

## 1. Identification

<b>Product identifier</b>	<b>Vincristine Sulfate (Assay)</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1714018	
<b>Chemical name</b>	Vincalukoblastine, 22-oxo-, sulfate (1:1) (salt)	
<b>Synonym(s)</b>	Leurocristine sulfate	
<b>Recommended use</b>	Specified quality tests and assay use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
<b>Telephone</b>	RS Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 2
	Serious eye damage/eye irritation	Category 1
	Carcinogenicity	Category 2
	Reproductive toxicity	Category 1A
<b>OSHA hazard(s)</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger	
<b>Hazard statement</b>	Fatal if swallowed. Causes serious eye damage. Suspected of causing cancer. May damage fertility or the unborn child.	
<b>Precautionary statement</b>		
<b>Prevention</b>	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.	
<b>Response</b>	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. Immediately call a poison center/doctor. If exposed or concerned: Get medical advice/attention.	
<b>Storage</b>	Store locked up.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	Not classified.	

## 3. Composition/information on ingredients

### Substance

## Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Vincristine Sulfate (Assay)	Leurocristine sulfate	2068-78-2	100

## 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.
<b>Skin contact</b>	Wash the skin immediately with soap and water. Get medical attention if irritation develops and persists. Before washing use a dry brush to remove dust from skin. Remove and isolate contaminated clothing and shoes. Wash clothing separately before reuse. For minor skin contact, avoid spreading material on unaffected skin.
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Call a physician or poison control center immediately.
<b>Ingestion</b>	Call a physician or poison control center immediately. Never give anything by mouth to a victim who is unconscious or is having convulsions. 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. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
<b>Most important symptoms/effects, acute and delayed</b>	May cause temporary blindness and severe eye damage. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.
<b>Indication of immediate medical attention and special treatment needed</b>	Treatment of vinca alkaloid overdose should be symptomatic and supportive and 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. (Meditext)
<b>General information</b>	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

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

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Wear appropriate personal protective equipment.
<b>Methods and materials for containment and cleaning up</b>	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

## 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, when handling USP Reference Standards, 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. Use of a designated area is recommended for handling of potent materials.
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**Conditions for safe storage, including any incompatibilities**

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Exposure limit values

#### Industrial Use

Material	Type	Value
Vincristine Sulfate (Assay) (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

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Avoid any open handling of this material, particularly for grinding, crushing, weighing or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

#### Skin protection

##### Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

##### Other

For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

#### Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

#### Thermal hazards

Not available.

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

### Appearance

White or slightly yellow, amorphous or crystalline powder.

#### Physical state

Solid.

#### Form

Powder.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

3.5 - 4.5 (0.1% aqueous solution)

### Melting point/freezing point

523.4 - 537.8 °F (273 - 281 °C) ; >245 °C (decomposes)

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not applicable.

### Upper/lower flammability or explosive limits

#### Flammability limit - lower (%)

Not available.

#### Flammability limit - upper (%)

Not available.

<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	< 0.0000001 kPa at 25 °C
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility in water</b>	Freely soluble.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Vinca alkaloid.
<b>Molecular formula</b>	C <sub>46</sub> H <sub>56</sub> N <sub>4</sub> O <sub>10</sub> · H <sub>2</sub> SO <sub>4</sub>
<b>Molecular weight</b>	923.04
<b>Solubility (other)</b>	Soluble in methanol and in chloroform; slightly soluble in ethanol; practically insoluble in ether.

## 10. Stability and reactivity

<b>Reactivity</b>	No reactivity hazards known.
<b>Chemical stability</b>	Stable at normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	None known.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	NO <sub>x</sub> . SO <sub>x</sub> . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Fatal if swallowed.
<b>Inhalation</b>	Based on available data, the classification criteria are not met.
<b>Skin contact</b>	Based on available data, the classification criteria are not met.
<b>Eye contact</b>	Causes serious eye damage.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	Vinca alkaloids: Headache. Nausea. Vomiting. Constipation. 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. Black or bloody stools. Blood in urine. Pinpoint red spots on skin. Hair loss. Vision problems.
<b>Delayed and immediate effects of exposure</b>	Vinca alkaloids: Increase in blood pressure.
<b>Chronic effects</b>	Vinca alkaloids: Bone marrow suppression. Cancer.
<b>Medical conditions aggravated by exposure</b>	Vinca alkaloids: Bone marrow depression. Chickenpox, existing or recent. Herpes zoster. Heart disease. Skin disorders. Porphyria. Impaired liver function. Infection. Recent cytotoxic drug or radiation therapy. Charcot-Marie-Tooth syndrome. Neuromuscular disorders.
<b>Acute toxicity</b>	Fatal if swallowed.

<b>Product</b>	<b>Species</b>	<b>Test Results</b>
Vincristine Sulfate (Assay) (CAS 2068-78-2)		
<i>Inhalation</i>		
LC50	Rat	> 1200 mg/m <sup>3</sup> , 1 hr
<i>Oral</i>		
LD50	Rat	> 5 mg/kg
<i>Other</i>		
LD50	Rat	1.01 mg/kg, Intravenous
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Causes serious eye damage.	

## Local effects

1 mg Irritancy test  
Result: Irritant.  
Species: Rabbit  
Organ: Skin  
Severity: Slight.  
Irritancy test  
Result: Irritant.  
Species: Rabbit  
Organ: Eye  
Severity: Moderate.

## Respiratory sensitization

Due to lack of data the classification is not possible.

## Skin sensitization

Due to lack of data the classification is not possible.

## Germ cell mutagenicity

Based on available data, the classification criteria are not met.  
This material can cause genetic damage in humans.

## Mutagenicity

In vitro Comet assay in human lymphocytes  
Result: Positive.  
In vitro T-cell receptor gene mutation test in human lymphocytes  
Result: Positive.  
In vitro cytokinesis-block micronucleus assay in human lymphocytes  
Result: Positive.

## Carcinogenicity

Suspected of causing cancer.  
IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans. This product is not considered to be a carcinogen by NTP. This product is not listed as a carcinogen by OSHA. 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.

## Reproductive toxicity

May damage 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.  
This material can cause fetal toxicity in humans. This material has caused adverse fetal effects in animal studies. This material has caused birth defects in animal studies. This material has caused impaired fertility in animal studies.

## Reproductivity

0.05 - 0.075 mg/kg Gestational injection study  
Result: Increased incidence of eye defects and other malformations  
Species: Rat  
0.15 - 0.175 mg/kg Gestational injection study  
Result: Developmental effects (encephalocele and syndactyly)  
Species: Monkey

## Specific target organ toxicity - single exposure

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

## Specific target organ toxicity - repeated exposure

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

## Aspiration hazard

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

## 12. Ecological information

### Ecotoxicity

No ecotoxicity data noted for the ingredient(s).

### Persistence and degradability

No data is available on the degradability of this product.

### Bioaccumulative potential

Not available.

### Mobility in soil

Not available.

### Other adverse effects

Not available.

## 13. Disposal considerations

### Disposal instructions

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

### Local disposal regulations

Not available.

### Hazardous waste code

Not available.

**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)	6.1
Subsidiary class(es)	Not available.
Packing group	II

### IATA

UN number	UN1544
UN proper shipping name	Alkaloid salts, solid, n.o.s. (Vincristine Sulfate)
Transport hazard class(es)	6.1
Subsidiary class(es)	-
Packaging group	II

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

No information available.

**DOT; IATA**



## 15. Regulatory information

### US federal regulations

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

<b>Hazard categories</b>	Immediate Hazard - Yes
	Delayed Hazard - Yes
	Fire Hazard - No
	Pressure Hazard - No
	Reactivity Hazard - No

<b>SARA 302 Extremely hazardous substance</b>	No
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<b>SARA 311/312 Hazardous chemical</b>	No
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### Other federal regulations

<b>Safe Drinking Water Act (SDWA)</b>	Not regulated.
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<b>Food and Drug Administration (FDA)</b>	Not regulated.
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### US state regulations

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

### 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

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	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)

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

<b>Issue date</b>	01-11-2010
<b>Revision date</b>	07-15-2015
<b>Version #</b>	03
<b>Further information</b>	Not available.
<b>Disclaimer</b>	<p>USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard 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 Reference Standards 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.</p>
<b>Revision Information</b>	<p>Hazard(s) identification: &lt;INDENT&gt;Response  Hazard(s) identification: &lt;INDENT&gt;Disposal  First-aid measures: General information  Physical &amp; Chemical Properties: Multiple Properties</p>