MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Fluorouracil Injection

Trade Name: Fluoroblastin; Fluroblastin; Adrucil
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Colorless solution
Signal Word: WARNING

Statement of Hazard: Suspected of damaging fertility or the unborn child.
Suspected of causing genetic defects.

Additional Hazard Information:
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.

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

EU Indication of danger: T - Toxic
Toxic to reproduction, Category 2
Mutagenic Category 2

EU Hazard Symbols:

EU Risk Phrases:
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**
Fluorouracil	51-21-8	200-085-6	Muta. Cat.2;R46 Repr. Cat.2;R60-61 Xn;R22	5

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
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.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

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.

7. HANDLING AND STORAGE

General Handling: Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). It is recommended that all operations be fully enclosed and no air recirculated.

Storage Conditions: Protect from light. Do not refrigerate.

Storage Temperature: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	= 2 mg/m^3 Ceiling
Australia PEAK	= 2 mg/m^3 Peak
Austria OEL - MAKs	= 2 mg/m^3 MAK
Belgium OEL - TWA	= 2 mg/m^3 TWA
Bulgaria OEL - TWA	= 2.0 mg/m^3 TWA
Czech Republic OEL - TWA	= 1 mg/m^3 TWA
Finland OEL - TWA	= 2 mg/m^3 TWA
France OEL - TWA	= 2 mg/m^3 VME
Greece OEL - TWA	= 2 mg/m^3 TWA
Hungary OEL - TWA	= 2 mg/m^3 TWA
Latvia OEL - TWA	= 0.5 mg/m^3 TWA
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	= 0.5 mg/m^3 NDS
Slovakia OEL - TWA	= 2 mg/m^3 TWA
Slovenia OEL - TWA	= 2 mg/m^3 TWA
Sweden OEL - TWAs	= 1 mg/m^3 LLV

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Fluorouracil

Pfizer Occupational Exposure Band (OEB): OEB5 (control exposure to <1ug/m^3)

Analytical Method: Analytical method available for Fluorouracil. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. It is recommended that all operations be fully enclosed and no air recirculated.

Personal Protective Equipment:

Hands: Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Solution	**Color:**	Colorless
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Fluorouracil
Rat Oral LD 50 230 mg/kg
Rat Intravenous LD 50 245 mg/kg
Mouse Oral LD 50 115 mg/kg
Mouse Intravenous LD 50 81 mg/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Fluorouracil
5 Week(s) Dog Oral 175 mg/kg LOAEL Bone marrow

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Fluorouracil
Embryo / Fetal Development Mouse Intraperitoneal 10 - 40 mg/kg/day LOAEL Teratogenic
Embryo / Fetal Development Rat Intraperitoneal 12 - 37 mg/kg LOAEL Teratogenic
Embryo / Fetal Development Hamster Intraperitoneal 3 - 9 mg/kg LOAEL Teratogenic, Fetotoxicity
Embryo / Fetal Development Monkey Intramuscular 40 mg/kg NOAEL Not Teratogenic
Reproductive & Fertility-Males Mouse Intraperitoneal 25 - 50 mg/kg LOAEL Fertility

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Fluorouracil
In Vivo 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
In Vivo Micronucleus Mouse Positive

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Fluorouracil
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger:

T - Toxic
Toxic to reproduction, Category 2
Mutagenic Category 2

EU Risk Phrases:

R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

OSHA Label:
WARNING
Suspected of damaging fertility or the unborn child.
Suspected of causing genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
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	215-185-5

Fluorouracil

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 10000 lb upper threshold TPQ = 500 lb lower threshold TPQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 500 lb EPCRA RQ
California Proposition 65	Listed; Developmental Toxicity
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-085-6

Water for injection

Inventory - United States TSCA - Sect. 8(b)	Present

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

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet