

# SAFETY DATA SHEET

# spectrum®



Revision date 25-August-2022

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** ALPROSTADIL, USP

### Other means of identification

**Product Code(s)** P1679

**UN/ID no** UN2811

**Synonyms** None

### Recommended use of the chemical and restrictions on use

**Recommended use** No information available

**Restrictions on use** No information available

### Details of the supplier of the safety data sheet

#### Supplier Address

Spectrum Chemical Mfg. Corp.  
14422 South San Pedro St.  
Gardena, CA 90248  
(310) 516-8000

### Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

Acute toxicity - Oral	Category 3
Reproductive toxicity	Category 2

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

**Danger**

#### Hazard statements

Toxic if swallowed  
Suspected of damaging fertility or the unborn child



**Appearance** Crystalline powder or powder

**Physical state** Solid

**Odor** No information available

#### **Precautionary Statements - Prevention**

Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Wear protective gloves/protective clothing/eye protection/face protection  
Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product

#### **Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention  
Specific treatment (see .? on this label)  
IF SWALLOWED: Immediately call a POISON CENTER or doctor  
Rinse mouth

#### **Precautionary Statements - Storage**

Store locked up.

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

#### **Other information**

No information available.

### **3. Composition/information on ingredients**

#### **Substance**

Chemical name	CAS No	Weight-%	Trade secret
Alprostadil	745-65-3	100	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

### **4. First-aid measures**

#### **Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get medical attention.

#### **Most important symptoms and effects, both acute and delayed**

**Symptoms** No information available.

**Indication of any immediate medical attention and special treatment needed**

**Note to physicians** Treat symptomatically.

**5. Fire-fighting measures**

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Large Fire** CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

**Specific hazards arising from the chemical** No information available.

**Hazardous combustion products** Carbon monoxide. Carbon dioxide (CO<sub>2</sub>).

**Explosion data**

**Sensitivity to mechanical impact** none.

**Sensitivity to static discharge** none.

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**6. Accidental release measures**

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Ensure adequate ventilation.

**Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

**7. Handling and storage**

**Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up.

**8. Exposure controls/personal protection**

**Control parameters**

**Exposure Limits** The following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

### Appropriate engineering controls

**Engineering controls**                      Showers  
    Eyewash stations  
    Ventilation systems.

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

**Eye/face protection**                      No special protective equipment required.

**Hand protection**                              Wear suitable gloves.

**Skin and body protection**                      Wear suitable protective clothing.

**Respiratory protection**                      No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations**                      Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

## **9. Physical and chemical properties**

### Information on basic physical and chemical properties

**Physical state**                                      Solid  
**Appearance**                                      Crystalline powder or powder  
**Color**    White to Off-White  
**Odor**    No information available  
**Odor threshold**                                    No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	no data available	None known
<b>Melting point / freezing point</b>	115 °C / 239 °F	None known
<b>Boiling point / boiling range</b>	no data available	None known
<b>Flash point</b>	no data available	None known
<b>Evaporation rate</b>	no data available	None known
<b>Flammability (solid, gas)</b>	no data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	no data available	None known
<b>Relative density</b>	1.1	None known
<b>Water solubility</b>	Very slightly soluble in water	None known
<b>Solubility(ies)</b>	Slightly soluble in alcohol Slightly soluble in Acetone Slightly soluble in Ethyl acetate Slightly soluble in Dimethyl sulfoxide (DMSO)	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	no data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known

### Other information

<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available
<b>Softening point</b>	No information available
<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk density</b>	No information available

## 10. Stability and reactivity

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	None known based on information supplied.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on components).

### Symptoms related to the physical, chemical and toxicological characteristics

<b>Symptoms</b>	No information available.
-----------------	---------------------------

### Acute toxicity

### Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Alprostadil 745-65-3	= 228 mg/kg ( Rat )	-	-

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Reproductive toxicity</b>	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.
<b>STOT - single exposure</b>	No information available.

<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

## 12. Ecological information

<b>Ecotoxicity</b>	The environmental impact of this product has not been fully investigated.
<b>Persistence and degradability</b>	No information available.
<b>Bioaccumulation</b>	Inherently biodegradable.
<b>Other adverse effects</b>	No information available.

## 13. Disposal considerations

### Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

## 14. Transport information

### DOT

<b>UN/ID no</b>	UN2811
<b>Proper Shipping Name:</b>	Toxic solids, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing group:</b>	III
<b>Special Provisions</b>	IB8, IP3, T1, TP33
<b>Marine Pollutant</b>	Severe Marine Pollutant
<b>Description:</b>	UN2811, Toxic solids, organic, n.o.s., 6.1, III
<b>Emergency Response Guide Number</b>	154

### TDG

<b>UN-No:</b>	UN2811
<b>Proper Shipping Name:</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing Group:</b>	III
<b>Special Provisions</b>	16
<b>Description:</b>	UN2811, Toxic solid, organic, n.o.s., 6.1, III

### MEX

<b>UN-No</b>	UN2811
<b>Proper Shipping Name</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Special Provisions</b>	223, 274
<b>Packing Group</b>	III
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s., 6.1, III

### ICAO (air)

<b>UN-No:</b>	UN2811
<b>Proper Shipping Name:</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing Group:</b>	III

**Special Provisions** A3, A5  
**Description:** UN2811, Toxic solid, organic, n.o.s., 6.1, III

#### IATA

**UN number** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Transport hazard class(es)** 6.1  
**Packing group** III  
**ERG Code** 6L  
**Special Provisions** A3, A5  
**Description:** UN2811, Toxic solid, organic, n.o.s., 6.1, III

#### IMDG

**UN number** UN2811  
**Proper shipping name** Toxic solid, organic, n.o.s.  
**Transport hazard class(es)** 6.1  
**Packing group** III  
**EmS-No** F-A, S-A  
**Special Provisions** 223, 274  
**Marine pollutant** NP1  
**Description** UN2811, Toxic solid, organic, n.o.s., 6.1, III

#### RID

**UN number** UN2811  
**Proper Shipping Name:** TOXIC SOLID, ORGANIC, N.O.S.  
**Transport hazard class(es)** 6.1  
**Packing group** III  
**Classification code** T2  
**Special Provisions** 274, 614  
**Description:** UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, III  
**Labels** 6.1

#### ADR

**UN number** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Transport hazard class(es)** 6.1  
**Packing group** III  
**Classification code** T2  
**Tunnel restriction code** (E)  
**Special Provisions** 274, 614  
**Description:** UN2811, Toxic solid, organic, n.o.s., 6.1, III, (E)  
**Labels** 6.1

#### ADN

**UN/ID No** UN2811  
**Proper shipping name** Toxic solid, organic, n.o.s.  
**Transport hazard class(es)** 6.1  
**Packing Group** III  
**Classification code** T2  
**Special Provisions** 274, 614, 802  
**Description** UN2811, Toxic solid, organic, n.o.s., 6.1, III  
**Hazard label(s)** 6.1  
**Limited quantity (LQ)** 5 kg  
**Equipment Requirements** PP, EP

## 15. Regulatory information

### International Inventories

**TSCA** Not listed

**Note** \*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

<b>DSL/NDSL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	This product complies with ENCS:
<b>IECSC</b>	This product does not comply with china:
<b>KECL</b>	Does not Comply
<b>PICCS</b>	Does not Comply
<b>AICS</b>	This product does not comply with AICS

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**US Federal Regulations**

**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**US State Regulations**

**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

**16. Other information**

**NFPA**

**Health hazards** 0

**Flammability** 0

**Instability** 0

**Physical and chemical properties** -



**HMIS****Health hazards** \***Flammability** 0**Physical hazards** 0**Personal protection** X*Chronic Hazard Star Legend*

\* = Chronic Health Hazard

**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

**Revision date** 25-August-2022**Revision Note** No information available.**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**