
Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

<Product Name>

PATHFAST cTnI-II

(Product No.: PF1101-K)

Manufacturer: Mitsubishi Chemical Medience Corp.

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<General Use>

Reagent for in vitro diagnostics use

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<Product Description>

cTnI assay reagent kit packaging four components below.

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

MSDS No. UP010ac

2. COMPOSITION, INFORMATION ON INGREDIENTS

<Component, Chemical name and Content>

- 1) Reagent cartridge

- a. Alkaline phosphatase (calf intestine) conjugated anti cTnI monoclonal antibody (mouse) (50µL)

| <u>Substance</u> | <u>CAS No.</u> | <u>%Present</u> | <u>EC Symbol(s)</u> | <u>R-Phrases</u> |
|---|----------------|-----------------|-------------------------|------------------|
| Sodium azide (as Preservative) | 26628-22-8 | 0.06 | [T+, N] | R:28-32-50/53 |
| Zinc chloride | 7646-85-7 | 0.0007 | [C, N] | R:34-50/53 |
| MES (2-Morpholinoethanesulfonic acid, monohydrate) buffer solution containing Sodium chloride, Lipidure A101-BS(NOF Corp.) and so on. (pH6.0) (1) | | | | |

- b. Washing buffer (400µL)

| <u>Substance</u> | <u>CAS No.</u> | <u>%Present</u> | <u>EC Symbol(s)</u> | <u>R-Phrases</u> |
|--|----------------|-----------------|-------------------------|------------------|
| Sodium azide (as Preservative) | 26628-22-8 | 0.05 | [T+, N] | R:28-32-50/53 |
| MOPS(3-Morpholinopropanesulfonic acid) buffer solution containing Sodium chloride and so on. (pH7.5) | | | | |

- c. Magnetic particles coated with anti cTnI monoclonal antibody (mouse) (50µL)
- Suspension of Anti cTnI MoAb coated Polystyrene magnetic latex particles in MOPS (3-Morpholinopropanesulfonic acid) buffer solution containing Sodium chloride, Gelatin and so on. (pH7.0)
(cTnI: Cardiac Troponin I)

- d. Sample dilution buffer (25µL)

| <u>Substance</u> | <u>CAS No.</u> | <u>%Present</u> | <u>EC Symbol(s)</u> | <u>R-Phrases</u> |
|--|----------------|-----------------|-------------------------|------------------|
| Sodium azide (as Preservative) | 26628-22-8 | 0.05 | [T+, N] | R:28-32-50/53 |
| Tris buffer solution containing Sodium chloride, Glycerin and so on. (pH8.2) | | | | |

- e. Chemiluminescent substrate (CDP-Star) (100µL)
- Aqueous solution containing CDP-Star (Applied Biosystems) (pH9.2) (2)

- 2) Calibrator 1 (CAL-1)
Preparation of cTnI, Lactose, Human serum, MES (2-Morpholinoethanesulfonic acid, monohydrate) and so on.
(Lyophilized) (3)
- 3) Calibrator 2 (CAL-2)
Preparation of cTnI, Lactose, Human serum, MES (2-Morpholinoethanesulfonic acid, monohydrate) and so on.
(Lyophilized) (3)

- 4) Calibrator diluent (1mL)

| <u>Substance</u> | <u>CAS No.</u> | <u>%Present</u> | <u>EC Symbol(s)</u> | <u>R-Phrases</u> |
|--|----------------|-----------------|-------------------------|------------------|
| Sodium azide (as Preservative) | 26628-22-8 | 0.05 | [T+, N] | R:28-32-50/53 |
| Aqueous solution containing Glycerin and so on. (pH: Neutrality) | | | | |

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

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.

4. FIRST AID MEASURES

<Inhalation>

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 give 2 glasses of water and induce vomiting. Call a physician.

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.

6. ACCIDENTAL RELEASE MEASURES

Wear appropriate protective equipments. Inform others to keep a safe distance.

<Land spill>

Soak up clearly with paper or cloth.

<Water spill>

Dilute large quantity of water.

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.

Avoid prolonged contact with copper or lead, especially in drainage systems or mercury and other heavy metals which may result in the formation of explosive azides.

<Storage>

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

8. EXPOSURE CONTROLS, 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<Appearance>

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

<pH>

- 1) Reagent cartridge
 - a. Alkaline phosphatase (calf intestine) conjugated anti cTnI monoclonal antibody (mouse) 6.0
 - b. Washing Buffer 7.5
 - c. Magnetic particles coated with anti cTnI monoclonal antibody (mouse) 7.0
 - d. Sample Dilution Buffer 8.2
 - e. Chemiluminescent substrate (CDP-Star) 9.2
- 2) Calibrator 1 (CAL-1) —
- 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 cTnI monoclonal antibody (mouse) Mix free to water.
 - b. Washing Buffer Mix free to water.
 - c. Magnetic particles coated with anti cTnI 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

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>

Sodium azide reacts with acids and many metals.

No information available.
<Hazardous decomposition products>
No information available.
<Hazardous polymerization>
No information available.

11. TOXICOLOGICAL INFORMATION

<Acute inhalation effect>
No information available.
<Eye effect>
May cause eye irritation.
<Skin effect>
Ingestion may cause nausea, vomiting, stomach-ache and diarrhea.
<Acute oral effect>
Ingestion may cause nausea, vomiting, stomach-ache and diarrhea.
<Subchronic effect>
No information available.
<Chronic effect/Carcinogenicity>
Sodium azide may alter genetic material. Target organ(s): Nerves, Heart, Brain
No information available for the remaining components.
<Mutagenicity>
No information available.

Notes about Sodium azide and Zinc chloride for 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 delayed.

| | | | | |
|------|--------|------|----------|-----|
| p.o. | Human | TDL0 | 710µg/kg | (4) |
| p.o. | Rat | LD50 | 27mg/kg | (4) |
| i.p. | Mouse | LD50 | 28mg/kg | (4) |
| par | Rabbit | LD50 | 20mg/kg | (4) |

2) Zinc chloride

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

| | | | | |
|------|-------|------|-----------------------------|-----|
| inhl | Rat | LCL0 | 1,950mg/m ³ /10M | (5) |
| p.o. | Rat | LD50 | 329mg/kg | (5) |
| p.o. | Mouse | LD50 | 350mg/kg | (5) |

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

Proper shipping name : In vitro diagnostic reagents
Hazard Class : None
Identification Number : None

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

<reference>

- (1) Lipidure A101-BS Material Safety Data Sheet from supplier, NOF Corp.(NIHON YUSHI)
- (2) CDP-Star Material Safety Data Sheet from supplier, Applied Biosystems
- (3) Human Serum Product Specification from supplier, Golden West Biologicals, Inc.
- (4) Dangerous Properties of Industrial Materials (7th Edition)
- (5) RTECS (Registry of Toxic Effects of Chemical Substances. NIOSH)

<Others>

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