

Kinetichrome™ Heparin Anti-IIa 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:

Thrombin, human 40 IU
 IIa substrate 6.25 mg {Formula =H-D-Phe-Pip-Arg-pNA · HCl}
 Antithrombin, human 2.5 IU

***** Section 2 - Hazards Identification *****

Substance/Preparation Classification

Xn (for IIa 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 *****

For Thrombin, human 40 IU

| EC # | Component | Percent | Symbols | Risks |
|-----------|---|---------|---------|-------|
| 214-684-5 | 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride 1185-53-1 | 63.7 | | |
| 200-711-8 | D-Mannitol 69-65-8 | 32.4 | | |
| 232-936-2 | Albumins, blood serum 9048-46-8 | 3.9 | | |
| 232-648-7 | Thrombin 9002-04-4 | <0.1 | | |

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For IIa substrate 6.25 mg

| EC # | Component | Percent | Symbols | Risks |
|-----------|---|---------|---------|---------------------|
| 200-711-8 | D-Mannitol 69-65-8 | 76 | | |
| 202-810-1 | p-Nitroaniline (derivative) 100-01-6 | 24 | T | R:23/24/25-33-52-53 |

For Antithrombin, human 2.5 IU

| EC # | Component | Percent | Symbols | Risks |
|-----------|---|---------|---------|-------|
| 214-684-5 | 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride 1185-53-1 | 63 | | |
| 200-711-8 | D-Mannitol 69-65-8 | 32 | | |
| 232-936-2 | Albumins, blood serum 9048-46-8 | 3.8 | | |
| - | Human Antithrombin III | 1.1 | | |

*** 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.

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*** 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 | skin notation |
| 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 |
| France: | 3 mg/m3 VME | Potential for cutaneous absorption |
| 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.

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*** Section 9 - Physical and Chemical Properties ***

| | | | |
|--|--------------------|--|-----|
| Appearance: | Lyophilized powder | Odor: | N/A |
| Physical State: | Powder | pH: | N/A |
| Vapor Pressure: | N/A | Vapor Density: | N/A |
| Boiling Point: | N/A | Melting Point: | N/A |
| Solubility (H2O): | N/A | Specific Gravity: | N/A |
| Freezing Point: | N/A | Evaporation Rate: | N/A |
| VOC: | N/A | Molecular Weight: | N/A |
| Octanol/H2O Coeff.: | N/A | Flash Point: | N/A |
| Flash Point Method: | N/A | Upper Flammability Limit (UFL): | N/A |
| Lower Flammability Limit (LFL): | N/A | Burning Rate: | N/A |
| Auto Ignition: | N/A | | |

*** 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.

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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.

* * * 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)

Test & Species

Conditions

| | |
|--------------------------------|-----------------------------|
| 96 Hr LC50 Pimephales promelas | 110-142 mg/L [flow-through] |
| 96 Hr LC50 Pimephales promelas | 85.7-117 mg/L [static] |
| 96 Hr LC50 Brachydanio rerio | 87.6 mg/L [static] |
| 6 Hr EC50 Chlorella vulgaris | 0.14 mg/L |
| 48 Hr EC50 Daphnia magna | 17 mg/L |

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 and the Toxic Industrial Waste Regulations (TIWR) for proper disposal instructions.

* * * Section 14 - Transportation Information * * *

IATA Information

Shipping Name: Not Regulated

ICAO Information

Shipping Name: Not Regulated

IMDG Information

Shipping Name: Not Regulated

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*** Section 15 - Regulatory Information ***

EU MARKING AND LABELLING:

Symbol(s):

Xn (for IIa substrate 6.25 mg)

Risk Phrases

For IIa substrate 6.25 mg: R20/21/22 Harmful by inhalation, in contact with skin and if swallowed. R33 Danger of cumulative effects.

Safety Phrases

For IIa 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 Thrombin, human 40 IU

| Component/CAS | EC # | EEC | CAN | TSCA |
|---|-----------|--------|------|------|
| 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride 1185-53-1 | 214-684-5 | EINECS | DSL | Yes |
| D-Mannitol 69-65-8 | 200-711-8 | EINECS | DSL | Yes |
| Albumins, blood serum 9048-46-8 | 232-936-2 | EINECS | DSL | Yes |
| Thrombin 9002-04-4 | 232-648-7 | EINECS | NDSL | Yes |

For IIa substrate 6.25 mg

| Component/CAS | EC # | EEC | CAN | TSCA |
|----------------------------|-----------|--------|-----|------|
| D-Mannitol 69-65-8 | 200-711-8 | EINECS | DSL | Yes |
| p-Nitroaniline 100-01-6 | 202-810-1 | EINECS | DSL | Yes |

For Antithrombin, human 2.5 IU

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

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|---|
| * * * Section 16 - Other Information * * * |
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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