

天津普西唐生物医药科技有限公司

Tianjin Psaitong Biomedical Technology Co., Ltd

北京普西唐生物科技有限公司

Beijing Psaitong Biotechnology Co., Ltd

SAFETY DATA SHEETS

According to the UN GHS revision 8

Version: 1.0

Creation Date: July 15, 2024 Revision Date: July 15, 2024

1. Identification

1.1 GHS Product identifier

Product name 5-Azacytidine

1.2 Other means of identification

Product number A70028

Other names

1.3 Recommended use of the chemical and restrictions on use

Identified uses Industrial and scientific research uses.

Uses advised against no data available

1.4 Supplier's details

Company Tianjin Psaitong Biomedical Technology Co., Ltd

Beijing Psaitong Biotechnology Co., Ltd

Address Building 145, Yougu New Science Park, Qingguang Town, Beichen District, Tianjin City

Tel/Fax +86-10-60605840

1.5 Emergency phone number

Emergency phone number +86-10-60605840

Service hours Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

2. Hazard identification

2.1 Classification of the substance or mixture

Acute toxicity - Oral, Category 4 Carcinogenicity, Category 1B

2.2 GHS label elements, including precautionary statements

Pictogram(s)





Signal word Danger

Hazard statement(s) H302 Harmful if swallowed

H350 May cause cancer

Precautionary statement(s)

Prevention P264 Wash ... thoroughly after handling.

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

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor/...if you feel unwell.

P330 Rinse mouth.

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

Storage P405 Store locked up.

Disposal P501 Dispose of contents/container to an appropriate treatment and disposal facility in

accordance with applicable laws and regulations, and product characteristics at time of

disposal.

2.3 Other hazards which do not result in classification

no data available

3. Composition/information on ingredients

3.1 Substances

| Chemical name | Common names and synonyms | CAS number | EC number | Concentration |
|----------------------------------------------|----------------------------------------------|---------------|--------------|---------------|
| 2-(β-D-ribofuranosyl)-4-amino-1,3,5-triazin- | 2-(β-D-ribofuranosyl)-4-amino-1,3,5-triazin- | 320-67-2 | 206-280-2 | 100% |
| 2-one | 2-one | | | |

4. First-aid measures

4.1 Description of necessary first-aid measures

General advice

Medical attention is required. Consult a doctor. Show this safety data sheet (SDS) to the doctor in attendance.

If inhaled

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

Following ingestion

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

4.2 Most important symptoms/effects, acute and delayed

SYMPTOMS: Symptoms of exposure to this compound via intravenous route include nausea, vomiting, diarrhea, reduction in white cell count, leukopenia and agranulocytosis. Other symptoms via intravenous route include dose-related leukemia, thrombocytopenia, myelosuppression, gastrointestinal upset, alterations in hepatic function tests, fatal hepatic coma, myalgia, rhabdomyolysis, rash, stomatitis, fever, hypotension and reversible renal impairment. Symptoms of exposure to this type of compound include anorexia, local irritant effects, allergic reactions including pruritus and erythema, headache, malaise, weakness, anaphylaxis, vesicant or irritant effect on skin and mucous membranes, thrombophlebitis, anemia, bleeding, immunosuppressant effect, mouth ulcers, esophagitis, abdominal pain, hemorrhage, perforation of the stomach, alopecia, delayed wound healing, amenorrhea, inhibition of spermatogenesis, gynecomastia, hyperuricemia, acute renal failure due to uric acid nephropathy, hyperphosphatemia, disturbances of electrolyte balance, pigmentation of the skin and nails, jaundice and abnormal liver function tests. ACUTE/CHRONIC HAZARDS: This compound is harmful if swallowed, inhaled or absorbed through the skin. It may cause irritation. When heated to decomposition it emits toxic fumes of carbon monoxide, carbon dioxide and nitrogen oxides. (NTP, 1992)

4.3 Indication of immediate medical attention and special treatment needed, if necessary

Basic treatment: Establish a patent airway. Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if needed. Administer oxygen by nonrebreather mask at 10 to 15 L/min. Monitor for pulmonary edema and treat if necessary.

Monitor for shock and treat if necessary . Anticipate seizures and treat if necessary . For eye contamination, flush eyes immediately with water. Irrigate each eye continuously with normal saline during transport . Do not use emetics. For ingestion, rinse mouth and administer 5 ml/kg up to 200 ml of water for dilution if the patient can swallow, has a strong gag reflex, and does not drool . Cover skin burns with dry sterile dressings after decontamination . Poison A and B

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Fires involving this material can be controlled with a dry chemical, carbon dioxide or Halon extinguisher. A water spray may also be used. (NTP, 1992)

5.2 Specific hazards arising from the chemical

Flash point data for this chemical are not available; however, it is probably combustible. (NTP, 1992)

5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing mist, gas or vapours. Avoid contacting with skin and eye. Use personal protective equipment. Wear chemical impermeable gloves. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

6.2 Environmental precautions

Prevent further spillage or leakage if it is safe to do so. Do not let the chemical enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Collect and arrange disposal. Keep the chemical in suitable and closed containers for disposal. Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

7. Handling and storage

7.1 Precautions for safe handling

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

7.2 Conditions for safe storage, including any incompatibilities

Intact vials should be stored under refrigeration & are stable for a least 4 yr. Although the drug is stable for 3 yr at room temp, refrigeration is recommended because degradation may result at elevated temperatures. The constituted soln hydrolyzes at room temp & should be used within 30 min. ... Azacitidine 0.5 & 2 mg/ml in Ringer's injection, lactated, was stable for up to one month when frozen at -20 deg C in polypropylene syringes.

8. Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

no data available

8.2 Appropriate engineering controls

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

Skin protection

Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

Thermal hazards

no data available

9. Physical and chemical properties

Physical state PHYSICAL DESCRIPTION: White crystalline powder. (NTP, 1992)

ColourCrystals from methanolOdourno data available

Melting point/ freezing point 186°C(lit.)

Boiling point or initial boiling point 71°C/10mmHg(lit.)

and boiling range

Flammability no data available

Lower and upper explosion limit / no data available

flammability limit

Flash point 57°C(lit.)

Auto-ignition temperature no data available

Decomposition temperature no data available

pH no data available

Kinematic viscosity no data available

Solubility >36.6 [ug/mL]

Partition coefficient n- no data available

octanol/water

Vapour pressureno data availableDensity and/or relative density2.08 g/cm3Relative vapour densityno data availableParticle characteristicsno data available

10. Stability and reactivity

10.1 Reactivity

Slightly water soluble. Unstable in solution.

10.2 Chemical stability

Intact vials should be stored under refrigeration & are stable for a least 4 yr. Although the drug is stable for 3 yr at room temp, refrigeration is recommended because degradation may result at elevated temperatures. The constituted soln hydrolyzes at room temp & should be used within 30 min. The pH providing optimum soln stability has been reported to be about 6.5-7. Azacitidine 0.5 & 2 mg/ml in Ringer's injection, lactated, was stable for up to one month when frozen at -20 deg C in polypropylene syringes.

10.3 Possibility of hazardous reactions

5-AZACYTIDINE is sensitive to light (may discolor). It is sensitive to oxidation. It is unstable in solution. It undergoes hydrolysis in aqueous buffers. This chemical is incompatible with strong oxidizers. (NTP, 1992)

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

no data available

10.6 Hazardous decomposition products

When heated to decomposition it emits toxic fumes of /nitrogen oxides/.

11. Toxicological information

Acute toxicity

• Oral: LD50 Mouse oral 572 mg/kg

• Inhalation: no data available

• Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

Azacitidine: reasonably anticipated to be a human carcinogen.

Reproductive toxicity

no data available

STOT-single exposure

no data available

STOT-repeated exposure

no data available

Aspiration hazard

no data available

12. Ecological information

12.1 Toxicity

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

12.2 Persistence and degradability

no data available

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

12.5 Other adverse effects

no data available

13. Disposal considerations

13.1 Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

14. Transport information

14.1 UN Number

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.2 UN Proper Shipping Name

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.3 Transport hazard class(es)

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.4 Packing group, if applicable

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.5 Environmental hazards

ADR/RID: No IMDG: No IATA: No

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

15. Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

| Chemical name | Common names and synonyms | CAS number | EC number |
|--------------------------------------------------------------------------|---------------------------------------------------------|------------|-------------|
| 2-(β-D-ribofuranosyl)-4-amino-1,3,5-triazin-2- | 2-(β-D-ribofuranosyl)-4-amino-1,3,5-triazin-2-one | 320-67-2 | 206-280-2 |
| one | 2-(p-D-1100101 a1105y1)-4-a111110-1,3,3-111a2i11-2-011e | | |
| European Inventory of Existing Commercial Chemical Substances (EINECS) | | | |
| EC Inventory | | | Listed. |
| United States Toxic Substances Control Act (TSCA) Inventory | | | Not Listed. |
| China Catalog of Hazardous chemicals 2015 | | | |
| New Zealand Inventory of Chemicals (NZIoC) | | | |
| Philippines Inventory of Chemicals and Chemical Substances (PICCS) | | | |
| Vietnam National Chemical Inventory | | | Not Listed. |
| Chinese Chemical Inventory of Existing Chemical Substances (China IECSC) | | | Not Listed. |
| Korea Existing Chemicals List (KECL) | | | |

16. Other information

Information on revision

Creation Date July 15, 2024

Revision Date July 15, 2024

Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- · RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- · STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS The International Chemical Safety Cards (ICSC), website: http://www.ilo.org/dyn/icsc/showcard.home
- HSDB Hazardous Substances Data Bank, website: https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm
- IARC International Agency for Research on Cancer, website: http://www.iarc.fr/
- eChemPortal The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: http://cameochemicals.noaa.gov/search/simple
- ChemlDplus, website: http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp
- ERG Emergency Response Guidebook by U.S. Department of Transportation, website: http://www.phmsa.dot.gov/hazmat/library/erg
- Germany GESTIS-database on hazard substance, website: http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp
- ECHA European Chemicals Agency, website: https://echa.europa.eu/

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. We as supplier shall not be held liable for any damage resulting from handling or from contact with the above product.