg/kg

Irritation / Sensitization:

Sodium hydroxide:

Study Type	Species	Severity
Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Severe

Repeated Dose Toxicity:

Fluorouracil:

Duration	Species	Route	Dose	End Point	Target Organ
1 month	Rat	Oral	20 mg/kg/day	LOAEL	Male reproductive system
1 month	Rat	Oral	7.5 mg/kg/day	NOAEL	Bone marrow, Gastrointestinal system
6 months	Rat	Oral	15 mg/kg/day	NOAEL	Blood, Thymus, Spleen, Liver
1 month	Rat	Intraperitoneal	7.5 mg/kg/day	NOAEL	Bone marrow, Gastrointestinal system, Liver, Male reproductive system
6 months	Dog	Oral	2 mg/kg/day	LOAEL	Central nervous system

Reproduction & Development Toxicity:

Fluorouracil:

Study Type	Species	Route	Dose	End Point	Effect(s)
Embryo / Fetal Development	Mouse	Oral	10 mg/kg/day	NOAEL	Maternal toxicity, Fetotoxicity
Embryo / Fetal Development	Rat	Oral	Not specified	NOAEL	Maternal toxicity
Embryo / Fetal Development	Rat	Oral	10 mg/kg/day	NOAEL	Developmental toxicity

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Embryo / Fetal Development	Hamster	Intramuscular	3 mg/kg/day	LOAEL	Developmental toxicity
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Genetic Toxicity:

Fluorouracil:

Study Type	Cell Type/Organism	Result
<i>In Vivo</i> Chromosome Aberration	Rat Spermatogonia	Positive
Sister Chromatid Exchange	Human Lymphocytes	Positive
Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Positive
Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Positive
<i>In Vivo</i> Micronucleus	Mouse	Positive

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

Fluorouracil:

IARC Group 3 (not classifiable)

SECTION 12 – ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Aquatic toxicity:

Fluorouracil

Species	Method	End Point	Duration	Result
Desmodesmus subspicatus	OECD	EC50	72 hours	21 mg/L
Anabaena flos-aquae	OECD	ErC50	72 hours	0.024 mg/L
Anabaena flos-aquae	OECD	NOEC	72 hours	0.002 mg/L
Daphnia magna	OECD	EC50	48 hours	25 mg/L

Bacterial inhibition:

Fluorouracil

Inoculum	Method	End Point	Result
Activated sludge	NA	NOEC	100 mg/L

Chronic aquatic toxicity:

Fluorouracil

Species	Method	End Point	Duration	Result	Adverse
Daphnia magna	OECD	NOEC	21 days	0.003 mg/L	Reproduction
Brachydanio rerio	OECD	EC10	36 days	20.9 mg/L	Survival
Brachydanio rerio	OECD	NOEC	36 days	32 mg/L	Survival

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Persistence and Degradability: No data available.

Bio-accumulative Potential: No data available.

Mobility in Soil: No data available.

Other Adverse Effects: No data available.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

SECTION 14 - TRANSPORTATION INFORMATION

The following refers to all modes of transportation unless specified below.

UN number: UN3082

UN proper shipping name: Fluorouracil

Transport hazard classes and packing group: Hazard Class - 9; Packing Group III.

Environmental hazards: Based on the available data, this substance is regulated as an environmental hazard or a marine pollutant.

Special precautions for users: Not applicable.

5 kg/5L Exception: UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not subject to the dangerous goods transportation regulations by any mode:

* Single packaging containing a net quantity of 5 litres or less for liquids or a net mass of 5 kg or less for solids.

* Combination packaging containing a net quantity per inner packaging of 5 litres or less for liquids or a net mass of 5 kg or less for solids.

Note: When in final drug product packaged form, this material is not subject to the requirements of ADR as per SP 601.

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ADR 601 - Pharmaceutical products (medicines) ready for use, which are substances manufactured and packaged for retail sale or distribution for personal or household consumption are not subject to the requirements of ADR / RID / ADN.

SECTION 15 - REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Fluorouracil:

CERCLA/SARA 313 Emission reporting	: 1%
CERCLA/SARA Hazardous substances and their reportable quantities	: 500 lb
CERCLA/SARA – Section 302 Extremely hazardous TPQs	: 10000 lb
California Proposition 65	: Developmental toxicity 1/1/1989
Inventory - United States TSCA - Sect. 8(b)	: Present
Standard for the Uniform Scheduling for Drugs and Poisons	: Schedule 4
EU EINECS/ELINCS List	: 200-085-6

Sodium hydroxide:

CERCLA/SARA 313 Emission reporting	: Not Listed
CERCLA/SARA Hazardous substances and their reportable quantities	: 1000 lb
California Proposition 65	: Not Listed
Inventory - United States TSCA - Sect. 8(b)	: Present
Standard for the Uniform Scheduling for Drugs and Poisons	: Schedule 5 Schedule 6
Australia (AICS)	: Present
EU EINECS/ELINCS List	: 215-185-5

Hydrochloric acid:

CERCLA/SARA 313 Emission reporting	: 1.0%
CERCLA/SARA Hazardous substances and their reportable quantities	: 5000 lb 2270 kg
CERCLA/SARA – Section 302 Extremely hazardous TPQs	: 500 lb
California Proposition 65	: Not Listed
Inventory - United States TSCA - Sect. 8(b)	: Present
Australia (AICS)	: Present
Standard for the Uniform Scheduling for Drugs and Poisons	: Schedule 5 Schedule 6
EU EINECS/ELINCS List	: 231-595-7

Water for Injection:

CERCLA/SARA 313 Emission reporting	: Not Listed
California Proposition 65	: Not Listed
Inventory - United States TSCA - Sect. 8(b)	: Present

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Australia (AICS) : Present
REACH - Annex IV - Exemptions from the obligations of Register : Present
EU EINECS/ELINCS List : 231-791-2

SECTION 16 - OTHER INFORMATION

Abbreviations:

ACGIH : American Conference of Governmental Industrial Hygienists
AICS : Australian Inventory of Chemical Substances
AIHA : American Industrial Hygiene Association
ANSI : American National Standards Institute
CAS : Number Chemical Abstract Service Registry Number
CERCLA : Comprehensive Environmental Response Compensation and Liability Act
CHAN : Chemical Hazard Alert Notice
CHEMTREC : Chemical Transportation Emergency Center
DOT : Department of Transportation
DSL : Domestic Substances List
ECHA : European Chemicals Agency
EINECS : European Inventory of Existing Commercial Chemical Substances
ELINCS : European List of Notified Chemical Substances
EPA : Environmental Protection Agency
GHS : Globally Harmonized System of Classification and Labelling of Chemicals
HEPA : High Efficiency Particulate Air (Filter)
HMIS : Hazardous Materials Identification System
IARC : International Agency for Research on Cancer
ICAO/IATA : International Civil Aviation Organization/International Air Transport
IMO : International Maritime Organization
KOW : Octanol/Water Partition Coefficient
LEL : Lower Explosive Limit
MSDS : Material Safety Data Sheet
MSHA : Mine Safety and Health Administration
NA : Not Applicable, except in Section 14 where NA = North America
NE : Not Established
NADA : New Animal Drug Application
NAIF : No Applicable Information Found
NCI : National Cancer Institute
NDSL : Non-Domestic Substances List
NFPA : National Fire Protection Association
NIOSH : National Institute for Occupational Safety and Health
NPDES : National Pollutant Discharge Elimination System
NOS : Not Otherwise Specified
NTP : National Toxicology Program
OSHA : Occupational Safety and Health Administration
OEL : Occupational Exposure Limit
PEL : Permissible Exposure Limit (OSHA)
RCRA : Resource Conservation and Recovery Act

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RQ	: Reportable Quantity
RTECS	: Registry of Toxic Effects of Chemical Substances
SARA	: Superfund Amendments and Reauthorization Act
SDS	: Safety Data Sheet
STEL	: Short Term Exposure Limit
TLV	: Threshold Limit Value (ACGIH)
TPQ	: Threshold Planning Quantity
TSCA	: Toxic Substances Control Act
TWA	: Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	: Upper Explosive Limit
UN	: United Nations
USP	: United States Pharmacopeia
WEEL	: Workplace Environmental Exposure Level (AIHA)
WHMIS	: Workplace Hazardous Materials Information System

Data Sources: Information from published literature.

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall INTAS be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if INTAS has been advised of the possibility of such damages.