

1. Identification

Product identifier	Antithrombin III Human	
Other means of identification		
Catalog number	1040504	
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		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
Telephone	RS 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

Note	Contains material of human origin. The source material has been tested and found negative for HBsAg, anti-HIV, and HCV RNA. As with all materials of biological origin, this material should be regarded as potentially hazardous to health.	
Physical hazards	Not classified.	
Health hazards	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A
	Specific target organ toxicity, single exposure	Category 3 respiratory tract irritation
OSHA hazard(s)	Not classified.	
Label elements		
Signal word	Warning	
Hazard statement	Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.	
Precautionary statement		
Prevention	Use only outdoors or in a well-ventilated area. Wash thoroughly after handling. Wear protective gloves. Wear eye/face protection.	
Response	If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. 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.	
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	Not classified.	

3. Composition/information on ingredients

Mixture

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Sodium Chloride		7647-14-5	34.35
Tromethamine		77-86-1	21.38

Non-hazardous components

Chemical name	Common name and synonyms	CAS number	%
Human Serum Albumin		70024-90-7	35.05
Trehalose		6138-23-4	7.01
Anti-thrombin III Human		9000-94-6	2.21

4. First-aid measures

Inhalation	Move to fresh air. Call a POISON CENTER or doctor/physician if you feel unwell.
Skin contact	Remove contaminated clothing. Wash off with soap and plenty of water. If skin irritation occurs: Get medical advice/attention.
Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
Most important symptoms/effects, acute and delayed	Irritation of eyes, skin, and mucous membranes.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
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	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.
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	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Absorb spillage with suitable absorbent material wetted with a virucidal agent. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination. Wash spill site with a virucidal agent. Absorbent materials used to treat spillage should be treated as biologically hazardous waste.

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.
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

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.
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.
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.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing 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	Lyophilized powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	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.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.

Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents. Acids. Bases. Lithium. Bromine trifluoride.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx, Cl-, NaOx.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Based on available data, the classification criteria are not met.
Inhalation	May cause irritation to the respiratory system.
Skin contact	Causes skin irritation.
Eye contact	Causes serious eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics Gastrointestinal disturbances. Cramps. Thirst. Unpleasant taste. Headache. Dizziness. Tiredness. Confusion. Irritability. Muscle twitching, spasms, or weakness. Numbness of the face and extremities. Ringing in ears. Fever. Seizures. Difficulty breathing. Chest tightness.

Delayed and immediate effects of exposure Low blood pressure. Respiratory depression. Hypoglycemia. Alkalosis. Coma.

Medical conditions aggravated by exposure Hypertension. Pulmonary edema. Impaired cardiac function. Impaired kidney function. Hypernatremia. Anuria. Respiratory acidosis. Coagulation disorders.

Acute toxicity

Components	Species	Test Results
Sodium Chloride (CAS 7647-14-5)		
Acute		
<i>Oral</i>		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg
<i>Other</i>		
LD50	Mouse	2602 mg/kg
Trehalose (CAS 6138-23-4)		
<i>Oral</i>		
LD50	Mouse	> 5000 mg/kg
	Rat	> 5000 mg/kg
Tromethamine (CAS 77-86-1)		
Acute		
<i>Oral</i>		
LD50	Rat	5900 mg/kg

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes serious eye irritation.

Local effects

Tromethamine	500 mg Irritancy test Result: Irritant. Species: Rabbit Organ: Skin Severity: Severe
Sodium Chloride	Irritancy Result: Moderate; mild Species: Rabbit Organ: Eye Irritancy Result: Moderate; mild Species: Rabbit Organ: Skin
Trehalose	Irritancy test Result: Non-irritant. Species: Rabbit Organ: Eye.

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 Due to lack of data the classification is not possible.
Data from germ cell mutagenicity tests were not found.

Mutagenicity
Trehalose

Chinese hamster ovary cell chromosomal aberration
Result: Negative (with and without activation).
Mouse micronucleus formation
Result: Negative (with and without activation).
S. typhimurium reverse mutation assay
Result: Negative (with and without activation).

Carcinogenicity

Due to lack of data the classification is not possible.

Reproductive toxicity

Due to lack of data the classification is not possible.

Reproductivity

Tromethamine

100 - 300 mg/kg/day Reproductivity and development study in rats (OECD 421)
Result: High dose group experienced post-implantation loss and decreased litter size.

30 - 300 mg/kg/day Development study in pregnant rats (OECD 414), administered dermally
Result: No evidence of maternal or developmental toxicity. High dose group had scabbing and moderate to severe scaling at test site.

Observation Period: 15 days

< 5 g/kg Reproductivity study

Result: No reproductive effects were seen.

Species: Rat

< 6.9 g/kg Reproductivity study

Result: No evidence of developmental toxicity.

Species: Rat

<= 2.8 g/kg Reproductivity study

Result: No evidence of developmental toxicity.

Species: Rabbit

Reproductivity and development studies in rats and rabbits, administered in doses four times the human dose.

Result: No evidence of impaired fertility or harm to the fetus.

Trehalose

Anti-thrombin III Human

Specific target organ toxicity - single exposure

Respiratory tract irritation.

Specific target organ toxicity - repeated exposure

Due to lack of data the classification is not possible.

Aspiration hazard

Due to lack of data the classification is not possible.

12. Ecological information

Ecotoxicity

Components		Species	Test Results
Sodium Chloride (CAS 7647-14-5)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	340.7 - 469.2 mg/l, 48 hours
Fish	LC50	American eel (Anguilla rostrata)	0 - 27260 mg/l, 96 hours

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 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

Not available.

Hazardous waste code

Not available.

Waste from residues / unused products

Dispose of in accordance with local regulations. 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

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

General information DOT Regulated Marine Pollutant. IMDG Regulated Marine Pollutant.

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)

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

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
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)	No
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)	No
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

Issue date 06-19-2015

Version # 01

Further information Not available.

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