



MATERIAL SAFETY DATA SHEET

Revision date: 22-Jul-2009

Version: 1.3

Page 1 of 5

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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Material Name: Tranexamic Acid Solution for Injection

Trade Name: CYKLOKAPRON®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as blood clotting agent

2. HAZARDS IDENTIFICATION

Appearance: Colorless solution

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Short Term: May cause eye irritation; Not acutely toxic (based on animal data) . May produce allergic reactions after systemic administration.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include skin rash and gastrointestinal disturbances. Effects on blood and blood-forming organs have also occurred. Effects on vision have been seen during clinical use.

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Tranexamic Acid	1197-18-8	214-818-2	Not Listed	10

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Water	7732-18-5	231-791-2	Not Listed	*

TRANEXAMIC ACID AMPOULE

MATERIAL SAFETY DATA SHEET

Material Name: Tranexamic Acid Solution for Injection
Revision date: 22-Jul-2009

Page 2 of 5
Version: 1.3

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eye 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.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, and oxides of nitrogen may be generated in a fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

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

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage Conditions: Store in a cool, dry place away from light.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Tranexamic Acid
Pfizer OEL TWA-8 Hr: 1500µg/m³

MATERIAL SAFETY DATA SHEET

Material Name: Tranexamic Acid Solution for Injection
Revision date: 22-Jul-2009

Page 3 of 5
Version: 1.3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Aqueous solution	Color:	Colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture
pH:	6.5 - 8.0		

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Heat and light
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the active ingredient

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

Tranexamic Acid

Rat	Oral	LD 50	>10,000 mg/kg
Mouse	Oral	LD 50	>10,000 mg/kg
Rat	Intravenous	LD 50	1,330 mg/kg
Mouse	Intravenous	LD 50	1,350 mg/kg
Rat	Subcutaneous	LD 50	4,620 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Tranexamic Acid

6 Month(s)	Rat	Oral	4,000 mg/kg/day	LOAEL	Gastrointestinal system, Spleen
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MATERIAL SAFETY DATA SHEET

Material Name: Tranexamic Acid Solution for Injection
Revision date: 22-Jul-2009

Page 4 of 5
Version: 1.3

11. TOXICOLOGICAL INFORMATION

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Tranexamic Acid

Embryo / Fetal Development	Rat	Oral	300 mg/kg/day	NOAEL	Not teratogenic
Embryo / Fetal Development	Mouse	Oral	300 mg/kg/day	NOAEL	Not Teratogenic
Reproductive & Fertility	Rat Rabbit Mouse		No route specified		No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Tranexamic Acid

<i>In Vivo</i>	Not specified	Negative
<i>In Vitro</i>	Not specified	Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Tranexamic Acid

Not specified	Mouse	Oral	5 g/kg/day	LOAEL	Immune system, Bone marrow
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Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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.

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

EU Indication of danger: Not classified

MATERIAL SAFETY DATA SHEET

Material Name: Tranexamic Acid Solution for Injection
Revision date: 22-Jul-2009

Page 5 of 5
Version: 1.3

15. REGULATORY INFORMATION

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Tranexamic Acid

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	214-818-2

Water

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 13 - Disposal Considerations.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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