# U.S. Pharmacopeial Convention

# SAFETY DATA SHEET

## 1. Identification

Product identifier Alpha Tocopheryl Acid Succinate

Other means of identification

 Catalog number
 1667803

 CAS number
 4345-03-3

Synonyms Vitamin E succinate

Chemical name 4-oxo-4-(((S)-2,5,7,8-tetramethyl-2-((4S,8S)-4,8,12-trimethyltridecyl)chroman-6-yl)oxy)butanoic

acid

**Recommended use** Specified quality tests and assay 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** RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.
Health hazards Not classified.
Environmental hazards Not classified.
OSHA defined hazards Not classified.

Label elements

Hazard symbol None.
Signal word None.

Hazard statement Not available.

**Precautionary statement** 

PreventionNot available.ResponseNot available.StorageNot available.DisposalNot available.

Hazard(s) not otherwise

classified (HNOC) The physical properties of this material indicate that in large quantities accumulated dust may be

This product is supplied in a small quantity which does not constitute a combustible dust hazard.

hazardous.

Supplemental information None.

# 3. Composition/information on ingredients

#### **Substance**

Chemical name	Common name and synonyms	CAS number	%	
Alpha Tocopheryl Acid Succinate	Vitamin E succinate	4345-03-3	100	

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#### 4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Rinse skin with water/shower. Get medical attention if irritation develops and persists. Skin contact

Rinse with water. Get medical attention if irritation develops and persists. Eye contact

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Ingestion

Most important

symptoms/effects, acute and

delaved

Not available.

**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

Special protective equipment

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

and precautions for firefighters

Wear suitable protective equipment.

Fire fighting equipment/instructions

Specific methods

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.

Use standard firefighting procedures and consider the hazards of other involved materials.

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. Wear appropriate protective equipment and clothing during clean-up.

Methods and materials for containment and cleaning up For waste disposal, see section 13 of the SDS. 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.

**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 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. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). 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 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

Occupational exposure limits

No exposure limits noted for ingredient(s).

**Biological limit values** 

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

Appropriate engineering controls

For laboratory operations, use good technique and limit open handling. 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.

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## Individual protection measures, such as personal protective equipment

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Eye/face protection

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

considerations

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved Hand protection

or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and Other

solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias)

or out-of-doors.

Respirators are generally not required for laboratory operations. Choose respiratory protection Respiratory protection

appropriate to the task and the level of existing engineering controls.

Thermal hazards Not available.

Handling practices in this SDS are recommendations for laboratory use of reference standards. General hygiene

Procedures for any other uses or quantities should be determined after an appropriate

# 9. Physical and chemical properties

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

Physical state Solid.

Crystalline powder. **Form** 

Color White.

Odor Not available. Odor threshold Not available. Ha Not available. 168.8 °F (76 °C) Melting point/freezing point Initial boiling point and boiling Not available.

range

Not available. Flash point **Evaporation rate** Not available. Not available. Flammability (solid, gas) 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. Not available. Vapor pressure Not available. Vapor density Relative density Not available.

Solubility(ies)

Solubility (water) Practically insoluble

Organic solvents: Soluble. Solubility (other)

**Auto-ignition temperature** Not available. Not available. **Decomposition temperature** Not available. **Viscosity** 

Other information

Chemical family Benzopyran derivative; ester.

**Dust explosion properties** 

133 bar.m/s Kst Molecular formula C33H54O5 Molecular weight 530.8 Specific gravity 0.6

# 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 Oxidizing agents. Alkalis.

**Hazardous decomposition** 

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

#### Information on likely routes of exposure

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.Eye contactKnowledge about health hazard is incomplete.

**Ingestion** Health injuries are not known or expected under normal use.

Symptoms related to the

physical, chemical, and

toxicological characteristics

Not available.

### Information on toxicological effects

#### Acute toxicity

Product Species Test Results

Alpha Tocopheryl Acid Succinate (CAS 4345-03-3)

Oral

LD50 Rat > 7 g/kg

**Skin corrosion/irritation**Based on available data, the classification criteria are not met.

Serious eye damage/eye

irritation

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

# **Local effects**

Eye irritation Result: Negative. Species: Rabbit Skin irritation Result: Negative. 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 Knowledge about mutagenicity is incomplete.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

# OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

### US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

# **Reproductive toxicity** Knowledge about health hazard is incomplete.

#### Reproductivity

150 - 300 mg/kg/day Reproductivity, administered

subcutaneously during gestation.

Result: Increase in incidences of cleft palate

Species: Mouse

2252 mg/kg/day Reproductivity

Result: No fetotoxicity or increase in birth defects in offspring.

Species: Rat

## Reproductivity

Reproductivity, Human case-control study

Result: High maternal intake of Vitamin E was associated

with an increased of congenital heart defects.

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.

# 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
Bioaccumulative potential
Mobility in soil
Not available.
Not 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 in accordance with all applicable 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 of in accordance with local 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 Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

# 14. Transport information

#### DOT

Not regulated as dangerous goods.

#### **IATA**

Not regulated as dangerous goods.

Transport in bulk according to

Annex II of MARPOL 73/78 and

the IBC Code

General information It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

Not available.

## 15. Regulatory information

**US** federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard

Communication Standard, 29 CFR 1910.1200.

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)** 

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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

Hazard categories Immediate Hazard - No

Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No

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# SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous Yes

chemical

SARA 313 (TRI reporting)

Not regulated.

#### Other federal regulations

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

Not regulated.

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

Not regulated.

Safe Drinking Water Act

Not regulated.

Inventory name

(SDWA)

US state regulations This product does not contain a chemical known to the State of California to cause cancer, birth

defects or other reproductive harm.

## **International Inventories**

Country(s) or region

Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
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)	Yes

Korea Existing Chemicals List (ECL) Yes New Zealand New Zealand Inventory Yes Philippine Inventory of Chemicals and Chemical Substances **Philippines** Yes

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory Yes

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

08-29-2011 Issue date 10-23-2018 **Revision date** 

Version # 02

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the **Further information** 

Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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On inventory (yes/no)\*

<sup>\*</sup>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).