Sekisui Diagnostics, LLC
500 West Avenue, Stamford, CT 06902
Tel. (203) 602-7777 Fax (203) 602-2221

MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION

1.1 Product Name: IMUCLONE® D-dimer ELISA

1.2 Product REF: 602

1.3 Configuration: ELISA, 96 well

1.4 Use of Product: For Research Use Only.

1.5 Company

Manufacturer:
Sekisui Diagnostics, LLC
500 West Avenue
Stamford, CT 06902 USA
Tel: (203) 602 7777
Fax: (203) 602 2221
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American Diagnostica GmbH
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Pfungstadt 64319 Germany
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2. HAZARDS IDENTIFICATION

2.1 Classification: N, Danger, due to Sulfuric Acid

2.2 Potential Health and Environmental Effects

Skin Exposure: May cause severe skin damage.

Eye Exposure: May cause severe eye damage.

Inhalation Exposure: May be harmful.

Ingestion: May be harmful.

Environmental Exposure: Sulfuric Acid is toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Reagent/Component	Chemical Name	CAS Number	EINECS No.	Concentration, w/v, %
Antibody Coated Microwells	Monoclonal Anti-Human D-dimer IgG SiO_2 (silica gel desiccant packet)	NA 112926-00-8	NA 231-545-4	NA NA
D-dimer Calibrator	Human D-dimer Human Plasma Glycine Hepes Ciprofloxacine	9001-31-4 NA 56-40-6 7365-45-9 85721-33-1	232-590-7 NA 200-272-2 230-907-9 NA	< 1.0% < 75.0% < 50.0% < 30.0% < 10.0%
D-dimer Control I	Human D-dimer Human Plasma Glycine Hepes Ciprofloxacine	9001-31-4 NA 56-40-6 7365-45-9 85721-33-1	232-590-7 NA 200-272-2 230-907-9 NA	< 1.0% < 75.0% < 50.0% < 30.0% < 10.0%

D-dimer Control II	Human D-dimer	9001-31-4	232-590-7	< 1.0%
	Human Plasma	NA	NA	< 75.0%
	Glycine	56-40-6	200-272-2	< 50.0%
	Hepes	7365-45-9	230-907-9	< 30.0%
	Ciprofloxacine	85721-33-1	NA	< 10.0%
Sample Diluent	Sodium Phosphate Dihydrate	13472-35-0	231-449-2	< 50.0%
	Sodium Chloride	7647-14-5	231-598-3	< 50.0%
	Tween 20	9005-64-5	NA	< 20.0%
	Bovine Serum Albumin	9048-46-8	232-936-2	< 50.0%
	Kathon CG	26172-55-4	NA	< 20.0%
		2682-20-4	NA	
	Ciprofloxacine	85721-33-1	NA	< 10.0%
Anti-Human D-dimer HRP Immunoconjugate	Monoclonal Anti-Human D-dimer IgG	NA	NA	< 10.0%
	Sodium Phosphate Dihydrate	13472-35-0	231-449-2	< 50.0%
	Bovine Serum Albumin	9048-46-8	232-936-2	< 75.0%
	Peroxidase Type XII (from horseradish)	9003-99-0	232-668-6	< 10.0%
Conjugate Diluent	Sodium Phosphate Dihydrate	13472-35-0	231-449-2	< 50.0%
	Sodium Chloride	7647-14-5	231-598-3	< 50.0%
	Tween 20	9005-64-5	NA	< 20.0%
	Bovine Serum Albumin	9048-46-8	232-936-2	< 50.0%
	Kathon CG	26172-55-4	NA	< 20.0%
		2682-20-4	NA	
Wash Solution	Sodium Phosphate Dihydrate	13472-35-0	231-449-2	< 30.0%
	Sodium Chloride	7647-14-5	231-598-3	< 75.0%
	Tween 20	9005-64-5	NA	< 20.0%
	Kathon CG	26172-55-4	NA	< 20.0%
		2682-20-4		
	Ciprofloxacine	85721-33-1	NA	< 10.0%
Substrate	TMB (3,3',5,5'-tetramethylbenzidine)	54827-17-7	259-364-6	< 10.0%
Stop Solution	Sulfuric Acid	7664-93-9	231-639-5	4.4%

NA – Not Available

4. FIRST AID MEASURES

Skin Exposure: In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing. Seek medical attention if adverse symptoms appear.

Eye Exposure: In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Seek medical attention if adverse symptoms appear.

Inhalation Exposure: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen and seek medical attention.

Ingestion: If swallowed, wash out mouth with water provided person is conscious. Seek immediate medical attention.

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5. FIRE FIGHTING MEASURES

Flammability:	Solutions are non-flammable. Boxing, instruction papers and powdered reagents are flammable.
Suitable Extinguishing Media:	Use extinguishing media appropriate to the surrounding fire conditions, such as carbon dioxide, dry chemical powder, foam or water spray.
Equipment for fire fighting:	Wear self-contained breathing apparatus and protective clothing appropriate for fighting a fire involving chemical materials to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. In case of skin contact, flush with copious amounts of water and remove contaminated clothing.
Environmental Precautions:	Do not let the product enter the drainage system.
Methods For Cleaning Up:	Sweep up dry product, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

7. HANDLING AND STORAGE

7.1 Handling

Handling Procedure:	Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged exposure. Provide adequate ventilation in all work areas.
Safety:	This product contains human source material that has been found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus Type 1 and Type 2 (HIV-1, HIV-2) using registered methods. As no known test method can provide complete assurance that products derived from human specimens will not transmit HBsAg, HCV, HIV-1, HIV-2 or other blood-borne pathogens, this reagent should be handled as recommended for any potentially infectious human specimen. This product contains animal source material. As no known test method can provide complete assurance that products derived from animal specimens will not transmit blood-borne pathogens, this reagent should be handled as recommended for any potentially infectious human specimen.
Hygienic Practice:	Wash hands with soap and water following use.

7.2 Storage

Container:	Keep container tightly closed and labeled with the name of the product.
Recommended Temperature:	2°-8°C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure Limit Values

TLV/TWA: 0.2 mg/m^3 for Sulfuric Acid

OELV/TWA: 1 mg/m^3 for Sulfuric Acid per OSHA

8.2 Personal Protection

Respiratory Protection: Respirator protection is not required. Where protection is desired, use type N95 (US) or type P1 (EN 143) dust masks or. For higher level protection, use NIOSH (USA) or CEN (EU) approved respirators and filters.

Eye Protection: Chemical safety goggles.

Hand Protection: Compatible chemical resistant gloves. Use proper glove removal technique to avoid skin contact. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Skin Protection: Compatible chemical resistant gloves and other protective clothing as required to prevent skin contact.

General Hygiene Practices: Wash promptly if skin comes into contact with product. Wash thoroughly after handling. Remove any clothing that comes into contact with the product. Do not smoke or eat in the work environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Property	Anti-D-dimer Coated Microwells	D-dimer Calibrator	D-dimer Control I	D-dimer Control II	Sample Diluent	Immuno conjugate	Conjugate Diluent	Wash Solution	Substrate	Stop Solution
Appearance	N/A	straw-colored, powder	straw-colored, powder	straw-colored, powder	clear, colorless liquid	white powder	clear, colorless liquid	clear, colorless liquid	clear, blue colored liquid	clear, colorless liquid
Odor	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
pH	N/A	N/A	N/A	N/A	NA	N/A	NA	N/A	N/A	N/A
Freezing Point	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Vapor Pressure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Specific Gravity	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Solubility	N/A	water soluble	water soluble	water soluble	water soluble	water soluble	water soluble	water soluble	water soluble	water soluble
Evaporation Rate	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Viscosity	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Surface Tension	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Boiling Point	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Melting Point	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Flash Point	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Lower Explosive Limit	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Upper Explosive Limit	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Flammability	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Autoignition Temp.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

NA = not available

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10. STABILITY AND REACTIVITY

10.1 Stability: The product is stable until the expiration date stated on its label when properly stored at 2°-8°C.

10.2 Conditions To Avoid: Keep away from heat.

10.3 Materials To Avoid: Strong acids, strong reducing agents, strong oxidizing reagents.

10.4 Hazardous Decomposition Products: Hazardous decomposition products due to combustion may include carbon monoxide, carbon dioxide, sulfur oxides, and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

11.1 Acute Toxicity

Reagent/ Component	Chemical Name	Oral LD_{50}	Inhalation LC_{50}	Dermal LD_{50}
Antibody Coated Microwells	Monoclonal Anti-Human D-dimer IgG SiO_2 (silica gel desiccant packet)	No Data Available No Data Available	No Data Available No Data Available	No Data Available No Data Available
D-dimer Calibrator	Human D-dimer Human Plasma Glycine Hepes Ciprofloxacine	No Data Available No Data Available rat, 7,930 mg/kg No Data Available rat, > 2,000 mg/kg	No Data Available No Data Available No Data Available No Data Available No Data Available	No Data Available No Data Available No Data Available No Data Available No Data Available
D-dimer Control I	Human D-dimer Human Plasma Glycine Hepes Ciprofloxacine	No Data Available No Data Available rat, 7,930 mg/kg No Data Available rat, > 2,000 mg/kg	No Data Available No Data Available No Data Available No Data Available No Data Available	No Data Available No Data Available No Data Available No Data Available No Data Available
D-dimer Control II	Human D-dimer Human Plasma Glycine Hepes Ciprofloxacine	No Data Available No Data Available rat, 7,930 mg/kg No Data Available rat, > 2,000 mg/kg	No Data Available No Data Available No Data Available No Data Available No Data Available	No Data Available No Data Available No Data Available No Data Available No Data Available
Sample Diluent	Sodium Phosphate Dihydrate Sodium Chloride Tween 20 Bovine Serum Albumin Kathon CG Ciprofloxacine	No Data Available No Data Available rat, 40,554 mg/kg No Data Available rat, 3,350 mg/kg rat, > 2,000 mg/kg	No Data Available rat,1 hr >42,000 mg/m^3 No Data Available No Data Available rat, 4 hr, 330 mg/m^3 No Data Available	No Data Available rabbit, >10,000 mg/kg No Data Available No Data Available rabbit, > 5,000 mg/kg No Data Available
Anti-Human D-dimer HRP Immunoconjugate	Monoclonal Anti-Human D-dimer IgG Sodium Phosphate Dihydrate Bovine Serum Albumin Peroxidase Type XII (from horseradish)	No Data Available No Data Available No Data Available No Data Available	No Data Available No Data Available No Data Available No Data Available	No Data Available No Data Available No Data Available No Data Available
Conjugate Diluent	Sodium Phosphate Dihydrate Sodium Chloride Tween 20 Bovine Serum Albumin Kathon CG	No Data Available No Data Available rat, 40,554 mg/kg No Data Available rat, 3,350 mg/kg	No Data Available rat,1 hr >42,000 mg/m^3 No Data Available No Data Available rat, 4 hr, 330 mg/m^3	No Data Available rabbit, >10,000 mg/kg No Data Available No Data Available rabbit, > 5,000 mg/kg

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Wash Solution	Sodium Phosphate Dihydrate Sodium Chloride Tween 20 Kathon CG Ciprofloxacine	No Data Available No Data Available rat, 40,554 mg/kg rat, 3,350 mg/kg rat, > 2,000 mg/kg	No Data Available rat,1 hr >42,000 mg/m^3 No Data Available rat, 4 hr, 330 mg/m^3 No Data Available	No Data Available rabbit, >10,000 mg/kg No Data Available rabbit, > 5,000 mg/kg No Data Available
Substrate	TMB (3,3',5,5'-tetramethylbenzidine)	No Data Available	No Data Available	No Data Available
Stop Solution	Sulfuric Acid	rat, 2,140 mg/kg	rat, 2 hr, 510 mg/m^3	No Data Available

11.2 Irritation

Skin: Corrosive and destructive to tissue in rabbit (due to Sulfuric Acid).
Corrosive and destructive to tissue in rabbit (due to Kathon CG).
Mild skin irritation in human in 3 days (due to Tween 20)

Eye: Severe eye irritation in rabbit (due to Sulfuric Acid).
Severe corneal damage in rabbit (due to Kathon CG).

Inhalation: No Data Available

11.3 Sensitization

Skin: May cause skin sensitization.

Inhalation: No Data Available.

11.4 Carcinogenicity

The International Agency for Research on Cancer (IARC) has determined that occupational exposure to strong inorganic acid mists containing sulfuric acid is carcinogenic to humans (group 1).

11.5 Mutagenicity

Ciprofloxacine has shown germ cell mutagenicity in the following experimental situations

Genotoxicity in vitro - Human - lymphocyte
DNA damage

Genotoxicity in vitro - Human - lymphocyte
Unscheduled DNA synthesis

Genotoxicity in vitro - Hamster - Lungs
Micronucleus test

Genotoxicity in vitro - Hamster - Lungs
Cytogenetic analysis

Genotoxicity in vivo - mouse - Intraperitoneal
Cytogenetic analysis

Genotoxicity in vivo - mouse - Intraperitoneal
Sister chromatid exchange

11.6 Teratogenicity

No data available

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For the other components of this product, the health effects noted above are based on the extrapolation of data on the pure product ingredients. To the best of our knowledge, no health effects have been identified for the product mixture under normal conditions of use, although the health effects of the product have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Use in accordance with good laboratory practices. Do not waste into the environment. An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Toxicity to fish (Tween 20)	LC50, other fish – 350 mg/L, 24 hours
Toxicity to fish (Sulfuric Acid)	LC50, Gambusia affinis (Mosquito fish) – 42 mg/L, 96 hours
Toxicity to fish (Kathon CG)	No Data Available
Toxicity to daphnia (Sodium Chloride)	NOEC, Daphnia – 1,500 mg/L, 7 days
Toxicity to daphnia (Sodium Chloride)	EC50, Daphnia magna (water flea) – 1,661 mg/L, 48 hours

12.2 Mobility: No Data Available

12.3 Persistence and degradability: No Data Available

12.4 Bioaccumulative potential: No Data Available

12.5 PBT assessment: No Data Available

12.6 Other adverse effects: No Data Available

13. DISPOSAL CONSIDERATIONS

Contact a licensed professional waste disposal service to dispose of this material. Disposal should be made in accordance with existing disposal practices employed for infectious waste at your institution. Observe all federal, state and local environmental regulations and laws.

14. TRANSPORT INFORMATION

DOT (US):	Proper Name For Shipping:	Sulfuric Acid
	UN Number:	1830
	Hazard Class:	8
	Reportable Quantity:	1000 lbs.
	Packing Group:	II
	Marine Pollutant:	No
	Poison Inhalation Hazard:	No
IATA:	Proper name For Shipping:	Sulfuric Acid
	UN Number:	1830
	Hazard Class:	8
	Packing Group:	II
IMDG:	Proper name For Shipping:	Sulfuric Acid
	UN Number:	1830
	Hazard Class:	8
	Packing Group:	II
	Marine Pollutant	No

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15. REGULATORY INFORMATION

This product is classified and labeled in accordance with Directive 1999/45/EC and the following modifications. The health hazard classification has been determined based upon the composition and hazard data of each ingredient. Physical and health hazard information on the reagent mixture has not been determined. Any physical and health hazard information noted is based on a) evaluation of data of the pure ingredient and b) the concentration of each ingredient.

Hazard Classification

EC Symbol:	N
Indication of Danger:	Danger
Risk Code:	R20/22, R36/37/38
Safety Code:	S24/25, S26, S36/37/39, S46
Hazard Code:	H302, H303, H314, H315, H317, H318, H319, H335, H400, H402

OSHA Hazards:	Corrosive, Carcinogen, Skin sensitizer
SARA 302 Components:	Sulfuric Acid in this product is subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 Components:	Sulfuric Acid in this product is subject to reporting requirements of SARA Title III, Section 313.
SARA 311/312 Hazards:	Acute Health Hazard, Chronic Health Hazard (due to Kathon CG, Sulfuric Acid).
California Prop 65 Components:	This product contains a chemical (Sulfuric Acid) known to the State of California to cause cancer.

16. OTHER INFORMATION

The information supplied in this Material Safety Data Sheet represents the data and best information available on the date of preparation. It is provided to allow for the proper and safe use, storage, transport and disposal of the product. It is not to be considered as a warranty, guarantee or specification of the product quality. It is related to the materials specifically indicated and does not apply if these are used in combination with other materials or during processes not indicated in the text of this safety data sheet.

Sekisui Diagnostics, LLC and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.