

Safety Data Sheet

1. IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE SUPPLIER

Product name	Coagpia Fbg Thrombin Reagent (in vitro diagnostic)
Company name	SEKISUI MEDICAL CO., LTD.
Address	2-1-3 Nihonbashi, Chuo-ku, Tokyo, Japan
Supplier	
Address	3-3-1 Koyodai, Ryugasaki, Ibaraki, Japan
Division in charge	Quality Assurance Unit, Tsukuba Plant
Telephone	+81-297-62-7551
Fax	+81-297-62-5238
Reference No.	16-01-02

2. HAZARDS IDENTIFICATION

GHS classification Out of the classification criteria

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical or mixture Mixture (this product does not contain any hazardous substances at concentrations which are higher than those specified by laws and regulations).

4. FIRST AID MEASURES

Inhalation	Remove the victim to a place with fresh air. Let him gargle and keep him quiet and warm. If the victim feels ill, get medical advice.
Skin contact	Wash the skin immediately with large quantities of water. If itching, inflammation, or other symptoms occur, get medical advice. Remove contaminated clothes and wash them before reuse.
Eye contact	Wash the eye immediately with large quantities of water for at least 15 min and get medical advice. Remove the contact lens if it can be removed easily. Continue the eye washing subsequently.
Swallowing	Rinse mouth and dilute this product by letting the victim drink large quantities of water. Immediately get medical advice.
Protection of first aid givers	Wear protective gear, such as globes, to avoid contact with harmful substances.
Special precautions for doctors	None.

5. FIREFIGHTING MEASURES

Extinguishing media	This product is incombustible, because it is available as a solution. Use powder, carbon dioxide, dry sand, or other materials depending on the type of fire in the surrounding area.
Prohibited extinguishing media	Pouring straight streams of water.
Special hazards arising from the product	Container breakage may occur due to heat. Irritant, corrosive, and toxic gases may be produced due to the fire.

Specific methods of fire fighting	If it is not dangerous, remove the containers from the fire. Even after extinguishment, cool the containers sufficiently with large quantities of water.
Protection of fire fighters	Perform fire fighting from the windward. Wear appropriate protective gear depending on the case.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	<p>Isolate the people immediately from the leakage zone which should be appropriately separated in all directions from the origin of the leakage.</p> <p>If leakage occurs indoors, continue adequate ventilation until the place is cleared up completely.</p> <p>Take appropriate measures, such as stretching a rope around the leakage zone, to forbid persons except authorized personnel to enter the leakage zone.</p> <p>Take measures for leakage from the windward, and remove the people from the lee.</p> <p>Caution should be observed to prevent slipping on the leaks. Keep out people except authorized personnel.</p> <p>Let the operators wear appropriate protective gear (see the "8. EXPOSURE CONTROLS/PERSONAL PROTECTION" section) to prevent contact with eyes and skin and inhalation.</p> <p>Forbid the operators without appropriate protective gear to touch broken containers or leaks.</p> <p>Ventilate closed places.</p>
Environmental precautions	<p>Caution must be exercised to prevent the outflow of drug leaks or concentrated effluents into rivers or other places.</p> <p>When leaks are diluted with large quantities of water, caution must be exercised to avoid the outflow of contaminated water which has failed to be treated adequately into the environment.</p>
Collection and neutralization	Wipe the leaks with rags or the like and then clean the affected area with a damp cloth.
Methods and materials for containment and cleaning up	Stop the leakage, if it is not dangerous.
Measures against secondary disasters	Prevent inflow into sewers, drains, basements, or closed places.

7. HANDLING AND STORAGE

Handling

Technical measures (Local ventilation/general Ventilation)	Take the facility measures mentioned in the "8. EXPOSURE CONTROLS/PERSONAL PROTECTION" section and wear appropriate protective gear. Ventilate closed places.
Precautions for safe handling	<p>Avoid contact with eyes and skin.</p> <p>Avoid swallowing.</p> <p>Avoid breathing mist, vapor, and spray.</p> <p>After use, seal the container tightly.</p>

Avoid leakage, overflow, and scattering.
 Avoid rough handling of containers, such as inverting, dropping, strongly pressurizing, and pulling.
 Avoidance of contact See the "10. STABILITY AND REACTIVITY" section.
 Sanitation measures After handling, wash the hands thoroughly.
 Avoid eating and drinking or smoking when this product is used.

Storage

Conditions for safe storage Place in a tightly closed container and store in a cool place (2-10°C), protected from direct sunlight. Store separately from oxidants, acidic substances, and metals.
 Prohibit the use of frozen product, because accurate results may not be obtained due to qualitative change.
 Safe container and package materials Keep in the dedicated containers.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Facility measures When using indoors, ventilate the workplace. Install a restroom with washbasins in the workrooms where this product is stored or handled and show clearly where it is.
 Control parameters Not specified
 Acceptable concentration
 Japan Society for Occupational Health Not specified
 ACGIH Not specified
 Personal protective equipment
 Respiratory protection Wear appropriate personal protective gear for breathing as necessary.
 Hand protection Wear appropriate personal protective gloves.
 Eye protection Wear appropriate personal safety goggles.
 Skin/body protection Wear appropriate personal protective gear, such as protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance		pH	Flashing point	Upper/lower flammability or explosive limits	Specific gravity (relative density)	Solubility
Physical state	Color					
Liquid	Colorless and clear	6.3 (25°C)	Non flammable	Non explosive	1.005	This product is available as a solution.

10. STABILITY AND REACTIVITY

Chemical stability Stable under usual handling conditions.
 Possibility of hazardous reactions Nonreactive under usual conditions.
 Conditions to avoid Direct sunlight, heat, and air.
 Incompatible materials Data not available.
 Hazardous decomposition products Data not available.

11. TOXICOLOGICAL INFORMATION

This product does not contain any hazardous substances at concentrations which are higher than those specified by laws and regulations.

12. ECOLOGICAL INFORMATION

Ecotoxicity	Data not available.
Persistence and degradability	Data not available.
Bioaccumulative potential	Data not available.
Mobility in soil	Because this product is available as a liquid, its ingredients could be transported into water and soil.
Results of PBT and vPvB assessment	Data not available.

13. DISPOSAL CONSIDERATIONS

Surplus or waste (residues)	When extremely small quantities of waste is discarded through a drainage outlet, let it flow together with large quantities of water to avoid damage to water pipes. When large quantities of waste is discarded, commission their disposal to a waste disposal company licensed by the prefectural governor.
Contaminated containers and packaging	Rinse contaminated containers thoroughly with water, classify them, and discard.

14. TRANSPORT INFORMATION

UN number	UN proper shipping name	Transport hazard class	Packaging group	Environmental hazards
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

Special precautions for user	In compliance with the "7. HANDLING AND STORAGE" section. Before transportation, confirm the absence of breakage, corrosion, leakage, etc. in the containers. Place the containers on board in a manner that will cause no tumbling, falling, and damage and take reliable measures against container collapsing on board.
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15. REGULATORY INFORMATION

Law concerning Pollutant Release and Transfer Register (PRTR Law)	Not applicable.
Industrial Safety and Health Law	Not applicable.
Poisonous and Deleterious Substances Control Law	Not applicable.
Pharmaceutical and Medical Device Act	In vitro diagnostic
Ship Safety Law	Not applicable.
Civil Aeronautics Act	Not applicable.

16. OTHER INFORMATION

References	(1) National Institute of Technology and Evaluation: http://www.safe.nite.go.jp/ghs/list.html
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Other

(2) Ministry of Health, Labour and Welfare Workplace

Safety Site: http://anzeninfo.mhlw.go.jp/anzen_pg/GHS_MSD_FND.aspx

(3) All data about the substances covered by the Law concerning Pollutant Release and Transfer Register (PRTR) MSDS (The Chemical Daily Co., Ltd.)

(4) All data about the substances covered by the Industrial Safety and Health Law MSDS (The Chemical Daily Co., Ltd.)

The information of this product safety data sheet is based on the present state of our knowledge. It does not include all information. If new information is obtained, it may be added or the original information may be corrected. The information is applicable to the product with regard to appropriate safety precautions and does not represent any guarantee of the properties of the product. It is requested that the user be responsible for ensuring conditions for safe use.

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