Alprostadil USP

SAFETY DATA SHEET

Section 1 Identification of the substance/mixture and of the company/undertaking

Product Identifier: Alprostadil USP

Identification on the label/ Tradename: Alprostadil USP

Identification of the Product: CAS#745-65-3

Formula: C20-H34-O5

Cl No.: Not Available

Synonyms: (11 alpha,13E,15S)-11,15-Dihydroxy-9-oxoprost-13-enoic Acid

Relevant identified uses of the substance and uses advised against:

Identified Uses: For research use only, not for human or veterinary consumption.

Uses Advised Against: Not information available

Name, address, and telephone number of the manufacturer:

Refer to Supplier

Name, address, and telephone number of the supplier:

Encore Scientific
801 West New Orleans Street Broken Arrow, OK, USA 74011

Supplier's Telephone #
800-454-2304 Monday to Friday 8:00 am to 6:00 pm (Central time)
24 Hr. Emergency Tel #
INFOTRAC: (800) 535-5053 (Within Continental US and Canada); (352)323-3500 (International)

Section 2 Hazards Identification

Classification of the Substance or Mixture

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

Acute Toxicity: Oral, Category 3

Adverse physicochemical, human health and environmental effects

Toxic to Reproduction, Category 2

Label elements

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

Signal Word: Danger
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Section 2 Hazards Identification (continued)

Hazard Phrases
H301: Toxic if swallowed.
H361: Suspected of damaging fertility or the unborn child.

Precaution Phrases
P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P264: Wash [hands] thoroughly after handling.
P280: Wear [protective gloves/protective clothing/eye protection/face protection].

Response Phrases
P301+310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P308+313: IF exposed or concerned: Get medical attention/advice.
P330: Rinse mouth.

Other hazards
Other hazards not contributing to the classification:
Exposure may cause sensitization.
Exposure may cause vasodilation and an inhibition of platelet aggregation.
Material may be irritating to the mucous membranes and upper respiratory tract.
May be harmful by inhalation or skin absorption.
May cause eye, skin, or respiratory system irritation.
Suspected of damaging fertility or the unborn child.
Toxic if swallowed.
To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

Section 3 Composition/information on ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS No.</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprostadil</td>
<td>745-65-3</td>
<td>100</td>
</tr>
</tbody>
</table>

Section 4 First aid measures

General Advice: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

Inhalation: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

Skin Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
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Section 4 First aid measures (continued)

Eye Contact: Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

Ingestion: Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Exposure may cause: Nausea, diarrhea, headache, vomiting, flushing, shivering, hypotension, and dizziness.

Symptoms/injuries Inhalation: No available information

Symptoms/injuries Skin Contact: No available information

Symptoms/injuries Eye Contact: No available information

Symptoms/injuries Ingestion: No available information

Chronic Symptoms: No available information

Indication of any immediate medical attention and special treatment needed

If you feel unwell, seek medical advice (show the label where possible).

Section 5 Fire-Fighting measures

Extinguishing media

Suitable extinguishing media: Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.

Unsuitable extinguishing media: A solid water stream may be inefficient.

Special hazards arising from the substance or mixture

Fire hazard: Not considered flammable but may burn at high temperatures.

Explosion hazard: No Data

Reactivity: Emits toxic fumes under fire conditions.

Advice for firefighters

Precautionary measures fire: Exercise caution when fighting any chemical fire.

Firefighting instructions: As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent).

Protection during firefighting: Wear full protective gear to prevent contact with skin and eyes.

Other information: No available information
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Section 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures
General measures: Avoid raising and breathing dust, and provide adequate ventilation.

For non-emergency personnel
Protective equipment: As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).
Emergency procedures: No information available

Section 6 Accidental release measures (cont.)

For emergency responders
Protective equipment: Equip cleanup crew with proper protection.
Emergency procedures: Contain spill and collect, as appropriate.

Environmental precautions
Take steps to avoid release into the environment, if safe to do so.

Methods and material for containment and cleaning up
For containment: Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.
Methods for cleaning up:
Small Spill Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements
Large Spill Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Reference to other sections
See Heading 8. Exposure controls and personal protection.

Section 7 Handling and storage

Precautions for safe handling
Additional hazards when processed: Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label.
Precautions for safe handling: Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid prolonged or repeated exposure.
Hygiene measures: Do not take internally. Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower. Wash thoroughly after handling.
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Section 7 Handling and storage (continued)

Conditions for safe storage, including any incompatibilities

Technical measures: Comply with applicable regulations. Use explosion proof equipment. Proper grounding procedures to avoid static electricity should be followed.


Incompatible products: No available information

Specific end use(s)

Not for human or veterinary consumption

Section 8 Exposure Controls/Personal Protection

Control parameters

No additional information available

Exposure controls

Appropriate engineering controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment:

Materials for protective clothing:
Chemically resistant materials and fabrics.

Hand protection:
Compatible chemical-resistant gloves

Eye protection:
Safety glasses.

Skin and body protection:
Wear suitable protective clothing.

Respiratory protection:
Use a NIOSH-approved respirator or self-contained breathing apparatus whenever conditions warrant

Environmental exposure controls: Take steps to avoid release into the environment, if safe to do so.

Consumer exposure controls: Do not take internally. Do not eat, drink or smoke during use.
## Section 9 Physical and chemical properties

**Information on basic physical and chemical properties:**

- **Physical state:** Solid (crystalline)
- **Color:** White. Off-white
- **Odor:** No data available
- **Odor threshold:** No data available
- **pH:** No data available
- **Evaporation rate:** No data available
- **Melting point:** 110°C (230°F) - 116°C
- **Freezing point:** No data available
- **Boiling point:** No data available
- **Flash point:** No data available
- **Auto-ignition temperature:** No data available
- **Decomposition temperature:** No data available
- **Flammability (solid, gas):** No data available
- **Vapor pressure:** No data available
- **Relative vapor density at 20°C:** No data available
- **Relative density:** No data available
- **Solubility:** ~1.67 mg/ml in PBS (pH 7.2); ~50 mg/ml in EtOH, DMF, & DMSO;
- **Partition coefficient: n-octanol/water:** No data available
- **Viscosity:** No data available
- **Explosive properties:** No data available
- **Oxidizing properties:** No data available
- **Explosive limits:** No data available

**Other information**

No additional information available

## Section 10 Stability and reactivity

**Reactivity:** Sensitive to light.

**Chemical stability:** Stable under recommended handling and storage conditions (see section 7).

**Possibility of hazardous reactions**

Hazardous polymerization will not occur.

**Conditions to avoid**

Direct sunlight. Excess heat.

**Incompatible materials**

Strong oxidizing agents

**Hazardous decomposition products**

Carbon oxides (CO, CO2). Nitrogen oxides
Section 11 Toxicological information

The toxicological effects of this compound have not been thoroughly studied.

Information on toxicological effects

Acute toxicity: Acute oral toxicity (LD50): 186 mg/kg [Mouse].

Skin corrosion/irritation: May cause skin irritation.
Serious eye damage/irritation: May cause eye irritation.
Respiratory or skin sensitization: May cause respiratory tract irritation
Germ cell mutagenicity: Not classified
Carcinogenicity: Not classified
Reproductive toxicity: May cause adverse reproductive effects and birth defects (teratogenic). May affect genetic material (mutagenic).

Ingestion:
Hazardous in case of ingestion. Harmful if swallowed. It may cause gastrointestinal tract irritation with flushing, fever, nausea, gastric regurgitation, diarrhea. It may affect behavior/central nervous system(seizures, hyperirritability, dizziness, jitteriness, lethargy), respiration (bronchial wheezing, bradypnea, respiratory depression, dyspnea, tachypnea, respiratory distress), cardiovascular system (hypotension, bradycardia, tachycardia, cardiac arrest, congestive heart failure, 2nd degree heart block, ventricular fibrillation, spasm of the right ventricle), blood (hyperbilirubinemia, anemia, thrombocytopenia, disseminated intravascular coagulation), and urinary system (anuria, hematuria). Hypoglycemia or hyperkalemia may also occur. Prolonged or repeated ingestion may have similar effects to that of acute ingestion.

Specific target organ toxicity (single exposure): Not classified
Specific target organ toxicity (repeated exposure): Not classified
Aspiration hazard: Not classified

Section 12 Ecological information

Toxicity: Avoid release into the environment.
Runoff from fire control or dilution water may cause pollution.

Persistence and degradability: No additional information available
Bio-accumulative potential: No additional information available
Mobility in soil: No additional information available
Results of PBT and vPvB assessment: No additional information available

Other adverse effects
Other information: Avoid release to the environment.
Section 13 Disposal considerations

Waste treatment methods
Waste disposal recommendations
Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.
Ecology - waste materials: Avoid release to the environment.

Section 14 Transport information

In accordance with ADR / RID / IMDG / IATA / ADN
UN number: 2811
UN proper shipping name: Toxic solid, organic, n.o.s. (Alprostadil)
Transport hazard class(es): 6.1 POISON
Packing group: III
Environmental hazards
Other information: No supplementary information available.

Special precautions for user
Added DOT regulation as "Toxic solids, n.o.s. per Federal Register Part IV section 173.133 establishing new criteria for assignment of packing groups to poisonous (Division 6.1) materials. This amendment to the toxicity criteria was adopted to be consistent with the criteria adopted in the UN Recommendations based on the limits established in GHS. As a result, substances that were not previously regulated would now be regulated as Division 6.1, Packing Group III. The new Oral LD50 criteria for Hazard Class 6.1, PG III is greater than 200 mg/kg to equal to or less than 300 mg/kg.

Section 15 Regulation information

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

<table>
<thead>
<tr>
<th>CAS #</th>
<th>Hazardous Components (Chemical Name)</th>
<th>S. 302 (EHS)</th>
<th>S. 304 RQ</th>
<th>S. 313 (TRI)</th>
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<tbody>
<tr>
<td>745-65-3</td>
<td>Prostaglandin E1</td>
<td>No</td>
<td>No</td>
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</table>

<table>
<thead>
<tr>
<th>CAS #</th>
<th>Hazardous Components (Chemical Name)</th>
<th>Other US EPA or State Lists</th>
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<tr>
<td>745-65-3</td>
<td>Prostaglandin E1</td>
<td>CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No</td>
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Alprostadil USP

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Section 15 Regulation information (continued)

<table>
<thead>
<tr>
<th>EU-Regulations</th>
<th>No additional information available</th>
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</thead>
<tbody>
<tr>
<td>National regulations</td>
<td>No additional information available</td>
</tr>
<tr>
<td>Chemical safety assessment</td>
<td>No chemical safety assessment has been carried out</td>
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</table>

Section 16 Other information

Further information: This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

Notice to reader:
Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.