

SAFETY DATA SHEET

ANGUS CHEMICAL COMPANY

Product name: TRIS AMINO ULTRA PURE USP/EP

Biologics Grade

Revision Date: 04/06/2023 Date of last issue: 03/20/2023 Date of first issue: 08/09/2018

ANGUS CHEMICAL COMPANY encourages and expects you to read and understand the entire (M)SDS, as there is important information throughout the document. We expect you to follow the precautions identified in this document unless your use conditions would necessitate other appropriate methods or actions.

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : TRIS AMINO ULTRA PURE USP/EP Biologics Grade

Manufacturer or supplier's details

Company name of supplier Address

: 150

ANGUS CHEMICAL COMPANY 1500 E. LAKE COOK ROAD Buffalo Grove IL 60089-6553

Customer Information Number +1-847-808-3711

E-mail address NAR_CC@ANGUS.COM

Emergency telephone

number

+1 800-424-9300 (24x7)

Recommended use : Biological buffer.

Pharmaceutical intermediate.

For industrial use.

The ANGUS Chemical Company recommends that you use this product in a manner consistent with the listed use. If your intended use is not consistent with the stated use, please contact the Customer Information Group (see Section 1 of this

data sheet).

2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

Date of last issue: 03/20/2023 Product name: TRIS AMINO ULTRA PURE USP/EP

Biologics Grade

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a substance.

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------------------------|---------|-----------------------|
| | 77-86-1 | >= 99 |
| Tris(hydroxymethyl)aminomethane | | |
| | | |

4. FIRST AID MEASURES

Move person to fresh air; if effects occur, consult a physician. If inhaled

Wash off with plenty of water. In case of skin contact

Flush eyes thoroughly with water for several minutes. In case of eye contact

Remove contact lenses after the initial 1-2 minutes and continue flushing for several additional minutes. If effects occur, consult a physician, preferably an ophthalmologist.

If swallowed No emergency medical treatment necessary. None known.

Most important symptoms

and effects, both acute and

delayed

Protection of first-aiders If potential for exposure exists refer to Section 8 for specific

personal protective equipment.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water.

> Carbon dioxide fire extinguishers. Dry chemical fire extinguishers.

Specific hazards during

firefighting

Pneumatic conveying and other mechanical handling operations can generate combustible dust. To reduce the

potential for dust explosions, do not permit dust to

accumulate.

Container may rupture from gas generation in a fire situation.

Hazardous combustion

products

During a fire, smoke may contain the original material in

addition to combustion products of varying composition which

may be toxic and/or irritating.

Combustion products may include and are not limited to:

Carbon dioxide. Carbon monoxide. Nitrogen oxides.

Further information Hand held dry chemical or carbon dioxide extinguishers may

be used for small fires.

Soak thoroughly with water to cool and prevent re-ignition. Keep people away. Isolate fire and deny unnecessary entry.

Biologics Grade

Fight fire from protected location or safe distance. Consider the use of unmanned hose holders or monitor nozzles. Immediately withdraw all personnel from the area in case of rising sound from venting safety device or discoloration of the

container.

Move container from fire area if this is possible without

hazard.

Use water spray to cool fire exposed containers and fire affected zone until fire is out and danger of reignition has

passed.

Special protective equipment :

for firefighters

Wear positive-pressure self-contained breathing apparatus (SCBA) and protective fire fighting clothing (includes fire

(SCBA) and protective fire fighting clothing (includes fire fighting helmet, coat, trousers, boots, and gloves).

If protective equipment is not available or not used, fight fire

from a protected location or safe distance.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures Keep unnecessary and unprotected personnel from entering

the area.

Use appropriate safety equipment. For additional information, refer to Section 8, Exposure Controls and Personal Protection.

Environmental precautions

Prevent from entering into soil, ditches, sewers, waterways and/or groundwater. See Section 12, Ecological Information.

Methods and materials for containment and cleaning up

Contain spilled material if possible.

Collect in suitable and properly labeled containers. Use care to minimize generation of airborne dust. See Section 13, Disposal Considerations, for additional

information.

7. HANDLING AND STORAGE

Advice on safe handling : Avoid generating and breathing dust.

Good housekeeping and controlling of dusts are necessary for

safe handling of product. Keep container closed.

See Section 8, EXPOSURE CONTROLS AND PERSONAL

PROTECTION.

Conditions for safe storage : Store in

Store in a dry place. Do not store in:

7inc

Galvanized containers.

Aluminum. Copper. Copper alloys.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Biologics Grade

Engineering measures : Local exhaust ventilation may be necessary for some

operations.

Use local exhaust ventilation, or other engineering controls to maintain airborne levels below exposure limit requirements or

guidelines. If there are no applicable exposure limit requirements or guidelines, general ventilation should be

sufficient for most operations.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally

required.

Hand protection

Remarks : Use gloves chemically resistant to this material when

prolonged or frequently repeated contact could occur. Examples of preferred glove barrier materials include:

Neoprene. Polyvinyl chloride ("PVC" or "vinyl").

Nitrile/butadiene rubber ("nitrile" or "NBR"). NOTICE: The selection of a specific glove for a particular application and duration of use in a workplace should also take into account all relevant workplace factors such as, but not limited to:

Other chemicals which may be handled, physical

requirements (cut/puncture protection, dexterity, thermal protection), potential body reactions to glove materials, as well as the instructions/specifications provided by the glove

supplier

Eye protection : Use safety glasses (with side shields). Skin and body protection : Wear clean, body-covering clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Crystals

Colour : White

Odour : Odorless

Odour Threshold : No test data available

pH : 10.4

Method: Literature 1% aqueous solution.

Melting point/range : 340 - 342 °F / 171 - 172 °C

Method: Literature

Freezing point 340 - 342 °F / 171 - 172 °C

Method: Literature

Boiling point/boiling range : Not applicable

Flash point : Method: closed cup

Not applicable

Evaporation rate : No test data available

Biologics Grade

Upper explosion limit / Upper :

flammability limit

No test data available

Lower explosion limit / Lower :

flammability limit

No test data available

Vapour pressure : Method: Literature

Ni

Relative vapour density : Not applicable

Partition coefficient: n-

octanol/water

: log Pow: -2.31 (68 °F / 20 °C) Method: OECD Test Guideline 107

Bioconcentration potential is low (BCF < 100 or Log Pow < 3).

Auto-ignition temperature : No test data available

Decomposition temperature : No test data available

Viscosity

Viscosity, kinematic : Not applicable

Molecular weight : 121.14 g/mol

Method: Calculated.

Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Hygroscopic

Stable under recommended storage conditions. See Storage,

Section 7.

Possibility of hazardous

reactions

Polymerization will not occur.

Conditions to avoid : Exposure to elevated temperatures can cause product to

decompose.

Generation of gas during decomposition can cause pressure

in closed systems. Avoid moisture.

Incompatible materials : Avoid contact with:

Strong acids.
Strong oxidizers.

Avoid contact with metals such as:

Zinc.

Galvanized metals.

Aluminum. Copper. Copper alloys.

Avoid unintended contact with: Halogenated hydrocarbons.

Hazardous decomposition

products

Decomposition products depend upon temperature, air supply

and the presence of other materials.

Decomposition products can include and are not limited to:

Biologics Grade

Carbon dioxide. Carbon monoxide. Nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Toxicological information on this product or its components appear in this section when such data is available.

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Remarks: Very low toxicity if swallowed.

Harmful effects not anticipated from swallowing small

amounts.

LD50 (Rat): > 5,000 mg/kg

Method: OECD Test Guideline 425

Symptoms: No deaths occurred at this concentration.

Acute dermal toxicity : Remarks: Prolonged skin contact is unlikely to result in

absorption of harmful amounts.

LD50 (Rat, male and female): > 5,000 mg/kg

Method: OECD 402 or equivalent

Symptoms: No deaths occurred at this concentration.

Skin corrosion/irritation

Not classified based on available information.

Product:

Species : Rabbit

Assessment : No skin irritation

Method : OECD Test Guideline 404

Remarks : Prolonged contact is essentially nonirritating to skin.

Brief contact is essentially nonirritating to skin.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Species : Rabbit

Assessment : No eye irritation

Method : OECD Test Guideline 405

Remarks : May cause slight temporary eye irritation.

Corneal injury is unlikely.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Biologics Grade

Product:

Remarks : For skin sensitization:

Did not cause allergic skin reactions when tested in guinea

pigs.

Remarks : For respiratory sensitization:

No relevant data found.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC No component of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Teratogenicity

Product

For similar material(s):

Did not cause birth defects or any other fetal effects in laboratory animals.

Mutagenicity

Product

For similar material(s):

In vitro genetic toxicity studies were negative.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Product:

Assessment : Evaluation of available data suggests that this material is not

an STOT-SE toxicant.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Product:

Species : Rat Application Route : Oral

Method : OECD Test Guideline 421

Remarks : Based on available data, repeated exposures are not

anticipated to cause significant adverse effects.

Date of last issue: 03/20/2023 Product name: TRIS AMINO ULTRA PURE USP/EP

Biologics Grade

Aspiration toxicity

Not classified based on available information.

Product:

Product test data not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Toxicity to fish

Remarks: Material is practically non-toxic to fish on an acute

basis (LC50 > 100 mg/L).

LC50 (zebra fish (Brachydanio rerio)): 460 mg/l

Exposure time: 96.0 h

Remarks: For similar material(s):

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 980.00 mg/l

Exposure time: 48.0 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): 397

mg/l

End point: Growth rate Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other :

aquatic invertebrates (Chronic toxicity)

NOEC (water flea Daphnia magna): 3.99 mg/l

End point: number of offspring

Exposure time: 21 d

Remarks: For similar material(s):

Components:

trometamol:

Toxicity to fish Remarks: Material is practically non-toxic to fish on an acute

basis (LC50 > 100 mg/L).

LC50 (zebra fish (Brachydanio rerio)): 460 mg/l

Exposure time: 96.0 h

Remarks: For similar material(s):

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 980.00 mg/l

Exposure time: 48.0 h

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): 397

mg/l

End point: Growth rate Exposure time: 72 h

Toxicity to daphnia and other : NOEC (water flea Daphnia magna): 3.99 mg/l

Product name: TRIS AMINO ULTRA PURE USP/EP

Biologics Grade

aquatic invertebrates End point: number of offspring

(Chronic toxicity) Exposure time: 21 d

Remarks: For similar material(s):

Persistence and degradability

Product:

Biodegradability : Result: Readily biodegradable.

Remarks: Material is readily biodegradable. Passes OECD

Date of last issue: 03/20/2023

test(s) for ready biodegradability.

Test Type: O2 consumption Biodegradation: 100 % Exposure time: 28 d

Method: OECD Test Guideline 301F Remarks: 10-day Window: Pass

Biochemical Oxygen

Demand (BOD)

0 %

Incubation time: 5 d

84%

Incubation time: 28 d

Photodegradation : Test Type: Half-life (indirect photolysis)

Sensitiser: OH radicals Rate constant: 3.35E-11 cm3/s

Method: Estimated.

Components:

trometamol:

Biodegradability : Result: Readily biodegradable.

Remarks: Material is readily biodegradable. Passes OECD

test(s) for ready biodegradability.

Biodegradation: 100 % Exposure time: 28 d

Method: OECD Test Guideline 301F or Equivalent

Remarks: 10-day Window: Pass

Bioaccumulative potential

Components:

trometamol:

Partition coefficient: n- : log Pow: -2.31 octanol/water : Method: Measured

Remarks: Bioconcentration potential is low (BCF < 100 or Log

Pow < 3).

Mobility in soil

Product:

Distribution among : Koc: 22 - 75 environmental compartments Method: Estimated.

Biologics Grade

Remarks: Potential for mobility in soil is high (Koc between 50

and 150).

Components:

trometamol:

Distribution among : Koc: 75

environmental compartments Method: Estimated.

Remarks: Potential for mobility in soil is high (Koc between 50

and 150).

Other adverse effects

Product:

Endocrine disrupting

potential

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Components:

trometamol:

Results of PBT and vPvB

assessment

This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulating

(vPvB).

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : DO NOT DUMP INTO ANY SEWERS, ON THE GROUND,

OR INTO ANY BODY OF WATER.

All disposal practices must be in compliance with all Federal,

State/Provincial and local laws and regulations. Regulations may vary in different locations.

Waste characterizations and compliance with applicable laws

are the responsibility solely of the waste generator.

THE INFORMATION PRESENTED HERE PERTAINS ONLY TO THE PRODUCT AS SHIPPED IN ITS INTENDED

CONDITION AS DESCRIBED IN MSDS SECTION:

Composition Information.

FOR UNUSED & UNCONTAMINATED PRODUCT, the preferred options include sending to a licensed, permitted:

Incinerator or other thermal destruction device.

Landfill.

ANGUS HAS NO CONTROL OVER THE MANAGEMENT PRACTICES OR MANUFACTURING PROCESSES OF PARTIES HANDLING OR USING THIS MATERIAL.

Biologics Grade

14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

Special precautions for user

Not applicable

This information is not intended to convey all specific regulatory or operational requirements/information relating to this product. Transportation classifications may vary by container volume and may be influenced by regional or country variations in regulations. Additional transportation system information can be obtained through an authorized sales or customer service representative. It is the responsibility of the transporting organization to follow all applicable laws, regulations and rules relating to the transportation of the material.

15. REGULATORY INFORMATION

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

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

Biologics Grade

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

trometamol 77-86-1

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

New Jersey Right To Know

trometamol 77-86-1

California Prop. 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

The components of this product are reported in the following inventories:

TSCA : All substances listed as active on the TSCA inventory y

(positive listing)

TSCA list

No substances are subject to a Significant New Use Rule.

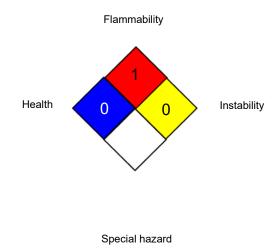
No substances are subject to TSCA 12(b) export notification requirements.

16. OTHER INFORMATION

Further information

Biologics Grade

NFPA 704:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AllC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx -Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS -Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA -International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO -International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL -Industrial Safety and Health Law (Japan): ISO - International Organisation for Standardization: KECI -Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 -Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Biologics Grade

Revision Date 04/06/2023

Version 0.0

Identification Number: 000040004635

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.

US / EN