

1 Identification of the substance/mixture and of the company/undertaking· **Product details**· **Trade name:** Epirubicin hydrochloride· **Article number:** 89880120· **Application of the substance / the preparation** Active pharmaceutical ingredients· **Manufacturer/Supplier:**

W.C. Heraeus GmbH

Chemicals Division - Pharmaceutical Ingredients

Heraeusstr. 12-14, D-63450 Hanau

Germany/ Deutschland

· **Further information obtainable from:**

Michael Schwarz Tel: +49-(0)6181-355255

e-mail: michael.schwarz@heraeus.com

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· **Information in case of emergency:**

factory security offices: +49 - (0)6181-35213

werkschutz@heraeus.com

2 Hazards identification· **Classification of the substance or mixture**· **Classification according to Regulation (EC) No 1272/2008**

GHS08 health hazard

Muta. 1B H340 May cause genetic defects.

Carc. 1A H350 May cause cancer.

Repr. 1B H360FD May damage fertility. May damage the unborn child.



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

Acute Tox. 4 H312 Harmful in contact with skin.

Acute Tox. 4 H332 Harmful if inhaled.

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**

T; Toxic

R45-46-60-61: May cause cancer. May cause heritable genetic damage. May impair fertility. May cause harm to the unborn child.



Xn; Harmful

R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.

· **Label elements**· **Labelling according to Regulation (EC) No 1272/2008**· **Hazard pictograms**

GHS07



GHS08

· **Signal word** Danger· **Hazard statements**

Harmful if swallowed.

Harmful in contact with skin.

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Harmful if inhaled.
May cause genetic defects.
May cause cancer.
May damage fertility. May damage the unborn child.

Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.
Do not eat, drink or smoke when using this product.
Obtain special instructions before use.
Dispose of contents/container in accordance with local/regional/national/international regulations.

Labelling according to EU guidelines:

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.

Code letter and hazard designation of product:

T Toxic

Risk phrases:

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

Safety phrases:

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

3 Composition/information on ingredients**Chemical characterization:****CAS No. Description**

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Identification number(s)**EINECS Number:** 260-145-2**4 First aid measures**

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

After inhalation:

Supply fresh air.
Call a doctor immediately.

After skin contact:

Immediately wash with water and soap and rinse thoroughly.
Immediately remove all soiled and contaminated clothing
Seek immediate medical advice.

After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing:

Rinse mouth with water.
Call for a doctor immediately.

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- **Information for doctor:**
- **Treatment** Cytostatic drug

5 Firefighting measures

- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards caused by the substance, its products of combustion or resulting gases:**
Formation of toxic gases is possible during heating or in case of fire.
Carbon monoxide (CO)
Nitrogen oxides (NO_x)
Hydrogen chloride (HCl)
- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental release measures

- **Person-related safety precautions:**
Wear protective equipment. Keep unprotected persons away.
Avoid formation of dust.
Use respiratory protective device against the effects of fumes/dust/aerosol.
Avoid contact with substance.
- **Measures for environmental protection:**
Do not allow to enter sewers/ surface or ground water.
Do not allow to penetrate the ground/soil.
- **Measures for cleaning/collecting:**
Pick up mechanically.
Send for recovery or disposal in suitable receptacles.
Dispose contaminated material as waste according to item 13.

7 Handling and storage

- **Handling:**
- **Information for safe handling:**
Wear protective equipment. Keep unprotected persons away.
Work only in fume cupboard.
Store under lock and key and with access restricted to technical experts or their assistants only.
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of dust.
- **Information about fire - and explosion protection:**
see chapter 5
Keep respiratory protective device available.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store in dry conditions.
Store in a cool location.
- **Information about storage in one common storage facility:**
Store away from flammable substances.
Store away from foodstuffs.
- **Further information about storage conditions:**
Protect from exposure to the light.
Keep container tightly sealed.

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· **Recommended storage temperature:** -20 ± 5 °C

8 Exposure controls/personal protection

· **Additional information about design of technical facilities:**

Ensure good ventilation/exhaustion at the workplace.
Work only in fume cupboard.
Waste air is to be released into the atmosphere only via suitable separators.

· **Ingredients with limit values that require monitoring at the workplace:**

We recommend the reference point of 1 µg/m³ for cytostatic drug.

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Work only in fume cupboard.
Do not eat or drink while working.
Shower or take a bath at the end of work.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Store protective clothing separately.
Avoid contact with the eyes and skin.

· **Respiratory protection:**

If dust or aerosol is present use respiratory protection filter P3 (push on filter EN 143 or screwed filter EN 149).

· **Protection of hands:**

Impervious gloves
Long cuffed gloves

· **For the permanent contact gloves made of the following materials are suitable:** Natural rubber, NR

· **Eye protection:**



Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **General Information**

· **Appearance:**

Form: Solid
Colour: Orange
Red

· **Odour:** Undetermined.

· **Change in condition**

Melting point/Melting range: 185°C (dec.)
Boiling point/Boiling range: Not applicable.

· **Flash point:** Not applicable.

· **Ignition temperature:**

Decomposition temperature: 185°C

· **Danger of explosion:** Product does not present an explosion hazard.

· **Vapour pressure:** Not applicable.

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- **Density:**
 Bulk density: Not determined.
- **Solubility in / Miscibility with water:** Soluble.
- **pH-value at 20°C:** 4 - 5.5

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
Protect from exposure to the light.
- **Materials to be avoided:**
- **Dangerous reactions** No dangerous reactions known.

11 Toxicological information

- **Acute toxicity:**
- **LD/LC50 values relevant for classification:**
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Oral	LD50	1350 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** No irritating effects known.
- **on the eye:** No irritating effects known.
- **Sensitization:** No sensitizing effects known.
- **Subacute to chronic toxicity:**
The substance effects in a genotoxic way. Therefore it may be carcinogenic, mutagenic or/and reproductive toxic.
Cytostatic drugs are classified in category 1 or 2 concerning the carcinogenic potential under german regulation (TRGS 905). This means the substance is carcinogenic for human or animal.
- **Additional toxicological information:** Ames test: positive

12 Ecological information

- **Ecotoxicological effects:**
- **Remark:** No data available.
- **Additional ecological information:**
- **General notes:** Avoid transfer into the environment.

13 Disposal considerations

- **Product:**
- **Recommendation**
After prior treatment product has to be disposed of in an incinerator for hazardous waste adhering to the regulations pertaining to the disposal of particularly hazardous waste.
- **European waste catalogue**

18 01 08*	cytotoxic and cytostatic medicines
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· Land transport ADR/RID (cross-border)



- **ADR/RID class:** 6.1 Toxic substances.
- **Danger code (Kemler):** 60
- **UN-Number:** 2811
- **Packaging group:** III
- **Hazard label:** 6.1
- **Description of goods:** 2811 TOXIC SOLID, ORGANIC, N.O.S. (Epirubicin hydrochloride)
- **Tunnel restriction code** E

· Maritime transport IMDG:



- **IMDG Class:** 6.1
- **UN Number:** 2811
- **Label:** 6.1
- **Packaging group:** III
- **EMS Number:** F-A,S-A
- **Marine pollutant:** No
- **Proper shipping name:** TOXIC SOLID, ORGANIC, N.O.S. (Epirubicin hydrochloride)

· Air transport ICAO-TI and IATA-DGR:



- **ICAO/IATA Class:** 6.1
- **UN/ID Number:** 2811
- **Label:** 6.1
- **Packaging group:** III
- **Proper shipping name:** TOXIC SOLID, ORGANIC, N.O.S. (Epirubicin hydrochloride)
- **UN "Model Regulation":** UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, III

15 Regulatory information

- **Chemical safety assessment** A Chemical Safety Assessment has not been carried out.
- **National regulations:**
- **Information about limitation of use:**
Employment restrictions concerning juveniles must be observed.
Employment restrictions concerning pregnant and lactating women must be observed.

GB

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16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing MSDS: HH-US**

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

· *** Data compared to the previous version altered.**