



SAFETY DATA SHEET

1. Identification

Product identifier	Vincristine Sulfate	
Other means of identification		
Catalog number	1714007	
CAS number	2068-78-2	
Synonyms	Vincal leukoblastine, 22-oxo-, sulfate (1:1) (salt)	
Chemical name	Leurocristine sulfate (1:1) (salt)	
Recommended use	For analytical laboratory use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 2
	Serious eye damage/eye irritation	Category 2A
	Germ cell mutagenicity	Category 1B
	Reproductive toxicity	Category 2
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Fatal if swallowed. Causes serious eye irritation. May cause genetic defects. Suspected of damaging fertility or the unborn child.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.

Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Vincristine Sulfate	Vincalcaleukoblastine, 22-oxo-, sulfate (1:1) (salt)	2068-78-2	100

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Nervous system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment of vinca alkaloid overdose may include the following: For eye contact, treat with a steroid eye ointment or drops to minimize inflammation. Administer activated charcoal as a slurry. For seizures, administer a benzodiazepine intravenously, followed by phenobarbital or propofol if the seizures recur. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, hypoxia. For SIADH, administer saline and manage fluid restriction. For neutropenia, administer hematopoietic colony stimulating factor (e.g. filgrastim, sargramostim). Monitor the patient carefully, especially for cardiovascular status. Manage airway. Folinic acid (leucovorin) may help reduce neurotoxic effects.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
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Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage**Precautions for safe handling**

As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection**Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values**Industrial Use
Material****Type****Value**

Vincristine Sulfate (CAS
2068-78-2)

STEL

1.68
micrograms/m3

TWA

0.14
micrograms/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment**Eye/face protection**

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection**Hand protection**

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

9. Physical and chemical properties**Appearance**

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Crystalline powder.

Color

White. Off-white. Light yellow.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

> 473 °F (> 245 °C) Decomposes

	523.4 - 537.8 °F (273 - 281 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa (77 °F (25 °C))
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Freely soluble.
Solubility (other)	Chloroform: Soluble. Ethanol: Slightly soluble. Ether: Practically insoluble. Methanol: Soluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Vinca alkaloid.
Molecular formula	C ₄₆ H ₅₆ N ₄ O ₁₀ · H ₂ SO ₄
Molecular weight	923.04 g/mol
pH in aqueous solution	3.5 - 4.5 Solution: 0.1%

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. SOx.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Causes serious eye irritation.
Ingestion	Fatal if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics	Vinca alkaloids: Headache. Gastrointestinal disturbances. Fever. Chills. Cough. Hoarseness. Shortness of breath. Numbness, pain, tingling, or weakness in hands or feet. Lower back or side pain. Joint pain. Bone pain. Painful or difficult urination. Mouth sores. Bleeding or bruising. Pinpoint red spots on skin. Hair loss. Vision problems.
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Information on toxicological effects

Acute toxicity	Fatal if swallowed.
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Product	Species	Test Results
Vincristine Sulfate (CAS 2068-78-2)		
Acute		
Inhalation		
LC50	Rat	> 1200 mg/m3, 1 hr
Oral		
LD50	Rat	> 5 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Causes serious eye irritation.	
Local effects		
Eye irritancy test		
Result: Moderate irritation.		
Species: Rabbit		
Skin irritancy test		
Result: Slight to mild irritation.		
Species: Rabbit		
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Knowledge about health hazard is incomplete.	
Germ cell mutagenicity	May cause genetic defects.	
	An investigation of workers occupationally exposed to vincristine sulfate indicated this material can cause genetic damage.	
Mutagenicity		
In vivo mouse dominant lethal test		
Result: Positive.		
In vivo mouse micronucleus test		
Result: Positive.		
In vivo test in Chinese hamsters		
Result: Increased frequency of hyperploidy in spermatogonial and germ cells.		
In vivo test in pregnant mice		
Result: Increased incidence of chromosomal aberrations in embryonic tissue.		
Carcinogenicity	Knowledge about carcinogenicity is incomplete.	
	Secondary malignancies are potential delayed effects of many antineoplastic agents, although it is not clear whether the effect is related to their mutagenic or immunosuppressive action. The effect of dose and duration of therapy is also unknown, although risk seems to increase with long-term use. Some individuals who received chemotherapy with vinca alkaloids in combination with anti-cancer drugs known to be carcinogenic have developed secondary malignancies.	
0.06 - 0.12 mg/kg Carcinogenicity study, administered intraperitoneally.		
Result: Tumor incidence comparable to that of controls.		
Species: Rat		
Test Duration: 6 months		
Observation Period: 18 months		
0.075 - 0.15 mg/kg Carcinogenicity study, administered intraperitoneally.		
Result: Tumor incidence comparable to that of controls.		
Species: Mouse		
Test Duration: 6 months		
Observation Period: 18 months		
IARC Monographs. Overall Evaluation of Carcinogenicity		
Vincristine Sulfate (CAS 2068-78-2)	3 Not classifiable as to carcinogenicity to humans.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)		
Not listed.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		

Reproductive toxicity

Suspected of damaging fertility or the unborn child.
Antineoplastic therapy can adversely affect male and female fertility through gonadal suppression, resulting in the absence of menstruation or sperm. The effects appear to be related to dose and length of therapy and may be irreversible.
Vincristine sulfate can cause fetal toxicity in humans. Studies in animals have shown that vincristine causes impaired fertility, embryotoxicity, and birth defects at very low doses.

Reproductivity

0.05 - 0.075 mg/kg Reproductivity and development study, administered by injection during gestation

Result: Increased incidence of eye defects and other malformations.

Species: Rat

0.15 - 0.175 mg/kg Reproductivity and development study, administered by injection during gestation

Result: Developmental effects (encephalocele and syndactyly).

Species: Monkey

Reproductivity and development study, intraperitoneal administration.

Result: LOAEL for teratogenicity = 0.2 mg/kg.

Species: Mouse

Reproductivity and development study, intraperitoneal administration.

Result: LOAEL for teratogenicity = 0.5 mg/kg.

Species: Rat

Reproductivity study in male mice

Result: Decreased sperm count, fertility, and normal sperm morphology.

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose of contents/container in accordance with local/regional/national/international regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number UN1544

UN proper shipping name Alkaloid salts, solid, n.o.s. (Vincristine Sulfate)

Transport hazard class(es)**Class** 6.1**Subsidiary risk** -**Packing group** II**IATA****UN number** UN1544**UN proper shipping name** Alkaloid salts, solid, n.o.s. (Vincristine Sulfate)**Transport hazard class(es)****Class** 6.1**Subsidiary risk** -**Packing group** II**Other information****Passenger and cargo aircraft** Allowed with restrictions.**Cargo aircraft only** Allowed with restrictions.**Transport in bulk according to** Not applicable.**Annex II of MARPOL 73/78 and the IBC Code****DOT; IATA****General information**

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information**US federal regulations**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Vincristine Sulfate (CAS 2068-78-2) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical Yes**Classified hazard categories** Acute toxicity (any route of exposure)
Serious eye damage or eye irritation
Germ cell mutagenicity
Reproductive toxicity**SARA 313 (TRI reporting)**

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Vincristine Sulfate (CAS 2068-78-2)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

California Proposition 65



WARNING: This product can expose you to Vincristine Sulfate, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Developmental toxin

Vincristine Sulfate (CAS 2068-78-2)

Listed: July 1, 1990

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Vincristine Sulfate (CAS 2068-78-2)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 01-11-2010

Revision date 09-07-2021

Version # 05

Disclaimer USP materials are sold for analytical laboratory use only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.