

W. C. Heraeus	Safety Data Sheet	revised: 02.03.2005
		Rev. Nr.: ---
trade name: Epirubicin hydrochloride		Ident.- Nr.: 89880120

1. Identification of the substance/preparation and company

Identity number: 89880120
 Empirical formula: $C_{27}H_{29}NO_{11} \cdot HCl$
 Molecular weight: 580.03 [g/Mol]

1.1 Trade name

Epirubicin hydrochloride

Other name: (8S,10S)-10-[(3-Amino-2,3,6-trideoxy- α -L-arabino-hexopyranosyl)-oxy]-6,8,11-trihydroxy-8-(hydroxyacetyl)-1-methoxy-7,8,9,10-tetrahydro-tetracene-5,12-dione hydrochloride

1.2 Application

The substance is used as cytostatic drug in cancer therapy.

1.3 Informations about manufacturer/supplier

W. C. Heraeus GmbH
 Chemicals Division - Pharma
 Heraeusstraße 12-14, D-63450 Hanau, Germany
 Post box 1553, D-63405 Hanau, Germany

Marketing manager: Michael Schwarz Phone: +49-(0)6181-35-5255
 Fax: +49-(0)6181-35-4302

2. Composition/information on ingredients

Chemical characterization (substance)

Epirubicin hydrochloride

CAS-Nr.	EINECS-Nr.	Index-Nr.	Elincs-Nr.
56390-09-1	260-145-2	---	---

3. Hazards identification

Characterization of hazards

Toxic.

Hazard indications

Harmful by inhalation, in contact with skin and if swallowed.

May cause cancer.

May cause heritable genetic damage.

May impair fertility.

May cause harm to the unborn child.

W. C. Heraeus	Safety Data Sheet	revised: 02.03.2005
trade name:		Rev. Nr.: ---
Epirubicin hydrochloride		Ident.- Nr.: 89880120

4. First-aid measures

General information

In case of accident or if you feel unwell, seek medical advice immediately.

After inhalation:	Call a physician immediately.
After contact with skin:	Wash off with soap and plenty of water. Remove immediately contaminated clothing and shoes.
After contact with eyes:	Rinse thoroughly with plenty of water, also under the eyelids. Summon eye specialist.
After ingestion:	If conscious rinse mouth with water and seek medical advise.
Medical advice:	Area of application: cytostatics .

5. Fire-fighting measures

Suitable extinguishing media:

Use extinguishing media that are appropriate to the environment.
Water spray, dry chemical, carbon dioxide or foam.

Not suitable extinguishing media:

Full water jet.

Specific danger by the substance, its burning products or developing gases:

Hazardous vapours caused by fire: NO_x, HCl, CO, CO₂ .

Special protective equipment for fire-fighting:

Use of selfcontained breathing apparatus and special chemical resistant clothes are required in fighting fires when chemicals are involved.

6. Accidental release measures

Personal precautions:

The usual precautionary measures for the handling of chemicals have to be observed.
Use personal protection equipment.
Do not breathe dust or aerosols.

Environmental precautions:

Do not allow to enter surface and ground water, the sewage system or soil.

Methods for cleaning up/taking up:

Take up mechanically. Clean up affected area. Avoid generation of dust.

W. C. Heraeus	Safety Data Sheet	revised: 02.03.2005
trade name: Epirubicin hydrochloride		Rev. Nr.: ---
		Ident.- Nr.: 89880120

Further information:

Residues and solutions, which can not be recycled, transfer to an approved waste disposal company.

Label transport container of waste with "Attention Cytostatic drug".

7. Handling and storage

7.1 Handling

Advice on safe handling:

Use only in a chemical fume hood.

The usual precautionary measures for the handling of chemicals have to be observed.

Do not eat, drink and smoke at working place.

Only accessible to qualified persons.

Wear personal protective equipment.

Avoid formation of respiratory particles.

Precautionary measures against fire and explosion:

Heating may cause decomposition; hazardous gases may be generated (refer to section 5).

7.2 Storage

Requirements for storage rooms and vessels:

Store in tightly closed container in dry and cool area.

Store at temperatures lower than 8 °C .

Protect against light.

Further information for storage

Do not store together with flammable or fire promoting substances.

Keep away from food and drink.

Only accessible to qualified persons.

Storage class

8. Exposure controls / Personal protection

8.1 Additional advice on system design

See to good ventilation/exhaustion at the working place; handle in a chemical fume hood.

Do not lead back the exhausted air into the working area.

8.2 Advice on limits

We recommend the reference point of 0,001 mg/m³ for cytostatic drug in cancer therapy.

8.3 Personal protection equipment

Respiratory protection:

Use P3 respiratory protection filter
(push on filter EN 143 or screwed filter EN 149).

W. C. Heraeus	Safety Data Sheet	revised: 02.03.2005
		Rev. Nr.: ---
trade name: Epirubicin hydrochloride		Ident.- Nr.: 89880120

Thermal decomposition: > 185 °C

9.3 Further information

10. Stability and reactivity

Conditions to avoid

Heating.

Materials to avoid

Dangerous compounds of decomposition

Hazardous vapours/ gases caused by fire: NO_x, HCl, CO, CO₂ .

Further information

11. Toxicological information

Acute toxicity

LD₅₀(oral/rat): 1350 mg/kg

LD₅₀(intravenous/rat): 17 mg/kg

TD_{Lo}(intravenous/rat): 7,5 mg/kg

(RTECS-Nr. QI9295750, Nov. 2003)

The substance is classified as harmful with R20/21/22 concerning to directive 67/548/EEC.

Subacute and Chronic toxicity

The substance shows mutagenic potential in the ames test.

Under the German jurisdiction (TRGS 905) cytostatic drug are classified in category 1 or 2 concerning the carcinogenic potential. This means the substance is known to be carcinogenic or there are many hints for this.

Further information

12. Ecological information

Information on elimination, persistence and decomposition

No data available.

W. C. Heraeus	Safety Data Sheet	revised: 02.03.2005
trade name:		Rev. Nr.: ---
Epirubicin hydrochloride		Ident.- Nr.: 89880120

Effects on environmental compartments

No data available.

Ecotoxic effects

No data available.

Further informations:

Do not allow to enter surface and ground water, the sewage system or soil.

13. Advice on disposal

Disposal

If residues of products are classified as waste from administrative bodies use the legal requirements to assign the European Waste Code (depending on branche of industry and industrial process).

The following classification is valid for the EU:

EAK-No: 180108 Cytotoxic and cytostatic medicines
(Waste requires supervision)

Inform disposer that delivery contains cytostatic drug (s. chapt. 6).

Disposal of uncleaned packing / recommended detergents

Uncleaned or with product residues contaminated packing should be treated like the product itself.

Packages, which do not contain product residues, should be recycled; if there does not exist a collecting system, packages can be treated as rubbish.

14. Transport information

14.1 Land transport (ADR/RID/GGVS/GGVE)

UN-No.: UN 2811
Proper Shipping Name : TOXIC SOLID, ORGANIC, N.O.S.
(CYTOSTATIC DRUG)
Class: 6.1
Packing group: III
Subsidiary risk: ---
Label: 6.1

14.2 Inland water ways transport

Not classified.

W. C. Heraeus	Safety Data Sheet	revised: 02.03.2005
		Rev. Nr.: ---
trade name: Epirubicin hydrochloride		Ident.- Nr.: 89880120

14.3 Marine transport (IMDG/GGVSee)

UN-No.: UN 2811
Proper Shipping Name : TOXIC SOLID, ORGANIC, N.O.S.
 (CYTOSTATIC DRUG)
Class: 6.1
Packing group: III
Subsidiary risk: ---
Marine pollutant: no
Label: 6.1

14.4 Air transport(IATA/ICAO)

UN-No.: UN 2811
Proper Shipping Name : TOXIC SOLID, ORGANIC, N.O.S.
 (CYTOSTATIC DRUG)
Class: 6.1
Packing group: III
Subsidiary risk: ---
Label: 6.1

14.5 Further information

15. Regulatory information

15.1 Labelling

T Toxic.

R-Phrases:

20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
 45 May cause cancer.
 46 May cause heritable genetic damage.
 60 May impair fertility.
 61 May cause harm to the unborn child.

S-Phrases:

20/21 When using do not eat, drink or smoke.
 36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
 53 Avoid exposure-obtain special instructions before use.
 60 This material and its container must be disposed of as hazardous waste.

15.2 National regulations

Germany:

Prohibition to employ: teenager under 18 years (Jugendarbeitsschutzgesetz),
 pregnant and nursing mothers (Mutterschutzverordnung)

W. C. Heraeus	Safety Data Sheet	revised: 02.03.2005
trade name: Epirubicin hydrochloride		Rev. Nr.: ---
		Ident.- Nr.: 89880120

Water Endangerment WGK-class: 3 strongly water pollutant
 (following the regulation VwVwS, Annex 3)

16. Other information

The data given here is based on today`s stand of our knowledge and experience. The purpose of this Safety Data Sheet is to describe the product in terms of its safety requirements. The data does not signify any warranty with regard to the products properties.

Safety data sheet prepared by: HH-SUS