
Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

<Product Name>
PATHFAST CK-MB-II
(Product No.: PF1121-K)

<General Use>
Reagent for in vitro diagnostics use

Manufacturer: Mitsubishi Chemical Medience Corp.
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<Product Description>

CK-MB assay reagent kit packaging four components below.

- 1) Reagent cartridge (containing below)
 - a. Well #2; Alkaline phosphatase conjugated anti CK-MB monoclonal antibody (mouse)
 - b. Well #3,4,5; Washing Buffer
 - c. Well #7; Magnetic particles coated with anti CK-MB 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. UP012ac

2. COMPOSITION, INFORMATION ON INGREDIENTS

<Component, Chemical name and Content>

1) Reagent cartridge

- a. Alkaline phosphatase conjugated anti CK-MB monoclonal antibody (mouse) (50u EC

<u>Substance</u>	<u>CAS No.</u>	<u>%Present</u>	<u>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	7E-04	[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)
(CK-MB: Creatine kinase isozyme MB)

- b. Washing Buffer (400uL)

<u>Substance</u>	<u>CAS No.</u>	<u>%Present</u>	<u>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 CK-MB monoclonal antibody (mouse) (50uL)

Suspension of anti CK-MB MoAb coated Polystyrene magnetic latex particles in MOPS (3-Morpholinopropanesulfonic acid) buffer solution containing Sodium chloride, Gelatin and so on. (pH7.0)

- d. Sample Dilution Buffer (25uL)

<u>Substance</u>	<u>CAS No.</u>	<u>%Present</u>	<u>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 Sodium chloride, Bovine serum albumin and so on. (pH: Neutrality) (3)

- e. Chemiluminescent substrate (CDP-Star) (100uL)

Aqueous solution containing CDP-Star (Applied Biosystems) (pH9.2) (2)

- 2) Calibrator 1 (CAL-1)

Preparation of CK-MB, Human serum, MOPS and so on. (Lyophilized) (4)

- 3) Calibrator 2 (CAL-2)

Preparation of CK-MB, Human serum, MOPS and so on. (Lyophilized) (4)

- 4) Calibrator diluent (1mL)

<u>Substance</u>	<u>CAS No.</u>	<u>%Present</u>	<u>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 conjugated anti CK-MB monoclonal antibody (mouse) | Liquid |
| b. Washing Buffer | Liquid |
| c. Magnetic particles coated with anti CK-MB 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 conjugated anti CK-MB monoclonal antibody (mouse) | Clear-Slightly yellow, Odorless |
| b. Washing Buffer | Clear, Odorless |
| c. Magnetic particles coated with anti CK-MB 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 conjugated anti CK-MB monoclonal antibody (mouse) | 6.0 |
| b. Washing Buffer | 7.5 |
| c. Magnetic particles coated with anti CK-MB monoclonal antibody (mouse) | 7.0 |
| d. Sample Dilution Buffer | Neutrality |
| 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 conjugated anti CK-MB monoclonal antibody (mouse) | Mix free to water. |
| b. Washing Buffer | Mix free to water. |
| c. Magnetic particles coated with anti CK-MB 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 for the remaining components.

<Hazardous decomposition products>

Sodium azide may liberates very toxic gas in contact with acids. Forms readily detonatable salts with many metals, particularly heavy metals.
No information available for the remaining components.

<Hazardous polymerization>

No information available.

11. TOXICOLOGICAL INFORMATION

<Acute inhalation effect>

No information available for the components.

<Eye effect>

May cause eye irritation.

<Skin effect>

May cause skin irritation.

<Acute oral effect>

Ingestion of the components 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>

Mutagenicity of Sodium azide: *E.coli* 150nmol/L, *Salmonella typhimurium* 1µg/plate (6)
No information available for the remaining components.

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

p.o.	Human	TDL0	710µg/kg	(5)
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p.o.	Rat	LD50	27mg/kg	(5)
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i.p.	Mouse	LD50	28mg/kg	(5)
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par	Rabbit	LD50	20mg/kg	(5)
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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/m3/10M	(6)
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p.o.	Rat	LD50	329mg/kg	(6)
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p.o.	Mouse	LD50	350mg/kg	(6)
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12. ECOLOGICAL INFORMATION

<Ecotoxicity>

Sodium azide is toxic for aquatic organisms.

<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) Bovine serum albumin Product Specification from supplier, SERACARE
- (4) Human Serum Product Specification from supplier, Golden West Biologicals, Inc.
- (5) Dangerous Properties of Industrial Materials (7th Edition)
- (6) RTECS (Registry of Toxic Effects of Chemical Substances. NIOSH)

<Others>

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