Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

＜Product Name＞
PATHFAST D-Dimer
(Product No.: PF1051-KUS)

＜General Use＞
Reagent for in vitro diagnostics use

Manufacturer: Mitsubishi Chemical Medience Corp.
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First issue : Nov. 5, 2004
Revised : Aug, 15, 2011

＜Product Description＞
D-Dimer assay reagents packaging in a cartridge below.

1) Reagent cartridge (containing below)
   a. Well #2; Alkaline phosphatase conjugated anti D-Dimer monoclonal antibody (mouse)
   b. Well #3,4,5; Washing Buffer
   c. Well #7; Magnetic particles coated with anti D-Dimer monoclonal antibody (mouse)
   d. Well #11; Sample Dilution Buffer
   e. Well #13; Chemiluminescent substrate (CDP-Star)
2) Calibrator 1 (CAL-1)
3) Calibrator 2 (CAL-2)
4) Calibrator diluent (2bottles)

MSDS No. UP005ac

2. COMPOSITION, INFORMATION ON INGREDIENTS

＜Component, Chemical name and Content＞

1) Reagent cartridge

a. Alkaline phosphatase (calf intestine) conjugated anti D-Dimer monoclonal antibody (mouse) (50uL)

Substance	CAS No.	%Present	EC Symbol(s)	EC R-Phrases
Sodium azide（as Preservative）	26628-22-8	0.05	[T+, N]	R:28-32-50/53
Zinc chloride	7646-85-7	0.0007	[C, N]	R:34-50/53

MES buffer solution containing sodium chloride, Lipidure A101-BS(NOF Corp.) and so on. (pH6.0) (1)

b. Washing Buffer (400uL)

Substance	CAS No.	%Present	EC Symbol(s)	EC R-Phrases
Sodium azide（as Preservative）	26628-22-8	0.05	[T+, N]	R:28-32-50/53

MES (2-Morpholinoethanesulfonic acid, monohydrate) buffer solution containing sodium chloride and so on. (pH6.5)

c. Magnetic particles coated with anti D-Dimer monoclonal antibody (mouse) (50uL)
Suspension of magnetic particles coated with anti D-Dimer monoclonal antibody (mouse) in MOPS（3-Morpholinopropanesulfonic acid）buffer solution containing sodium chloride, gelatin and so on. (pH7.0)
（D-Dimer: fibrin degradation product fragments）

d. Sample Dilution Buffer (25uL)

Substance	CAS No.	%Present	EC Symbol(s)	EC R-Phrases
Sodium azide（as Preservative）	26628-22-8	0.05	[T+, N]	R:28-32-50/53

Tris buffer solution containing sodium chloride, bovine serum albumin and so on. (pH7.0) (2)

e. Chemiluminescent substrate (CDP-Star) (100uL)
Aqueous solution containing CDP-Star（Applied Biosystems). (pH8.7) (3)

2) Calibrator 1 (CAL-1)

Substance	CAS No.	w% Present	EC Symbol(s)	EC R-Phrases
Sodium azide（as Preservative）	26628-22-8	0.05	[T+, N]	R:28-32-50/53

Tris buffer solution containing Bovine serum albumin, Sodium chloride and so an. (pH7.0) (3)

3) Calibrator 2 (CAL-2)
Preparation of D-Dimer, Human fibrinogen, Human serum, Micro-O-protect and so on. (Lyophilized) (4)(5)

4) Calibrator diluent (1 bottle)

Substance	CAS No.	w% Present	EC Symbol(s)	EC R-Phrases
Sodium azide（as Preservative）	26628-22-8	0.05	[T+, N]	R:28-32-50/53

Aqueous solution. (pH: Neutrality)

All components are at concentrations that do not meet EU or US OSHA criteria for classifying as dangerous or hazardous, respectivery, under these regulations.

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3. HAZARDS IDENTIFICATION

＜Emergency Overview＞

No Information available for the components of this kit. However, may be harmful by inhalation, in contact with skin and if swallowed and may be irritating to skin and eyes.

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4. FIRST AID MEASURES

＜Inharation＞

If inhaled, immediately remove to fresh air. Call a physician if necessary.

＜Eye contact＞

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
Call a physician if necessary.

＜Skin contact＞

In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

＜Ingestion＞

If swallowed, immediately wash out mouth thoroughly with water. Do not induce vomiting. Call a physician.

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5. FIRE FIGHTING MEASURES

＜Flammable properties＞

Nonflammable

＜Extinguishing media＞

Use suitable extinguishing media for the fire conditions. (water, foam, dry chemical etc.)

＜Fire fighting instructions＞

Wear suitable extinguishing apparatus for the fire conditions.
Do not contact to the components when extinguish fire.

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6. ACCIDENTAL RELEASE MEASURES

＜Land spill＞

Soak up clearly with paper or cloth.

＜Water spill＞

Dilute large quantity of water.

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7. HANDLING AND STORAGE

＜Handling＞

Seal the cap exactly.
Use suitable equipments.
Do not mouth pipette.
Do not leak, overflow and scatter.
Do not fall down and damage.

＜Storage＞

Store in cool and dark place at 36-47˚F (2-8˚C).

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8. EXPOSURE CONTOROLS, PERSONAL PROTECTION

＜Engineering controls＞

Equip sink and flushing eyes facilities near operating place.

＜Personal protective equipment＞

To prevent any contact, wear protective equipments such as safety glasses, rubber gloves, as appropriate.
Eye/face protection：Wear safety glasses.
Skin protection：Wear disposable rubber gloves.
Respiratory protection：Do not breathe mist.

＜Exposure guidelines＞

The preparation does not have established guidelines.

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9. PHYSICAL AND CHEMICAL PROPERTIES

＜Appearance＞

1) Reagent cartridge	
a. Alkaline phosphatase (calf intestine) conjugated anti D-Dimer monoclonal antibody (mouse)	Liquid
b. Washing Buffer	Liquid
c. Magnetic particles coated with anti D-Dimer monoclonal antibody (mouse)	Liquid
d. Sample Dilution Buffer	Liquid
e. Chemiluminescent substrate (CDP-Star)	Liquid
2) Calibrator 1 (CAL-1)	Liquid
3) Calibrator 2 (CAL-2)	Lyophilized solid or powder
4) Calibrator diluent	Liquid

＜Color and Odor＞

1) Reagent cartridge	
a. Alkaline phosphatase (calf intestine) conjugated anti D-Dimer monoclonal antibody (mouse)	Clear-Slightly yellow, Odorless
b. Washing Buffer	Clear, Odorless
c. Magnetic particles coated with anti D-Dimer monoclonal antibody (mouse)	Brown-Dark brown, Ordorless
d. Sample Dilution Buffer	Clear-yellow, Odorless
e. Chemiluminescent substrate (CDP-Star)	Clear, Odorless
2) Calibrator 1 (CAL-1)	Clear-Slightly yellow, Odorless
3) Calibrator 2 (CAL-2)	White-Slightly yellow, Odorless
4) Calibrator diluent	Clear, Odorless

＜pH＞

1) Reagent cartridge	
a. Alkaline phosphatase (calf intestine) conjugated anti D-Dimer monoclonal antibody (mouse)	6.0
b. Washing Buffer	6.5
c. Magnetic particles coated with anti D-Dimer monoclonal antibody (mouse)	7.0
d. Sample Dilution Buffer	7.0
e. Chemiluminescent substrate (CDP-Star)	8.7
2) Calibrator 1 (CAL-1)	7.0
3) Calibrator 2 (CAL-2)	－
4) Calibrator diluent	Neutrality

＜Vapor pressure＞

No information available.

＜Vapor density＞

No information available.

＜Boiling point＞

No information available.

＜Freezing/melting point＞

No information available.

＜Solubility in water＞

1) Reagent cartridge	
a. Alkaline phosphatase (calf intestine) conjugated anti D-Dimer monoclonal antibody (mouse)	Mix free to water.
b. Washing Buffer	Mix free to water.
c. Magnetic particles coated with anti D-Dimer monoclonal antibody (mouse)	Mix free to water.
d. Sample Dilution Buffer	Mix free to water.
e. Chemiluminescent substrate (CDP-Star)	Mix free to water.
2) Calibrator 1 (CAL-1)	Mix free to water.
3) Calibrator 2 (CAL-2)	Mix free to water.
4) Calibrator diluent	Mix free to water.

＜Specific gravity or density＞

No information available.

＜Molecular weight＞

Not applicable

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10. STABILITY AND REACTIVITY

＜Chemical stability＞

Product is stable under normal handling and storage conditions.

＜Conditions to avoid＞

Do not freeze.

＜Incompatibility with other materials＞
No information available.
＜Hazardous decomposition products＞
No information available.
＜Hazardous polymerization＞
No information available.

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11. TOXICOLOGICAL INFORMATION
＜Acute inhalation effect＞
No information available.
＜Eye effect＞
May cause eye irritation.
＜Skin effect＞
May cause skin irritation.
＜Acute oral effect＞
Ingestion may cause nausea, vomiting, stomach-ache and diarrhea.
＜Subchronic effect＞
No information available.
＜Chronic effect/Carcinogenicity＞
No information available.
＜Mutagenicity＞
No information available.

Notes about Sodium azide and Zinc chloride for additional information.

1) Sodium azide
Cause inflammation and irritation of eyes, nose, throat and bronchus.
Inhalation and ingestion cause headache, vomiting, dizziness, low blood pressure, difficulty breathing, sense disorder. In serious case, fatality may occur from acute cardiac collapse, and unconsciousness, systemic convulsion. The symptoms may be

p.o.	Human	TDL0	710μg/kg	(6)
p.o.	Rat	LD50	27mg/kg	(6)
i.p.	Mouse	LD50	28mg/kg	(6)
par	Rabbit	LD50	20mg/kg	(6)

2) Zinc chloride
Cause inflammation and irritation of eyes, skin and mucous menbrane.
Inhalation and ingestion may cause nausea, vomiting, diarrhea, fever, sense of fatigue, joint-ache and leucocytosis.

inhl	Rat	LCL0	1,950mg/m3/1	(7)
p.o.	Rat	LD50	329mg/kg	(7)
p.o.	Mouse	LD50	350mg/kg	(7)

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12. ECOLOGICAL INFORMATION
＜Ecotoxicity＞
No information available.
＜Environmental fate＞
No information available.
＜Physical/Chemical Properties＞
No information available.

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13. DISPOSAL CONSIDERATIONS
Comply with all EU, national (U.S.federal, state) and local regulations.

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14. TRANSPORT INFORMATION
Proper shipping name : In vitro diagnostic reagents
Hazard Class : None
Identification Number : None

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15. REGULATORY INFORMATION

Follow all the regulations in your country.
Please refer to national measures that may be relevant.

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16. OTHER INFORMATION

＜reference＞

(1) Lipidure A101-BS Material Safety Data Sheet from supplier, NOF Corp.(NIHON YUSHI)
(2) Bovine serum albumin Product Specification from supplier, SIGMA.
(3) CDP-Star Material Safety Data Sheet from supplier, Applied Biosystems
(4) Human fibrinogen Product Specification from supplier, ENZYME RESEARCH LABORATORIES.
(5) Human Serum Product Specification from supplier, MIDLAND BIOPRODUCTS CORPORATION.
(6) Dangerous Properties of Industrial Materials（7th Edition）
(7) RTECS (Registry of Toxic Effects of Chemical Substances. NIOSH)

＜Others＞

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