Material Safety Data Sheet

1.	CHEMICAL PRODUCT AND COMPAN <product name=""> PATHFAST NTproBNP (Product No.: PF1061-KUS) <general use=""> Reagent for in vitro diagnostics use <product description=""> NTproBNP assay reagents packaging in 1) Description></product></general></product>	IY IDENTIFICAT	ION v.	Manufacturer Address : First issue : Revised :	 Mitsubishi Chemical Medience Corp. Regulatory Affairs Dept. 2-8, Shibaura 4-Chome, Minato-ku, TOKYO 108-8559 JAPAN Phone; +81-3-6722-4205 FAX; +81-3-6722-4206 Aug. 24, 2006 Aug, 15, 2011 	
	 a. Well #2; Alkaline phosphatase b. Well #3,4,5; Washing Buffer c. Well #7; Magnetic particles co d. Well #11; Sample Dilution Buf e. Well #13; Chemiluminescent s 2) Calibrator 1(CAL-1) (2vials) 3) Calibrator 1(CAL-2) (2vials) 4) Calibrator Diluent (2bottles) 	conjugated anti I ated with anti NT- fer ubstrate (CDP-St	NT-proBNP polyclona -proBNP polyclonal a :ar)	al antibody (shee ntibody (sheep)	(q:	
	MSDS No. UP006ac					
2.	COMPOSITION, INFORMATION ON INGREDIENTS <component, and="" chemical="" content="" name=""> 1) Reagent Cartridge a. Alkaline phosphatase (microorganism) conjugated anti NT-proBNP polyclonal antibody (sheep) (50uL) EC</component,>					
	Substance	CAS No.	<u>%Present</u>	Symbol(s)	R-Phrases	
	MOPS (3-Morpholinopropanesulfo protect and so on. (pH6.5) (1)(2)	nic acid) buffer s	solution containing sc	dium chloride, Li	pidure A101-HL (NOF Corp.), Micr-O-	
	b. Washing Buffer (400uL) <u>Substance</u> Sodium azide (as Preservative) MOPS buffer solution containing s	<u>CAS No.</u> 26628-22-8 odium chloride ar	<u>%Present</u> 0.05 nd so on. (pH7.5)	<u>EC</u> Symbol(s) [T+, N]	<u>R-Phrases</u> R:28-32-50/53	
	 c. Magnetic particles coated with anti NT-proBNP polyclonal antibody (sheep) (50uL) Suspension of magnetic particles coated with anti NT-proBNP polyclonal antibody (sheep) in MOPS (3- Morpholinopropanesulfonic acid) buffer solution containing sodium chloride, gelatin and so on. (pH7.5) (NT-proBNP: N-terminal pro B-type Natriuretic Peptide) d. Sample Dilution Buffer (25uL) MOPS buffer solution containing sodium chloride, sheep IgG, Micr-O-protect and so on. (pH7.0) (3) e. Chemiluminescent substrate (CDP-Star) (100uL) Aqueous solution containing CDP-Star(Applied Biosystems). (pH9.2) (4) 					
	 Calibrator 1(CAL-1) <u>Substance</u> Sodium azide (as Preservative) Saline solution with 0.05% sodium 	<u>CAS No.</u> 26628-22-8 azide as preserva	<u>%Present</u> 0.05 ative.	<u>Symbol(s)</u> [T+, N]	<u>R-Phrases</u> R:28-32-50/53	
	 Calibrator 2 (CAL-2) Lyophilized preparation containing 	NT-pBNP, BSA a	and Micr-O-protect as	s preservative. (2	?)(5)(6)	
	 Calibrator Diluent <u>Substance</u> Sodium azide (as Preservative) Aqueous solution with 0.05% sodiu 	<u>CAS No.</u> 26628-22-8 ım azide.	<u>%Present</u> 0.05	<u>EC</u> <u>Symbol(s)</u> [T+, N]	<u>R-Phrases</u> R:28-32-50/53	

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

<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 <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

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 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.

9.

<appearance></appearance>	•
---------------------------	---

PHYSICAL AND CHEMICAL PROPERTIES	
<appearance></appearance>	
 Reagent Cartridge Alkaline phosphatase (microorganism) conjugated anti NT-proBNP polyclonal antibody (sheep) 	Liquid
b. Washing Buffer	Liquid
c. Magnetic particles coated with anti NT-proBNP polyclonal antibody (sheep)	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=""></color>	
1) Reagent Cartridge	
a. Alkaline phosphatase (microorganism) conjugated anti NT-proBNP polyclonal antibody (sheep)	Clear-Slightly yellow, Odorless
b. Washing Buffer	Clear, Odorless
c. Magnetic particles coated with anti NT-proBNP polyclonal antibody (sheep)	Brown-Dark brown, Ordorless
d. Sample Dilution Buffer	Clear, Odorless
e. Chemiluminescent substrate (CDP-Star)	Clear, Odorless
2) Calibrator 1 (CAL-1) 2) Calibrator 2 (CAL-2)	Clear, Odorless
4) Calibrator Diluent	Clear blue. Odorless
1) Reagent Cartriage	0.5
a. Alkaline prosphatase (microorganism) conjugated anti N I-proBNP polycional antibody (sneep)	6.5
D. Washing Buffer	7.5
d. Sample Dilution Buffer	7.5
u. Sample Dilution Burlet e. Chamiluminescent substrate (CDP Star)	0.2
2) Calibrator 1 (CAL-1)	9.2 Neutrality
3) Calibrator 2 (CAL-2)	—
4) Calibrator Diluent	Neutrality
	-
< vapor pressure >	
Nu initiation available.	
No information available	
<pre>Kelling noint ></pre>	
No information available	
< Freezing/melting point >	
No information available.	
< Solubility in water >	
1) Reagent Cartridge	
a. Alkaline phosphatase (microorganism) conjugated anti NT-proBNP polyclonal antibody (sheep)	Mix free to water
b. Washing Buffer	Mix free to water.
c. Magnetic particles coated with anti NT-proBNP polyclonal antibody (sheep)	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 density="" gravity="" or=""></specific>	

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 Human TDL0 710µg/kg (7) p.o. Rat LD50 27mg/kg (7) p.o. i.p. Mouse LD50 28mg/kg (7) LD50 (7) Rabbit 20mg/kg par 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 LCL0 1,950mg/m3/10M (8) Rat Rat LD50 329mg/kg p.o. (8)p.o. Mouse LD50 350mg/kg (8) 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-HL Material Safety Data Sheet from supplier, NOF Corp.(NIHON YUSHI)
- (2) Micr-O-protect Product Specification from supplier, Roche
- (3) Sheep IgG Certificate of Analysis from supplier, SOUTH PACIFIC SERA LIMITED
- (4) CDP-Star Material Safety Data Sheet from supplier, Applied Biosystems
- (5) NT-proBNP Product Specification from supplier, Roche Applied Science
- (6) Bovine serum albumin (BSA) Certification of Analysis from supplier, Seracare
- (7) Dangerous Properties of Industrial Materials (7th Edition)
- (8) RTECS (Registry of Toxic Effects of Chemical Substances. NIOSH)

<Others>

This information is furnished without warranty, express or implied, expect that it is accurate to the best knowledge of Mitsubishi Chemical Medience Corporation. It relates only to the specific material designated herein, and does not relate to use in combination with any other material or in any process.

Mitsubishi Chemical Medience Corporation assumes no legal responsibility for use of or reliance upon this information.