# DIAPHARMA GROUP, INC.



# Safety Data Sheet Human alpha-Thrombin

# **SECTION 1: Identification**

# 1.1 Product identifier

Product nameHuman alpha-ThrombinProduct numberDPGEZ006A

# **1.2** Other means of identification

Human alpha-Thrombin, plasma protein

# 1.4 Supplier's details

Name Address	Diapharma Group, Inc. 8948 Beckett Rd West Chester, OH 45069 USA
Telephone	+1 (513) 860-9324
Fax	+1 (513) 860-9635
Email	info@diapharma.com

# **SECTION 2: Hazard identification**

# General hazard statement

Product of human plasma. Handle as if capable of transmitting infectious agents. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

# 2.1 Classification of the substance or mixture

GHS classification in accordance with OSHA (29 CFR 1910.1200) Not a hazardous substance or mixture.

**2.2 GHS label elements, including precautionary statements** Not a hazardous substance or mixture.

# 2.3 Other hazards which do not result in classification

This product is formulated from 10mM 2-(*N*-morpholino)ethanesulfonic acid (MES), 150mM NaCl, pH 6.5 with PEG 8000 at 20mg/mL and BSA at 10 mg/mL.

# **SECTION 3: Composition/information on ingredients**

### 3.2 Mixtures

# Hazardous components

Component
POLYETHYLENE GLYCOL (PEG) 6000 (CAS no.: 25322-68-3; EC no.: 500-038-2)
CLASSIFICATIONS: No data available. HAZARDS: No data available.
BOVINE SERUM ALBUMIN (BSA) (CAS no.: 9048-46-8)
CLASSIFICATIONS: No data available. HAZARDS: No data available.
2-(N-morpholino)ethanesulfonic acid (MES) (CAS no.: 145224-94-8)
CLASSIFICATIONS: No data available. HAZARDS: No data available.
Water (CAS no.: 7732-18-5)
CLASSIFICATIONS: No data available. HAZARDS: No data available.
Human alpha-Thrombin
CLASSIFICATIONS: No data available. HAZARDS: No data available.

# **SECTION 4: First-aid measures**

#### 4.1 Description of necessary first-aid measures

General advice	Consult a physician. Show this safety data sheet to the doctor in attendence. Move out of dangerous area.
If inhaled	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
In case of skin contact	Rinse with plenty of water. Get medical attention if irritation develops and persists.
In case of eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
If swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

- **4.2** Most important symptoms/effects, acute and delayed The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11
- **4.3** Indication of immediate medical attention and special treatment needed, if necessary No data available.

# **SECTION 5: Fire-fighting measures**

#### **5.1** Suitable extinguishing media Carbon dioxide, dry chemical powder, or appropriate foam. Water spray.

- 5.2 Specific hazards arising from the chemical No data available.
- **5.3** Special protective actions for fire-fighters Special firefighting precautions: wear self-contained breathing apparatus and protective clothing to prevent inhalation and contact with eyes and skin.

### **Further information**

No data available.

# **SECTION 6: Accidental release measures**

- 6.1 Personal precautions, protective equipment and emergency procedures Chemical safety goggles, protective clothing and shoes, and protective rubber gloves.
- 6.2 Environmental precautions No data available.
- 6.3 Methods and materials for containment and cleaning up

Blot-up liquid spills with absorbent paper. Decontaminate area by soaking with a 5% bleach solution (0.25% sodium hypochlorite), and allowing a 15 minute contact time. Dispose of all contaminated materials by autoclaving or by following your institutions guidelines for disposal of biohazard material.

### **Reference to other sections**

For disposal see section 13.

# **SECTION 7: Handling and storage**

### 7.1 Precautions for safe handling

Wear chemical resistant gloves, chemical safety goggles, and protective clothing.

Human source material from which this product was derived was found negative (or non-reactive) for anti-HIV-1/2, Syphilis (STD), anti-HCV-2.0, anti-HBcore antigen, and anti-HTLV-1/2, using approved test methods. Since no test method can offer complete assurance that infectious agents are absent, this product should be handled observing the same safety precautions employed when handling any potentially infectious materials.

# 7.2 Conditions for safe storage, including any incompatibilities

Store this material in a container that will contain any accidental leaks or spills. Store at the temperature indicated on the product data sheet.

### Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

# **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

### 8.2 Appropriate engineering controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

### 8.3 Individual protection measures, such as personal protective equipment (PPE)

# Pictograms



### **Eye/face protection**

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

### Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

# **Body protection**

Impervious clothing, Flame retardant antistatic protective clothing., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

#### **Respiratory protection**

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

### Thermal hazards

No data available.

### **Environmental exposure controls**

No data available.

# **SECTION 9: Physical and chemical properties**

# Information on basic physical and chemical properties

Appearance/form Odor Odor threshold pH Melting point/freezing point Initial boiling point and boiling range Flash point Evaporation rate Flammability (solid, gas) Upper/lower flammability limits Upper/lower explosive limits Vapor pressure Vapor density Relative density Solubility(ies) Partition coefficient: n-octanol/water Auto-ignition temperature Decomposition temperature Viscosity Explosive properties	Clear liquid None No data available. No data available.
Oxidizing properties	No data available. No data available.

# **SECTION 10: Stability and reactivity**

10.1 Reactivity

No data available.

- **10.2 Chemical stability** No data available.
- **10.3 Possibility of hazardous reactions** No data available.
- **10.4 Conditions to avoid** No data available.
- **10.5** Incompatible materials No data available.
- **10.6 Hazardous decomposition products** No data available.

# **SECTION 11: Toxicological information**

### Information on toxicological effects

Acute toxicity PEG 6000: LC50 Oral - Rat - 28,000 mg/kg LC50 Skin - Rabbit - >20,000 mg/kg

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# Skin corrosion/irritation No data available.

#### Serious eye damage/irritation No data available.

#### **Respiratory or skin sensitization** No data available.

#### Germ cell mutagenicity No data available.

**Carcinogenicity** No data available.

# Reproductive toxicity

No data available.

# Summary of evaluation of the CMR properties No data available.

# STOT-single exposure

No data available.

#### STOT-repeated exposure No data available.

# Aspiration hazard

No data available.

# Additional information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated; however:

May be harmful by inhalation, ingestion, or skin absorption. May cause irritation. Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

Human source material. The toxicological properties have not been thoroughly investigated.

# **SECTION 12: Ecological information**

**Toxicity** No data available.

**Persistence and degradability** No data available.

**Bioaccumulative potential** No data available.

Mobility in soil No data available.

# Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

### Other adverse effects

No data available.

# **SECTION 13: Disposal considerations**

#### Disposal of the product

Disposal should be done in accordance with the existing disposal practices employed for infectious waste at your institution.

#### Disposal of contaminated packaging

Soak with a 5% bleach solution (0.25% sodium hypochlorite), and allowing a 15 minute contact time. Dispose of all contaminated materials by autoclaving or by following your institutions guidelines for disposal of biohazard material.

# **SECTION 14: Transport information**

### DOT (US)

Not dangerous goods

IMDG Not dangerous goods

IATA Not dangerous goods

# **SECTION 15: Regulatory information**

#### 15.1 Safety, health and environmental regulations specific for the product in question

# SARA 302 Components

None present or none present in regulated quantities.

#### SARA 311/312 Hazards

Acute/Chronic Health Hazard

### SARA 313 Components

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.

# California Prop. 65 Components

No ingredient regulated by CA Prop 65 present.

#### US State Right To Know Components

POLYETHYLENE GLYCOL (PEG) 6000	CAS no.: 25322-68-3
BOVINE SERUM ALBUMIN (BSA)	CAS no.: 9048-46-8
2-(N-morpholino)ethanesulfonic acid (MES)	CAS no.: 145224-94-8

# **SECTION 16: Other information**

### 16.1 Further information/disclaimer

DISCLAIMER: The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigation to determine the suitability of information for their particular purposes. In no event shall Diapharma Group, Inc. be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, whatsoever arising, even if Diapharma Group, Inc. has been advised of the possibility of such damages.