

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH), Annex II

Version: 1.0/EN
Product name: Vinorelbine Tartrate

Revision date: 25/09/2010
Printing date: 25/09/2010

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Vinorelbine Tartrate
REACH registration No.: The substance need not be registered according to REACH Regulation.
CAS No.: 125317-39-7

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: As an active pharmaceutical ingredients to produce pharmaceutical preparations.
Uses advised against: Not available.

1.3 Details of the supplier of the SDS

Company name (Manufacture): JIANGSU HANSO PHARMACEUTICAL CO., LTD.
Address: Econ. & Tech. Development Zone, Lianyungang, Jiangsu, China
Postcode: 222047
E-mail: suzuki@hansoh.cn, hansoh@hansoh.cn
Telephone: +86 518-82342293
Fax: +86 518-82342629

1.4 Emergency telephone number

+86 518-82342293 (Only office hours available.)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008[CLP]

Acute oral toxicity Category 2, H300

Classification according to Council Directive 67/548/EEC

T+; R28

Additional information

Full text of R-phrase(s) and H-statement(s): see section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP/GHS]

Product identifier:

Chemical name: Vinorelbine Tartrate, 100%

Hazard pictogram(s):



GHS06

Signal word: Danger.

Hazard statement(s): H300: Fatal if swallowed.

Precautionary statements:

Prevention: P264 Wash hand thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

Response: P301 + P310 IF SWALLOWED: Immediately call a POISON Center or doctor/physician.

P321 Specific treatment (see the label).

P330 Rinse mouth.

Storage: P405 Store locked up.

Disposal: P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards

May cause damage to the bone marrow, gastrointestinal system, central nervous system, peripheral nervous system, lungs, skin, and gonads through prolonged or repeated exposure.

The substance may be irritating to eyes, respiratory system, and skin.

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH), Annex II

Version: 1.0/EN
Product name: Vinorelbine Tartrate

Revision date: 25/09/2010
Printing date: 25/09/2010

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance information

Product Name	Synonym	CAS No.	Molecular Formula	Molecular Weight	Concentration
Vinorelbine Tartrate	3',4'-Didehydro-4'-deoxy-C'-norvincal leukoblastine	125317-39-7	C ₄₅ H ₅₄ N ₄ O ₈ ·2C ₄ H ₆ O ₆	1079.12	100%

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:

In all cases of doubt, or when symptoms persist, seek medical attention.

Following inhalation:

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Following skin contact:

Wash off with soap and plenty of water. Consult a physician.

Following eye contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

Following ingestion:

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Notes for the doctor:

No additional requirements.

4.2 Most important symptoms and effects, both acute and delayed

Exposure might occur via skin; eyes; ingestion. Potential health effects:

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion: May be harmful if swallowed.

Skin contact: May be harmful if absorbed through skin. May cause skin irritation.

Eyes contact: May cause eye irritation.

4.3 Indication of the immediate medical attention and special treatment needed

Persons with pre-existing skin, eye, or respiratory disease may be at increased risk.

Attending physician should treat exposed patients symptomatically.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media:

No data available.

5.2 Special hazards arising from the substance or mixture

When heated to decomposition it emits acrid smoke and irritating fumes.

During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).

5.3 Advice for fire-fighters

Do not stay in dangerous zone without self-contained breathing apparatus.

In order to avoid contact with skin, keep a safety distance and wear suitable protective clothing.

Prevent fire-fighting water from entering surface water or groundwater.

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH), Annex II

Version: 1.0/EN
Product name: Vinorelbine Tartrate

Revision date: 25/09/2010
Printing date: 25/09/2010

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.

6.2 Environmental precautions

Do not allow to enter drains or water courses.

6.3 Methods and material for containment and cleaning up

Avoid generating airborne dusts of this product during spill response procedures.

Decontaminate the area of the spill thoroughly by using detergent and water.

Place all spill residues in an appropriate container and seal.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Vinorelbine tartrate is a cytotoxic anti-neoplastic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic anti-neoplastic agents to minimize potential exposures. Avoid ingestion, inhalation, skin contact, and eye contact. When handling, precautions may include the use of a containment cabinet during the weighing, reconstitution and/or solubilization of this anti-neoplastic agent. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials is required when working with this product. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: 2 - 8°C. Store the vial under refrigeration in the carton.

Packaging: 2 layers of PE bags, 1 layer of aluminum bag, 1 aluminum tin, 2 layers of PE bag, 1 layer of flaming box, 1 carton.

Protect from light. DO NOT FREEZE. Follow instructions provided in packaging.

7.3 Specific end use(s)

Not information available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limit values:

There are no currently occupational exposure limit values established for the substance.

8.2 Exposure controls

Appropriate engineering controls:

When handling, local exhaust ventilation is recommended to minimize employee exposure. The use of an enclosure, such as an approved ventilated cabinet designed to minimize airborne exposures, is also recommended.

Personal protective equipment:

Eye and face protection: Wear safety glasses with side-shields.

Hand protection: When handling this product, disposable gloves should be worn at all times. Further, the use of double gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to this product. Persons known to be allergic to latex rubber should select a nonlatex glove. Gloves should be changed regularly, and removed immediately after known contamination. Care should be taken to minimize inadvertent contamination when removing and/or disposing of gloves.

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH), Annex II

Version: 1.0/EN

Product name: Vinorelbine Tartrate

Revision date: 25/09/2010

Printing date: 25/09/2010

Respiratory protection: Wear lab coat to prevent skin exposure.
Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator may be used.

Additional precautions: Wash hands following use. No eating, drinking, or smoking while handling this product.

Environmental exposure controls:

Do not allow to enter drains or water courses.

Consumer exposure controls:

Handle in accordance with good industrial hygiene and safety practice.

Wash hands before breaks and at the end of workday.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Molecular formula:	C ₄₅ H ₅₄ N ₄ O ₈ ·2C ₄ H ₆ O ₆
Molecular weight:	1079.12
Appearance:	Powder. Amorphous (freeze-dried).
Colour:	White or almost white.
Odour:	Odourless.
pH:	3.3 to 3.8, 10 mg/ml in water
Melting point:	181 to 183 °C
Boiling point:	No data available.
Flash point:	No data available.
Vapour pressure:	No data available.
Density:	No data available.
Solubility(ies):	Freely soluble in water and in methanol, practically insoluble in hexane.
Partition coefficient (<i>n</i> -octanol/water):	No data available.
Explosive properties:	No explosive properties.
Oxidising properties:	No oxidising properties.

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No information available.

10.2 Chemical stability

Unopened vials of vinorelbine tartrate injection are stable at temperatures up to 25 deg C for up to 72 hours.

Vinorelbine tartrate injection should not be frozen. (HSDB)

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

None for normal handling of this product.

10.5 Incompatible materials

This product is reported to react with strong oxidizing agents and strong bases.

10.6 Hazardous decomposition products

During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes:

Carbon oxides (CO_x) and nitrogen oxides (NO_x).

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH), Annex II

Version: 1.0/EN
Product name: Vinorelbine Tartrate

Revision date: 25/09/2010
Printing date: 25/09/2010

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Toxicokinetics, metabolism and distribution

Based on best current information, there is no information known associated with this product.

11.2 Information on toxicological effects

Acute toxicity:

Substance

Vinorelbine tartrate (100%)

Vinorelbine tartrate (100%)

Acute toxicity

Oral, LD₅₀= 26-34 mg/kg (Rat);

Oral, LD₅₀= 77-89 mg/kg (mouse);

Intravenous, LD₅₀= 11-12 mg/kg (Rat);

Intravenous, LD₅₀= 32-42 mg/kg (mouse);

Skin corrosion/irritation:

None anticipated from normal handling of this product. However, inadvertent skin contact with this product may produce irritation with redness and discomfort.

Serious eye damage/irritation:

None anticipated from normal handling of this product. However, inadvertent eye contact of this product with eyes may produce irritation with stinging with redness, watering, and discomfort.

Respiratory or skin sensitization:

None anticipated from normal handling of this product. However, in clinical use, systemic allergic reactions including anaphylaxis, pruritus, urticaria, angioedema; and flushing have been reported occasionally (about 2% of patients).

CMR effects (Carcinogenicity, Mutagenicity and Toxicity for Reproduction):

Carcinogenicity: The carcinogenic potential of vinorelbine tartrate has not been fully evaluated in animal studies.

Mutagenicity: It was not mutagenic in the Ames test and gave inconclusive results in the mouse lymphoma TK Locus assay.

Reproductive effects: Vinorelbine did not affect fertility when administered to rats once-weekly at a dosage of 9 mg/m², or alternate-day schedule at a dosage of 4.2 mg/m².

STOT-single exposure and repeated exposure:

This product should be considered irritating to the skin, eyes and respiratory tract.

Following an accidental over-exposure, possible target organs may include the bone marrow, gastrointestinal system, central nervous system, peripheral nervous system, lungs, skin, gonads, and the fetus.

Signs and Symptoms of Exposure: Constipation, Alopecia, Nausea, Vomiting, Diarrhoea.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

IC₅₀ > 1000 mg/L for bacteria.

12.2 Persistence and degradability

This material is anticipated to degrade when exposed to sunlight. The photodegradation half-life is reported as 9.07 hours.

12.3 Bioaccumulative potential

No bioaccumulation is to be expected.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Based on best current information, there is no data known associated with this product.

12.6 Other adverse effects

No information available.

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH), Annex II

Version: 1.0/EN
Product name: Vinorelbine Tartrate

Revision date: 25/09/2010
Printing date: 25/09/2010

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used. The recommended method of disposal is incineration.

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

SECTION 14: TRANSPORT INFORMATION

14.1 Land transport (ADR/RID/GGVSE)

This product is not regulated as a hazardous material or dangerous goods for transportation.

14.2 Sea transport (IMDG-Code/GGVSee)

This product is not regulated as a hazardous material or dangerous goods for transportation.

The substance is not listed as a Marine Pollutant.

14.3 Air transport (ICAO-TI/IATA-DGR)

This product is not regulated as a hazardous material or dangerous goods for transportation.

14.4 Additional information

This material is not considered as dangerous goods.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulation:

Authorisations:	No information available.
Restrictions on use:	No information available.
EINECS:	CAS# 125317-39-7 is not listed in the inventory.
DSD (67/548/EEC):	CAS# 125317-39-7 is not listed in the Annex I.

Other chemical regulation:

USA - TSCA:	CAS# 125317-39-7 is not listed in the inventory.
Canada – DSL/NDSL:	CAS# 125317-39-7 is not listed in the inventory.
Australia - AICS:	CAS# 125317-39-7 is not listed in the inventory.
Japan - ENCS:	CAS# 125317-39-7 is not listed in the inventory.
China - IECSC:	CAS# 125317-39-7 is not listed in the inventory.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance.

SECTION 16: OTHER INFORMATION

16.1 Revision Information:

Date of the previous revision: Not applicable.

Date of this revision: 25/09/2010

Revision summary: New SDS

16.2 Abbreviations and acronyms

CLP:	EU regulation (EC) No 1272/2008 on classification, labelling and packaging of chemical substances and mixtures.
CAS:	Chemical Abstracts Service (division of the American Chemical Society).
EINECS:	European Inventory of Existing Commercial Chemical Substances.
ACGIH	American Conference of Governmental Industrial Hygienists
IARC	International Agency for Research on Cancer
NTP	National Toxicology Program
RID:	European Rail Transport.
IMDG:	International Maritime Code for Dangerous Goods.

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH), Annex II

Version: 1.0/EN

Product name: Vinorelbine Tartrate

Revision date: 25/09/2010

Printing date: 25/09/2010

IATA: International Air Transport Association.
TSCA: Toxic Substances Control Act, The American chemical inventory.
DSD: Dangerous Substance Directive (67/548/EEC).
DSL/NDSL: Domestic Substances List/ Non- Domestic Substances List, The Canadian chemical inventory.
AICS: The Australian Inventory of Chemical Substances.
ENCS: Japanese Existing and New Chemical Substances
IECSC: Inventory of existing chemical substances in China.

16.3 Key literature references and sources for data

HSDB: Hazardous Substances Data Bank

16.4 Relevant R-phrase(s) and H-statement(s)

R-phrase (code and full text):

R28: Very toxic if swallowed.

H-statement (code and full text):

H300: Fatal if swallowed.

16.5 Training advice

No data available.

16.6 Declare to reader

The information in this Safety Data Sheet (SDS) was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. According to REACH Article 31(5), the SDS shall be supplied in an official language of the Member State(s) where the substance or mixture is placed on the market, unless the recipient Member State(s) concerned provide otherwise. It should also be noted that this SDS is applicable to the countries with English as an official language.

----- End of the SDS -----