MATERIAL SAFETY DATA SHEET

TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10ML (100MG/ML)

1. IDENTIFICATION					
Material Identification	:	Tranexamic Acid Injection Solution 1000mg/10ml (100mg/ml)			
Active ingredient	:	Tranexamic Acid			
Molecular Formula	:	$C_8H_{15}NO_2$	**Molecular Weight**	:	157.21 g/mol
CAS Number	:	1197-18-8			
Product Use	:	Antifibrinolytics			
Manufactured by	:	**Micro Labs Limited** Plot no. 113-116, KIADB, Bommasandra Industrial Area, Bommasandra-Jigani Link Road, Anekal taluk, Bangalore-560099, Karnataka, India	**Manufactured for**	:	**Armas Pharmaceuticals Inc. ("Distributor")** 151 Route 33 East, Suite 203, Manalapan, NJ 07726
Emergency Contact	:	+91-80-27839033			

2. HAZARDS IDENTIFICATION		
Label Elements		
Signal	:	Warning 
Physical hazards	:	Not classified
Hazard statements	:	H315: Causes skin irritation H319: Causes serious eye irritation H335: May cause respiratory irritation
Precautionary statements	:	None known
Hazard(s) not otherwise classified (HNOC)	:	None known

3. COMPOSITION/INFORMATION ON INGREDIENTS				
Chemical Name	**CAS #**	**EINECS #**	**% w/w**	**Label Elements EU classification (67/548/EEC) GHS US classification Risk phrases/Hazard statements**
Tranexamic Acid Cyclohexanecarboxylic Acid, 4-(aminomethyl)-trans	1197-18-8	214-818-2	Proprietary	EU 67/548/EEC: Classification: Serious eye damage/eye irritation Category 2A, Skin corrosion/ irritation Category 2, Specific target organ toxicity (single exposure) Category 3 Hazard codes: Eye Irrit. 2A, Skin Irrit. 2, STOT SE 3 GHS US: Classification: Causes skin irritation, eye irritation, may cause respiratory irritation Hazard codes: H315, H319, H335 Hazard symbol/Pictogram: GHS07, GHS08

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES		
Eyes Contact	:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact	:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation	:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
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 exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

5. FIRE FIGHTING MEASURES		
Extinguishing media	:	Use carbon dioxide, dry chemical, or water spray.
Firefighting instructions	:	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Protection during firefighting	:	During all fire fighting 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 Minimize exposure.
Measures for Cleaning / Collecting-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, state, and federal regulations.
Measures for Cleaning / Collecting-large spill	:	Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container for disposal.
Environmental precautions	:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

7. HANDLING AND STORAGE		
Precautions for safe handling	:	Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Keep locked up. Keep away from heat, sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material.
Hygiene measures	:	Do not ingest. Avoid contact with skin. Wear suitable protective clothing in case of insufficient ventilation. If you feel unwell, seek medical attention and show label when possible. Use only in accordance with directions.

Conditions for safe storage, including any incompatibilities		
Storage conditions	:	Store at 25°C (77°F); excursions permitted to 15°C TO 30°C (59°F TO 86°F).
Incompatible products	:	Strong oxidizers. Strong acids.
Incompatible materials	:	Keep away from strong oxidizing agents.
Specific end use(s)	:	No additional information available.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION		
Engineering Controls	:	No special ventilation requirements. May use process enclosure, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.
Personal Protective Equipment	:	Splash goggles. Lab coat. Nitrile or latex gloves. Respirator. Be sure to use an approved/ certified respirator or equivalent. In case of large spill, splash goggles. Full suit. Respirator. Boots. Nitrile or latex gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist before handling this product.
Respiratory Protection	:	Under normal use, respirators are not required. If vapor or mists are generated, use a disposable mask (N95). Personnel wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.
Hands	:	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eye Protection	:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin protection	:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
9. PHYSICAL AND CHEMICAL PROPERTIES		
Physical State	:	Injection
Color	:	Clear colorless solution
Appearance	:	Tranexamic Acid Injection Solution 1000mg/10ml (100mg/ml): Clear colorless solution, practically free from visible particles.
Molecular Formula	:	$C_8H_{15}NO_2$
Molecular Weight	:	157.21 g/mol
10. STABILITY AND REACTIVITY		
Reactivity	:	Reactive with oxidizing agents.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Non-hazardous

Conditions to Avoid	:	Excess heat, light, oxidizing agents, air contact.
Incompatible Materials	:	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	:	Nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity :

Toxic if swallowed.

Ingredient	Percent	Test type	Route of Administration	Value	Units	Species
Tranexamic Acid	100	LD50	Oral	>10,000 >10,000	mg/kg mg/kg	Rat Mouse
Tranexamic Acid	100	LD50	Intravenous	1,350 1,330	mg/kg mg/kg	Mouse Rat
Tranexamic Acid	100	LD50	Subcutaneous	4,620	mg/kg	Rat

Signs and Symptoms :

Short term: Hazardous in case of skin contact (irritant), of ingestion (with nausea vomiting and diarrhea), of inhalation (irritant).

Long term: Prolonged or repeated ingestion may affect metabolism. The toxicological properties of this substance have not been fully investigated.

Reproduction & Developmental Toxicity :

Ingredient	Stage of reproduction	Test type	Route of Administration	Value	Units	Species
Tranexamic Acid	Embryo/Fetal development	LD50	Oral	300 300	mg/kg mg/kg	Rat Mouse
Tranexamic Acid	Reproductive & Fertility	LD50	No route specified	NA	NA	Mouse Rat

Dermal Irritation/ Corrosion : Not specified

Ocular Irritation/ Corrosion : Not specified

Dermal or Respiratory Sensitization : Not specified

Germ cell mutagenicity : Not specified

Carcinogenicity :

Ingredient	Test type	Route of Administration	Value	Units	Species
Tranexamic Acid	LD50	Oral	5	g/kg/day	Mouse

IARC: : No data available

NTP: : No data available

12. ECOLOGICAL INFORMATION

Aquatic Toxicity: : No data available

Persistence and degradability	:	Possibly hazardous short-term degradation products are not likely. However, long term degradation products may arise.
Bioaccumulative potential	:	No data available
Mobility in soil	:	No data available
Effect on ozone layer	:	No data available
Other information	:	No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods	:	Dispose of waste in accordance with all applicable federal, state and local laws.

14. TRANSPORTATION INFORMATION

Environmental hazards	:	No data available
Special precautions for user	:	No data available
Transport hazard class(es)	:	No data available
Packing group	:	No data available
IATA UN number	:	No data available
Environmental hazards	:	No data available
Special precautions for user	:	No data available

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

15. REGULATORY / STATUTORY INFORMATION

This safety data sheet complies with the requirements of WHMIS (Canada), OSHA 1910.1200 (US), and EU Regulation EC No. 1907/2006 (European Union).

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

A) EU Indication of danger: Not classified
B) OSHA Label: Non-hazardous in accordance with international standards for workplace safety.
C) Canada - WHMIS Classifications: None required
D) United States - TSCA Status: This product is not listed on the US EPA TSCA
E) European Union - ECHA Status: This product is not registered with the EU ECHA.

15.2 Chemical Safety Assessment
No data available

16. OTHER INFORMATION

Date of preparation: 27/05/21

Other information: None.
NFPA health hazard: 1 – May ccause health issues
NFPA fire hazard: 0 - Materials that will not burn.

NFPA reactivity: 0 - Normally stable, even under fire exposure conditions and are not reactive with water.
HMIS III Rating
Health: 1 Slight Hazard
Flammability: 0 Minimal Hazard
Physical: 0 Minimal Hazard
Personal Protection: E

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End of Safety Data Sheet