Safety Data Sheet

Kinetichrome™ Heparin Anti-Xa Kit

**Section 1 - Identification of the Substance/Preparation and of the Company/Undertaking**

Manufacturer Information
Provision Kinetics, Inc
107 Skyline Drive
P.O. Box 289
Arlington, WI 53911-0289

Phone: 608-635-7777
Fax: 608-635-8818

Use of the Substance/Preparation:
Test Kit

Substance Registration Number(s):
None

Product is comprised of the following three Reagents and Components:
Factor Xa, bovine 25 µg
Xa Substrate, 6.25 mg \{Formula =CH₃0CO-(D)-CHA-Gly-Arg-pNA · AcOH\}
Antithrombin, human 5 IU

**Section 2 - Hazards Identification**

Substance/Preparation Classification
Xn (for Xa Substrate, 6.25 mg)

Human and Environmental Hazards
Toxic if swallowed. Causes skin, eye, and respiratory tract irritation.

Potential Health Effects: Eyes
Causes eye irritation

Potential Health Effects: Skin
Causes skin irritation.

Potential Health Effects: Ingestion
Not considered a likely route of exposure under normal product use conditions. Toxic if swallowed.

Potential Health Effects: Inhalation
Material may be irritating to mucous membranes and upper respiratory tract. May be harmful if inhaled.

**Section 3 - Composition/Information on Ingredients**

<table>
<thead>
<tr>
<th>EC #</th>
<th>Component</th>
<th>Percent</th>
<th>Symbols</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>214-684-5</td>
<td>1,3-Propanediol, 2-amino-2-</td>
<td>63.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(hydroxymethyl)-, hydrochloride</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1185-53-1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>200-711-8</td>
<td>D-Mannitol 69-65-8</td>
<td>32.4</td>
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<td></td>
</tr>
<tr>
<td>232-936-2</td>
<td>Albumins, blood serum 9048-46-8</td>
<td>3.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-</td>
<td>Factor Xa</td>
<td>&lt;0.1</td>
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</table>
For Xa Substrate, 6.25 mg

<table>
<thead>
<tr>
<th>EC #</th>
<th>Component</th>
<th>Percent</th>
<th>Symbols</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>200-711-8</td>
<td>D-Mannitol</td>
<td>76</td>
<td></td>
<td></td>
</tr>
<tr>
<td>202-810-1</td>
<td>p-Nitroaniline (derivative)</td>
<td>24</td>
<td>T</td>
<td>R:23/24/25-33-52-53</td>
</tr>
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</table>

For Antithrombin, human 5 IU

<table>
<thead>
<tr>
<th>EC #</th>
<th>Component</th>
<th>Percent</th>
<th>Symbols</th>
<th>Risks</th>
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</thead>
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<tr>
<td>214-684-5</td>
<td>1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride</td>
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<tr>
<td>200-711-8</td>
<td>D-Mannitol</td>
<td>31.7</td>
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<td></td>
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<tr>
<td>232-936-2</td>
<td>Albumins, blood serum</td>
<td>3.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-</td>
<td>Human Antithrombin III</td>
<td>2.2</td>
<td></td>
<td></td>
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</tbody>
</table>

*** Section 4 - First Aid Measures ***

First Aid: Eyes
In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.

First Aid: Skin
In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. Call a physician.

First Aid: Ingestion
If swallowed, wash out mouth with water provided person is conscious. Call a physician immediately.

First Aid: Inhalation
If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

*** Section 5 - Fire-Fighting Measures ***

General Fire Hazards
None anticipated.

Hazardous Combustion Products
N/A

Suitable Extinguishing Media
Suitable: water spray, carbon dioxide, dry chemical powder, or appropriate foam.

Unsuitable Extinguishing Media
None

Fire Fighting Equipment/Instructions
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

*** Section 6 - Accidental Release Measures ***

Containment Procedures
Stop the flow of material, if this is without risk.

Clean-Up Procedures
Vacuum or sweep up material and place into a suitable disposal container. Avoid generating dusty conditions. Provide ventilation. Do not let this chemical enter the environment.

Personal Precautions
None necessary
Environmental Precautions

None necessary

*** Section 7 - Handling and Storage ***

Handling Procedures

Use with adequate ventilation. Minimize dust generation and accumulation. Do not get in eyes, on skin, or on clothing. Do not ingest or inhale.

Storage Procedures

Keep container tightly closed and in a dry and well-ventilated place.

Specific Use

Test Kit

*** Section 8 - Exposure Controls / Personal Protection ***

Substance Exposure Limits

p-Nitroaniline (202-810-1)

ACGIH: 3 mg/m3 TWA
Skin - potential significant contribution to overall exposure by the cutaneous route

Austria: 1 ppm MAK; 6 mg/m3 MAK

Belgium: 3 mg/m3 TWA

Skin

Denmark: 0.5 ppm TWA; 3 mg/m3 TWA
Potential for cutaneous absorption

Finland: 3 ppm STEL; 17 mg/m3 STEL
1 ppm TWA; 5.7 mg/m3 TWA
Potential for cutaneous absorption

France: 3 mg/m3 VME

Greece: 1 ppm TWA; 6 mg/m3 TWA

Ireland: 6 mg/m3 TWA
Potential for cutaneous absorption

Portugal: 3 mg/m3 TWA

Spain: 3 mg/m3 VLA-ED

Skin - potential for cutaneous exposure

Occupational Exposure Controls

Provide adequate local exhaust ventilation to maintain worker exposure below exposure limits.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Personal Protective Equipment: Skin

Normal work clothing (long sleeved shirts and long pants) is recommended.

Personal Protective Equipment: Hands

Wear appropriate protective gloves to prevent skin exposure.

Personal Protective Equipment: Respiratory

A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements or European Standard EN 149 must be followed whenever workplace conditions warrant a respirator's use.

Environmental Exposure Controls

Airborne emissions, spills, and releases to the environment (discharge to streams, sewer systems, groundwater, surface soil etc.) should be controlled immediately.

*** Section 9 - Physical and Chemical Properties ***
**Safety Data Sheet**

**Kinetichrome™ Heparin Anti-Xa Kit**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Lyophilized powder</td>
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<tr>
<td>Physical State</td>
<td>Powder</td>
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<tr>
<td>Vapor Pressure</td>
<td>N/A</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>N/A</td>
</tr>
<tr>
<td>Solubility (H2O)</td>
<td>N/A</td>
</tr>
<tr>
<td>Freezing Point</td>
<td>N/A</td>
</tr>
<tr>
<td>VOC</td>
<td>N/A</td>
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<tr>
<td>Octanol/H2O Coeff.</td>
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<tr>
<td>Flash Point Method</td>
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<tr>
<td>Lower Flammability Limit</td>
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</tr>
<tr>
<td>(LFL):</td>
<td>N/A</td>
</tr>
<tr>
<td>Auto Ignition</td>
<td>N/A</td>
</tr>
<tr>
<td>Odor</td>
<td>N/A</td>
</tr>
<tr>
<td>pH</td>
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<tr>
<td>Vapor Density</td>
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</tr>
<tr>
<td>Melting Point</td>
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<tr>
<td>Specific Gravity</td>
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<tr>
<td>Evaporation Rate</td>
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<tr>
<td>Molecular Weight</td>
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<td>Upper Flammability Limit</td>
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<td>(UFL):</td>
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</tr>
<tr>
<td>Burning Rate</td>
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<tr>
<td>Octanol/H2O Coeff.</td>
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<tr>
<td>Flash Point Method</td>
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<tr>
<td>Upper Flammability Limit</td>
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<tr>
<td>Burning Rate</td>
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<td>Molecular Weight</td>
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<td>Solubility (H2O)</td>
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<td>Specific Gravity</td>
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<tr>
<td>Molecular Weight</td>
<td>N/A</td>
</tr>
<tr>
<td>Flash Point</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*** Section 10 - Stability and Reactivity ***

**Chemical Stability**

Stable under recommended conditions of usage and storage.

**Conditions to Avoid**

No information available.

**Materials to Avoid**

None

**Hazardous Decomposition Products**

Oxides of carbon and nitrogen.

*** Section 11 - Toxicological Information ***

**Acute Toxicity**

**A: General Product Information**

No information available for the product.

**B: Component Analysis - LD50/LC50**

- **D-Mannitol (200-711-8)**
  - Oral LD50 Rat 13500 mg/kg

- **p-Nitroaniline (202-810-1)**
  - Oral LD50 Rat 750 mg/kg; Dermal LD50 Rat >2500 mg/kg

**Repeated Dose Toxicity**

No information available for the product.

**Skin Effects**

Causes irritation.

**Eye Effects**

Causes irritation.

**Ingestion Effects**

Toxic if swallowed.

**Inhalation Effects**

Causes irritation.

**Carcinogenicity**

**A: General Product Information**

No information available for the product.

**B: Substance Carcinogenicity**

- **p-Nitroaniline (202-810-1)**
  - Germany: Category 3A (could be carcinogenic for man)
**Mutagenicity**
No information available for the product.

**Reproductive Effects**
No information available for the product.

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**Section 12 - Ecological Information**

**Ecotoxicity**

**A: General Product Information**
No information available for the product.

**B: Component Analysis - Ecotoxicity - Aquatic Toxicity**

p-Nitroaniline (202-810-1)

<table>
<thead>
<tr>
<th>Test &amp; Species</th>
<th>Conditions</th>
<th>96 Hr LC50 Pimephales promelas</th>
<th>110-142 mg/L [flow-through]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>96 Hr LC50 Pimephales promelas</td>
<td>85.7-117 mg/L [static]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>96 Hr LC50 Brachydanio rerio</td>
<td>87.6 mg/L [static]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 Hr EC50 Chlorella vulgaris</td>
<td>0.14 mg/L</td>
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<tr>
<td></td>
<td></td>
<td>48 Hr EC50 Daphnia magna</td>
<td>17 mg/L</td>
</tr>
</tbody>
</table>

**Mobility**
No information available for the product.

**Persistence & Degradation**
No information available for the product.

**Bioaccumulative Potential**
No information available for the product.

**Other Adverse Effects**
No information available for the product.

---

**Section 13 - Disposal Considerations**

**Waste Disposal Instructions**
Prior to disposal, consider if the material has recovery value. National regulations may require specific labeling, packing, storage, transportation, and disposal procedures. Contact an environmental engineer or consultant familiar with waste disposal procedures.

**Disposal of Contaminated Packaging**
Avoid disposal, attempt to utilize preparation completely. Prior to disposal of unused preparation, consult an approved waste disposal operative to ensure regulatory compliance. Refer to local statutory requirements for proper disposal instructions.

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**Section 14 - Transportation Information**

**IATA Information**
Shipping Name: Not Regulated

**ICAO Information**
Shipping Name: Not Regulated

**IMDG Information**
Shipping Name: Not Regulated
### EU MARKING AND LABELLING:

**Symbol(s):**

Xn (for Xa Substrate, 6.25 mg)

### Risk Phrases

For Xa Substrate, 6.25 mg: R20/21/22  Harmful by inhalation, in contact with skin and if swallowed. Harmful by inhalation, in contact with skin and if swallowed.

R33  Danger of cumulative effects. Danger of cumulative effects.

### Safety Phrases

For Xa Substrate, 6.25 mg: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing and gloves. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

### Chemical Safety Assessment Information

None

### Other Information

#### A: General Product Information

None

#### B: Substance Analysis – Inventory

**For Factor Xa, bovine 25 µg**

<table>
<thead>
<tr>
<th>Component/CAS</th>
<th>EC #</th>
<th>EEC</th>
<th>CAN</th>
<th>TSCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3-Propanediol, 2-amino-2-(hydroxymethyl) -, hydrochloride</td>
<td>214-684-5</td>
<td>EINECS</td>
<td>DSL</td>
<td>Yes</td>
</tr>
<tr>
<td>1185-53-1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D-Mannitol 69-65-8</td>
<td>200-711-8</td>
<td>EINECS</td>
<td>DSL</td>
<td>Yes</td>
</tr>
<tr>
<td>Albumins, blood serum 9048-46-8</td>
<td>232-936-2</td>
<td>EINECS</td>
<td>DSL</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**For Xa Substrate, 6.25 mg**

<table>
<thead>
<tr>
<th>Component/CAS</th>
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<td>D-Mannitol 69-65-8</td>
<td>200-711-8</td>
<td>EINECS</td>
<td>DSL</td>
<td>Yes</td>
</tr>
<tr>
<td>p-Nitroaniline 100-01-6</td>
<td>202-810-1</td>
<td>EINECS</td>
<td>DSL</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**For Antithrombin, human 5 IU**

<table>
<thead>
<tr>
<th>Component/CAS</th>
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<td>232-936-2</td>
<td>EINECS</td>
<td>DSL</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Safety Data Sheet

Kinetichrome™ Heparin Anti-Xa Kit

*** Section 16 - Other Information ***

Key/Legend
ACGIH = American Conference of Governmental Industrial Hygienists; ADG = Australian Code for the Transport of Dangerous Goods by Road and Rail; ADR/RID = European Agreement of Dangerous Goods by Road/Rail; AS = Standards Australia; DFG = Deutsche Forschungsgemeinschaft; DOT = Department of Transportation; DSL = Domestic Substances List; EEC = European Economic Community; EINECS = European Inventory of Existing Commercial Chemical Substances; ELINCS = European List of Notified Chemical Substances; EU = European Union; HMIS = Hazardous Materials Identification System; IARC = International Agency for Research on Cancer; IMO = International Maritime Organization; IATA = International Air Transport Association; MAK = Maximum Concentration Value in the Workplace; NDSL = Non-Domestic Substances List; NFPA = National Fire Protection Association; NOHSC = National Occupational Health & Safety Commission; NTP = National Toxicology Program; STEL = Short-term Exposure Limit; TDG = Transportation of Dangerous Goods; TLV = Threshold Limit Value; TSCA = Toxic Substances Control Act; TWA = Time Weighted Average

Revision History
None

End of Sheet