	<b>Sagent Pharmaceuticals, Inc.</b>			
	<b>Epirubicin Hydrochloride Injection</b>		<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>Jun 19, 2009</b>	MSDS No.: <b>MSDS022</b>	Version No.: <b>1.0</b>	Form Number: <b>R-SOP-009-F001</b>

### Section 1 - Chemical Product and Company

**Distributor:**

Sagent Pharmaceuticals, Inc.  
1901 N. Roselle Rd, Suite 700  
Schaumburg, IL 60195  
847-908-1600

**Emergency Telephone:** 866-625-1618

**Product Identifier:**

Epirubicin Hydrochloride

**Product Code:**

NDC 25021-203-05  
NDC 25021-203-25  
NDC 25021-203-51

**Common/Trade Name:**

Ellence® , Farmorubicin®, RTU Injection

**Chemical Name:**

(8S-cis)-10-[(3-amino-2,3,6-trideoxy-(alpha)-L-arabino-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-8-(hydroxyacetyl)-1-methoxy-5,12-naphthacenedione hydrochloride

**Chemical Family:**

Anthracycline cytotoxic agent

**Product Use:**

Pharmaceutical

**Product Type:**

Regulated Prescription Drug

**Container Information:**

Vials


### Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	CAS No.
Epirubicin Hydrochloride	0.2	5639-09-1
Sodium Chloride	<1	7647-14-5
Hydrochloric Acid (pH adjust.)	Trace	7647-01-0
Water for Injection	Balance	7732-18-5

### Section 3 - Hazards Identification

**Primary Physical and Health Hazards:**

Material is a clear, red solution. May cause damage to the bone marrow, reproductive system and heart. Harmful to the fetus. Avoid contact with eyes, skin and clothing. Avoid exposure during pregnancy and while breastfeeding. Do not taste or swallow. Wash thoroughly after handling.

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**Routes of Entry:** Inhalation, eye/skin contact, ingestion or injection.

**Signs & Symptoms of Exposure:** This material is intended for intravenous injection under the supervision of physicians. It must NOT be given by the intramuscular or subcutaneous route.

Acute: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, effects such as nausea, vomiting diarrhea and loss of blood pressure may occur.

**Chemical Listed as Carcinogen:** **NTP:** Yes, Group 2 **IARC:** No **OSHA:** No  
Reasonably anticipated to be a Human carcinogen

**Medical Conditions Generally Aggravated by Exposure:** Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to the Physicians Desk Reference for additional treatment information.

#### Section 4 - First Aid Measures


**Eye Exposure:** If irritation or redness develops, move victim away from exposure and into fresh air. Flush eyes with clean water and seek medical attention.

**Skin Exposure:** Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

**Ingestion:** If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.


**Inhalation:** If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

**Notes to Physician:** See patient package insert in shipping carton for complete information.

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## Section 5 - Fire Fighting Measures

<b>Flash Point :</b>	Not flammable
<b>Autoignition Temperature:</b>	Not established
<b>Flammable Limits in Air:</b>	Lower %: Not established Upper %: Not established
<b>Flammable Limits:</b>	Not established
<b>Extinguishing Media:</b>	The size and nature of the product is such that it will not contribute to the intensity of a fire. Use extinguishing agent suitable for type of surrounding fire. (ex. Water spray, Carbon Dioxide, Halon, Foam, Dry Chemical or any "ABC" Class)
<b>Special Fire Fighting Procedures:</b>	For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.
<b>Unusual Fire/Explosion Hazards:</b>	When heated to decomposition, this product may emit toxic fumes.

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**Section 6 - Accidental Release Measures**

**Spill:** For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

**Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.


**Section 7 - Handling and Storage**

**General Handling:** As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities properly.

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

**Waste Disposal Method:** When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.

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**Storage Conditions:** Employees must be trained to properly use the product. Ensure the vials are properly labeled. Store only in approved containers. Protect from light. Keep away from any incompatible materials or conditions. Store refrigerated between 2-8°C (36-46°F). Do not freeze.

### Section 8 - Exposure Controls / Personal Protection

**Respiratory Protection:** Respiratory protection is not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.


**Eye Protection:** Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

**Ventilation:** Use with adequate ventilation. Follow standard medical product handling procedures.

**Skin Protection:** Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

**Other Protective Equipment:** No special body protection required for routine, medical administration of this product. Wear lab coat, gown or smock, as appropriate for procedure.

**Additional Exposure Precautions:** Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

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### Exposure Limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Epirubicin Hydrochloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

### Section 9 - Physical and Chemical Properties


<b>Physical State:</b>	Liquid	<b>Specific Gravity:</b>	1.005
<b>Appearance:</b>	Clear red solution	<b>Evaporation Rate:</b>	Not available
<b>Boiling Point:</b>	~100°C	<b>Solubility in Water:</b>	Soluble
<b>Vapor Pressure:</b>	Not available	<b>pH:</b>	3
<b>Vapor Density:</b>	Not available	<b>Molecular Weight:</b>	579.95

### Section 10 - Stability and Reactivity

<b>Stability:</b>	Stable under normal conditions of storage and handling.
<b>Incompatibility (Materials to avoid):</b>	None known
<b>Hazardous Decomposition:</b>	In extreme heat
<b>Hazardous Polymerization:</b>	Will not occur
<b>Conditions to Avoid:</b>	Heat may cause product to decompose, destroying the product or producing toxic fumes.

### Section 11 - Toxicological Information

Chronic: Based on animal data, Epirubicin Hydrochloride, is considered a potential developmental and reproductive toxicant.

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### Acute Toxicity

Component	Type	Route	Species	Dosage
Epirubicin Hydrochloride	LD <sub>50</sub>	Oral	Rat	1350 mg/kg
Epirubicin Hydrochloride	LD <sub>50</sub>	IV	Rat	17 mg/kg
Epirubicin Hydrochloride	LD <sub>50</sub>	IP	Rat	10800 ug/kg
Epirubicin Hydrochloride	LD <sub>50</sub>	Oral	Mouse	>2 gm/kg
Epirubicin Hydrochloride	LD <sub>50</sub>	IV	Mouse	31500 ug/kg
Epirubicin Hydrochloride	LD <sub>50</sub>	IP	Mouse	64 mg/kg
Epirubicin Hydrochloride		SubQ	Mouse	37500 ug/kg
Epirubicin Hydrochloride	LD <sub>50</sub>	IV	Dog	2250 ug/kg
Epirubicin Hydrochloride		SubQ	Rat	17600 ug/kg


Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS)

### Section 12 - Ecological Information

Environmental Stability: It is anticipated that this compound will decompose into a variety of organic compounds.

Effect of Materials on Plants or Animals: This product may be harmful to contaminated plant and animal life.

Effect of Chemicals on Aquatic Life: This product may be harmful to aquatic plant and animal life in contaminated bodies of water, especially if released in large quantities.

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### Section 13 - Disposal Considerations

**Waste Disposal:** This material, if discarded as produced, is not a RCRA “listed” hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

### Section 14 - Transport Information

**Regulatory Organizations:**

**DOT:** Not Regulated

**ICAO/IATA:** Not Regulated

**IMO:** Not Regulated

### Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**U.S. Regulations**

TSCA - *No*

CERCLA - *Not on this list*


SARA 302 - *Not on this list*

SARA 304 – *Not on this list*

SARA 313 - *Not on this list*

OSHA Substance Specific - *No*




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**Section 16 - Other Information**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. **THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE).** In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:  
 Sagent Pharmaceuticals, Inc.  
 1901 N. Roselle Rd, Suite 700  
 Schaumburg, IL 60195  
 847-908-1600

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**Glossary:** This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
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
NIOSH	National Institute for Occupational Safety and Health
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
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
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)