
Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

<Product Name>

PATHFAST hsCRP

(Product No.: PF1071-KUS)

<General Use>

Reagent for in vitro diagnostics use

Manufacturer: Mitsubishi Chemical Medience Corp.

Address : Regulatory Affairs Dept.

2-8, Shibaura 4-Chome, Minato-ku,

TOKYO 108-8559 JAPAN

Phone; +81-3-6722-4205

FAX; +81-3-6722-4206

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<Product Description>

CRP assay reagents packaging in a cartridge below.

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

MSDS No. UP007ac

2. COMPOSITION, INFORMATION ON INGREDIENTS

<Component, Chemical name and Content>

- 1) Reagent cartridge

- a. Alkaline phosphatase (Micro-organism) conjugated anti CRP monoclonal antibody (mouse) (50uL)

| <u>Substance</u> | <u>CAS No.</u> | <u>%Present</u> | <u>EC</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 |
| Zinc chloride | 7646-85-7 | 0.0007 | [C, N] | R:34-50/53 |
| MES(2-Morpholinoethanesulfonic acid) buffer solution containing Sodium chloride, Bovine serum albumin, Lipidure A101-HL (NOF Corp.), Micr-O-protect and so on. (pH5.6) (1)(2) (CRP: C Reactive Protein) | | | | |

- b. Washing buffer (400uL)

| <u>Substance</u> | <u>CAS No.</u> | <u>%Present</u> | <u>EC</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 |
| MES buffer solution containing Sodium chloride and so on. (pH6.5) | | | | |

- c. Magnetic particles coated with anti CRP monoclonal antibody (mouse) (50uL)

Suspension of anti CRP MoAb coated Polystyrene magnetic latex particles in MOPS (3-Morpholinopropanesulfonic acid) buffer solution containing Sodium chloride, Micr-O-protect, Gelatin and so on. (pH6.5) (2)

- d. Sample dilution buffer (25uL)

MOPS buffer solution containing Sodium chloride, Bovine serum albumin, Mouse IgG, Micr-O-protect and so on. (pH7.5) (4)

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

Aqueous solution containing CDP-Star(Applied Biosystems) (pH9.2) (3)

- 2) Calibrator 1(CAL-1)

| <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 |
| Sodium chloride aqueous solution (pH: Neutrality) | | | | |

- 3) Calibrator 2 (CAL-2)

CRP (4)
Human serum (5)
Amikacin (antibiotic CASNo. 37517-28-5)

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 wash out mouth thoroughly with water. Do not 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

<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.

<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 (Micro-organism) conjugated anti CRP monoclonal antibody (mouse) | Liquid |
| b. Washing buffer | Liquid |
| c. Magnetic particles coated with anti CRP 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) | Liquid |

<Color and Odor>

- | | |
|--|---------------------------------|
| 1) Reagent cartridge | |
| a. Alkaline phosphatase (Micro-organism) conjugated anti CRP monoclonal antibody (mouse) | Clear-Slightly yellow, Odorless |
| b. Washing buffer | Clear, Odorless |
| c. Magnetic particles coated with anti CRP 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) | Clear, Odorless |
| 3) Calibrator 2 (CAL-2) | Slightly yellow, Odorless |

<pH>

- | | |
|--|------------|
| 1) Reagent cartridge | |
| a. Alkaline phosphatase (Micro-organism) conjugated anti CRP monoclonal antibody (mouse) | 5.6 |
| b. Washing buffer | 6.5 |
| c. Magnetic particles coated with anti CRP monoclonal antibody (mouse) | 6.5 |
| d. Sample dilution buffer | 7.5 |
| e. Chemiluminescent substrate (CDP-Star) | 9.2 |
| 2) Calibrator 1(CAL-1) | Neutrality |
| 3) Calibrator 2 (CAL-2) | 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 (Micro-organism) conjugated anti CRP monoclonal antibody (mouse) | Mix free to water. |
| b. Washing buffer | Mix free to water. |
| c. Magnetic particles coated with anti CRP 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. |

<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>
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>
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 delayed.

| | | | | |
|------|--------|------|----------|-----|
| 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 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 | (7) |
| p.o. | Rat | LD50 | 329mg/kg | (7) |
| p.o. | Mouse | LD50 | 350mg/kg | (7) |

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.

14. TRANSPORT INFORMATION

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

Transport at 36-47°F (2-8°C).
Confirm no leakage and give no damage when loading.
Check loading exactly.

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-HL Material Safety Data Sheet from supplier, NOF Corp.(NIHON YUSHI)
- (2) Micr-O-protect Product Specification from supplier, Roche
- (3) CDP-Star Material Safety Data Sheet from supplier, Applied Biosystems
- (4) CRP is prepared from human plasma (manufactured by CLINIQA Corp.)
- (5) Human Serum Product Specification from supplier, CC Biotech
- (6) Dangerous Properties of Industrial Materials (7th Edition)
- (7) RTECS (Registry of Toxic Effects of Chemical Substances. NIOSH)

<Others>

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