

# SAFETY DATA SHEET



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Version 1.0

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## 1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND THE COMPANY / UNDERTAKING

### Product Identifier

**Material Name:** Aminosyn Injection

Trade Name: Not established

Synonyms: None

Chemical Family: Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

### Details of the supplier of the Safety Data Sheet:

ICU Medical, Inc.  
275 North Field Drive  
Lake Forest, IL 60045  
(844) 654-7780

### Emergency Telephone Number:

Phone: 1-(800) 241-4002, Option 6  
CHEMTREC (24 hours): 1-800-424-9300  
email: MedInfo\_US@icumed.onmicrosoft.com

## 2. HAZARD IDENTIFICATION

### Classification of the Substance or Mixture

**GHS – Classification** Not classified as hazardous

### Label Elements

**Signal Word:** Not classified

**Hazard Statements:** Not classified in accordance with international standards for workplace safety

**Other Hazards:** No data available

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

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## 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS / ELINCS List	GHS Classification	%
L-Glutamic Acid	56-86-0	200-293-7	Not Listed	<1.5
Aspartic Acid	56-84-8	200-291-6	Not Listed	<1.5
Arginine	74-79-3	200-811-1	Not Listed	<2
Tyrosine	60-18-4	200-460-4	Not Listed	<1
Leucine	328-39-2	206-328-2	Not Listed	<2
Isoleucine	73-32-5	200-798-2	Not Listed	<1.5
Taurine	107-35-7	203-483-8	Not Listed	<0.2
Phenylalanine	63-91-2	200-568-1	Not Listed	<0.5
Histidine	71-00-1	200-745-3	Not Listed	<0.5
Methionine	63-68-3	200-562-9	Not Listed	<0.5
Serine	56-45-1	200-274-3	Not Listed	<1
Threonine	72-19-5	200-774-1	Not Listed	<1
Valine	72-18-4	200-773-6	Not Listed	<1
Proline	147-85-3	205-702-2	Not Listed	<1.5
Lysine Acetate	52315-76-1	257-845-5	Not Listed	<3
Alanine	56-41-7	200-273-8	Not Listed	<2
Glycine	56-40-6	200-272-2	Not Listed	<2
N-Acetyl-L-Tyrosine	537-55-3	208-671-3	Eye Damage (H318)	< 0.5
Tryptophan	73-22-3	200-795-6	Not Listed	<0.5
Water for Injection, USP	7732-18-5	231-791-2	Not Listed	>80

**Additional Information:** Ingredient indicated as hazardous has been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For full text of the CLP/GHS abbreviation mentioned in this section, see Section 16.

## 4. FIRST AID MEASURES

### Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. If irritation occurs or persists, obtain medical attention.

**Skin Contact:** If irritation occurs, wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash mouth out with water and obtain medical attention immediately. Do not induce vomiting unless directed by medical personnel.

**Inhalation:** Not an expected route of exposure.

### Most Important Symptoms and Effects, Both Acute and Delayed

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**Symptoms and Effects of Exposure:** No data available

**Medical Conditions Aggravated by Exposure:** None Known

**Indication of the Immediate Medical Attention and Special Treatment Needed Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, dry chemical, foam, or water.

### Special Hazards Arising from the Substance or Mixture

#### Hazardous Combustion

**Products:** Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

**Fire / Explosion Hazards:** Not applicable

### Advice for Firefighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### Methods and Material for Containment and Cleaning Up

#### Measures for Cleaning /

**Collecting:** Contain the source of the spill, if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

#### Additional Consideration for

**Large Spills:** None

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment.

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## Conditions for safe storage, including any incompatibilities

**Storage Conditions:** Store as directed by product packaging

**Incompatible Materials:** None

Specific End Use(s): Pharmaceutical drug product

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

### Personal Protective

**Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Eye Protection:** Wear safety glasses or goggles if eye contact is possible.

**Hand Protection:** Impervious gloves (e.g. nitrile, etc.) are recommended if skin contact with drug product is possible for bulk processing operations.

**Skin Protection:** Impervious protective clothing is recommended if skin contact with drug product is possible for bulk processing conditions.

**Respiratory protection:** None required under normal conditions of use.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless
<b>Odor:</b>	None	<b>Odor Threshold:</b>	No data available
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH</b>	5.0-6.5		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Partition Coefficient:</b>	No data available		
<b>Decomposition Temperature (°C):</b>	No data available		
<b>Evaporation Rate (gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	1.02 – 1.05 g/mL at 25 deg. C		
<b>Viscosity:</b>	1.03 – 1.62 cps at 25 deg. C		

### Flammability:

<b>Autoignition Temperature (Solid)(°C):</b>	No data available
<b>Flammability (solids):</b>	No data available
<b>Flash Point (Liquid)(°C):</b>	No data available
<b>Upper Explosive Limits (Liquid)(% by vol.)</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by vol.)</b>	No data available

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## 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use
<b>Possibility of Hazardous Reactions:</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	None
<b>Incompatible Materials:</b>	None
<b>Hazardous Decomposition:</b>	No data available
<b>Products:</b>	

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

#### General Information:

The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

#### L Glutamic Acid

Human intravenous TDLo50 117 mg/kg

#### Leucine

Rat intraperitoneal LD50 5379 mg/kg

#### Isoleucine, USP

Rat intraperitoneal LD50 6822 mg/kg

#### Tyrosine, USP

Mouse intraperitoneal LD50 1450 mg/kg

#### Phenylalanine

Rat intraperitoneal LD50 5287 mg/kg

Rabbit intraperitoneal LD50 1322 mg/kg

#### Taurine

Rat Oral LD50 5000 mg/kg

Rat Intravenous LD50 7000 mg/kg

Mouse Oral LD50 7000 mg/kg

#### Histidine

Rat Oral LD50 15000 mg/kg

Rat intravenous LD50 2000 mg/kg

Mouse Oral LD50 15000mg/kg

Mouse intravenous LD50 2000mg/kg

#### Methionine

Rat Oral LD50 36000 mg/kg

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## **Threonine**

Rat intraperitoneal LD50 3098 mg/kg

## **Valine**

Rat intraperitoneal LD50 5390 mg/kg

## **Glycine**

Rat Oral LD50 7930 mg/kg

Rat intravenous LD50 2600 mg/kg

Mouse Oral LD50 4920 mg/kg

Mouse intravenous LD50 2370mg/kg

## **Tryptophan**

Human Oral LD50 1300 mg/kg

## **Aspartic Acid**

Rat Oral TDLo 3000 mg/kg

## **Lysine Acetate**

Rat intravenous LD50 2850 mg/kg

Mouse intravenous LD50 3200 mg/kg

## 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Releases to the environment should be avoided. No acute toxicity to aquatic organisms is expected.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

## 13. DISPOSAL CONSIDERATIONS

<b>Waste Treatment Methods:</b>	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
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## 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### L-Glutamic Acid

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-293-7

#### Aspartic Acid

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-291-6

#### Arginine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-811-1

#### Tyrosine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-460-4

#### Leucine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	206-328-2

#### Isoleucine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	627-025-5

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## Taurine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	203-483-8

## Phenylalanine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-568-1

## Histidine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-745-3

## Methionine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-562-9

## Serine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-274-3

## Threonine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-774-1

## Valine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-773-6

## Proline

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	205-702-2



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## Lysine Acetate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-294-2

## Alanine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	206-126-4

## Glycine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-272-2

## N-Acetyl-L-Tyrosine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	208-671-3

## Tryptophan

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	200-795-6

## Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory – United States TSCA	Present
Australia (AICS):	Present
EU EINECS / ELINCS List	231-791-2

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## 16. OTHER INFORMATION

### Text of CLP/GHS Classification abbreviations mentioned in Section 3

H318 – causes eye damage

**Data Sources:** Publicly available toxicity information.

**Reasons for Revision:** Company/Undertaking.

**Development date:** May 13, 2020

**Prepared by:** ICU Medical Environment, Health & Safety Department

ICU Medical believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**END OF SAFETY DATA SHEET**