

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Epi-AUS/DP-005

Effective Date: 16th September 2022

EPIRUBICIN HYDROCHLORIDE CONCENTRATED INJECTION, 10 MG/5 ML, 20 MG/10 ML, 50 MG/25 ML AND 200 MG/100 ML

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Epirubicin hydrochloride concentrated injection,
10 mg/5 mL, 20 mg/10 mL, 50 mg/25 mL and 200 mg/100 mL

Intended Use:	Pharmaceutical product.
Details of the Supplier of the Safety Data Sheet	
Sponsor: Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia Telephone: 1800 222 673 (hours 8:30am – 4:30pm)	

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture:

Classification according to Regulation (EC) No. 1272/2008[CLP/GHS]:	Germ Cell Mutagenicity: Category 1B Reproductive Toxicity: Category 1B Carcinogenicity: Category 1B
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Label elements:

Hazard pictograms:



Signal Word:

Danger

Hazard statements:

H350 – May cause cancer.
H340 – May cause generic defects.
H360FD – May damage fertility. May damage the unborn child.

Precautionary statements:

Prevention:

P202 – Do not handle until all safety precautions have been read and understood.
P280 – Wear protective gloves/protective clothing/eye protection/face protection.

Response:

P308 + P313 – IF exposed or concerned: Get medical attention/advice.

Storage:

P405 – Store locked up.

Disposal:

P501 – Dispose of contents/container in accordance with all local, regional, national and international regulations.

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

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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

Product/Ingredient name	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Epirubicin Hydrochloride	56390-09-1	260-145-2	Acute Tox.4 (H302) Carc. 1B (H350) Muta. 1B (H340) Repr. 1B (H360FD)	0.2
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Hydrochloric acid	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
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 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.

Most Important Symptoms and Effects, Both Acute and Delayed:

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.

Indication of the Immediate Medical Attention and Special Treatment Needed:

Notes to Physician: None.

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SECTION 5 - FIRE FIGHTING MEASURES

Extinguishing Media:

Suitable extinguishing media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture:

Hazards combustion products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.
Fire / Explosion hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters:

Special protective equipment for fire-fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures:

For emergency personnel: 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:

Measures for Cleaning / Collecting: Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

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

SECTION 7 - HANDLING AND STORAGE

Precautions for Safe 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). Wash thoroughly after handling. 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.

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Conditions for Safe Storage, Including any Incompatibilities:

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product Antineoplastic.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters:

Occupational exposure limits

Product/ingredient name	Exposure limit values
Epirubicin Hydrochloride	OEL TWA-8 Hr: 0.6 µg/m ³
Sodium Chloride	Latvia OEL – TWA: 5 mg/m ³ Lithuania OEL – TWA: 5 mg/m ³
Sodium Chloride Occupational Exposure Band (OEB)	OEB 1 (control exposure to the range of 1000µg/m ³ to 3000µg/m ³)
Hydrochloric Acid	ACGIH Ceiling Threshold Limit: 2 ppm Australia PEAK: 5 ppm 7.5 mg/m ³

Exposure Controls:

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. It is recommended that all operations be fully enclosed and no air recirculated.

Personal protection measures:

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.

Eye/face protection: 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.)

Hand protection: 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.)

Skin protection: 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

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factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution
Colour:	Red
Odour:	No data available.
Odour Threshold:	No data available.
Molecular Formula:	Mixture.
Molecular Weight:	Mixture.
Solvent Solubility:	No data available.
Water Solubility:	No data available.
pH:	No data available.
Melting/Freezing Point (°C):	No data available.
Boiling Point (°C):	No data available.
Partition Coefficient	
Water for injection:	No data available.
Sodium chloride:	No data available.
Epirubicin hydrochloride:	No data available.
Hydrochloric acid:	No data available.
Decomposition Temperature (°C):	No data available.
Evaporation Rate (Gram/s):	No data available.
Vapor Pressure (kPa):	No data available.
Vapor Density (g/ml):	No data available.
Relative Density:	No data available.
Viscosity:	No data available.
Flammability (Solid)	No data available.
Auto-ignition Temperature (Solid) (°C):	No data available.
Flash Point (Liquid) (°C)	No data available.
Upper Explosive Limits (Liquid) (% by Vol.):	No data available.
Lower 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.
Oxidizing Properties:	No data available.
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.

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Hazardous Decomposition Products: No data available.

SECTION 11 - TOXICOLOGY INFORMATION

Information on Toxicological Effect:

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

Short Term: Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on testes, the developing fetus.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include local irritation, nausea, vomiting, inflammation of the mouth (stomatitis), facial flushing, conjunctivitis of the eye, tearing (lachrymation), loss of hair, and discoloration of skin. Effects on blood and blood-forming organs have also occurred.

Acute toxicity

Product/ingredient name	Species	Route	End Point	Dose
Epirubicin hydrochloride	Rat	Oral	LD50	1350 mg/kg
	Rat	Para-periosteal	LD50	17 mg/kg
	Mouse	Oral	LD50	> 2000 mg/kg
	Mouse	Intravenous	LD50	31.5 mg/kg
Sodium chloride	Rat	Oral	LD50	3000 mg/kg
	Mouse	Oral	LD50	4000 mg/kg
Hydrochloric acid	Rat	Oral	LD50	238-277 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization

Product/ingredient name	Study Type	Species	Severity
Sodium chloride	Eye Irritation	Rabbit	Moderate
	Skin Irritation	Rabbit	Mild

Repeated Dose Toxicity

Product/ingredient name	Duration	Species	Route	Dose	End Point	Target Organ
Epirubicin hydrochloride	6 week(s)	Rabbit	Intravenous	1 mg/kg/day	LOAEL	Heart, Kidney
	6 week(s)	Dog	Intravenous	0.4 mg/kg/day	LOAEL	Kidney

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Reproduction & Developmental Toxicity

Product/ingredient name	Study Type	Species	Route	Dose	End Point	Effect(s)
Epirubicin hydrochloride	Reproductive & Fertility	Rat	Oral	0.3 mg/kg/day	LOAEL	Fertility
		Rat	Oral	0.1 mg/kg/day	NOAEL	Fertility
	Embryo / Fetal Development	Rat	Intravenous	0.8 mg/kg/day	LOAEL	Fetotoxicity
		Rat	Intravenous	2 mg/kg/day	LOAEL	Teratogenic, Fetotoxicity
		Rat	Intravenous	0.2 mg/kg/day	NOAEL	Teratogenic, Fetotoxicity

Genetic Toxicity

Product/ingredient name	Study Type	Cell Type/Organism	Result
Epirubicin hydrochloride	Bacterial Mutagenicity (Ames)		Positive
	Mammalian Cell Mutagenicity	HGPRT	Positive
	Chromosome Aberration	Human Lymphocytes	Positive
	Chromosome Aberration	Mouse Lymphoma	Positive
Hydrochloric acid	Bacterial Mutagenicity (Ames)	Salmonella	Negative
	In Vivo Micronucleus	Rat	Negative

Carcinogenicity

Product/ingredient name	Duration	Species	Route	Dose	End Point	Effect(s)
Epirubicin hydrochloride	1 year(s)	Rat	Intravenous	3.6 mg/kg	LOAEL	Tumors, Female reproductive system
	18 month(s)	Rat	Intravenous	0.5 mg/kg	LOAEL	Tumors

Carcinogen Status: None of the components of this information are listed as carcinogen by IARC, NTP or OSHA.

Hydrochloric acid IARC: Group 3 (Not Classifiable)

SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Environmental Overview:	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative potential:	No data available
Mobility in Soil	No data available

SECTION 13 - DISPOSAL INFORMATION

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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.

No regulated for transport under USDOPT, EUADR, IATA, or IMDG regulations.

SECTION 15 - REGULATORY INFORMATION

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

Epirubicin Hydrochloride

CERCLA/SARA 313 Emission reporting:	Not listed.
California Proposition 65:	Not listed.
EU EINECS/ELINCS List:	260-145-2

Sodium Chloride

CERCLA/SARA 313 Emission reporting:	Not listed.
California Proposition 65:	Not listed.
Inventory - United States TSCA - Sect. 8(b):	Present
Australia (AICS):	Present
EU EINECS/ELINCS List:	231-598-3

Water for Injection

CERCLA/SARA 313 Emission reporting:	Not listed.
California Proposition 65:	Not listed.
Inventory - United States TSCA - Sect. 8(b):	Present
Australia (AICS):	Present
REACH – Annex IV – Exemption from the obligations of Register:	Present
EU EINECS/ELINCS List:	231-791-2

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting:	1.0%
CERCLA/SARA 313 Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA – Section 302 Extremely Hazardous TPQs:	500 lb
CERCLA/SARA – Section 302 Extremely Hazardous Substances EPCRA RQs:	5000 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

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EU EINECS/ELINCS List:

231-595-7

SECTION 16 - OTHER DATA

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Carcinogenicity-Cat.1B; H350 - May cause cancer

Germ cell mutagenicity-Cat.1B; H340 - May cause genetic defects

Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.

Key literature references and sources for data: Information from published literature.

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