

MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION

- 1.1 Product Name:** DIMERTEST® Latex kit
- 1.2 Product REF:** DLHK7
- 1.3 Configuration:** Four (4) reagent kit
- 1.4 Use of Product:** For In Vitro Diagnostic Use

- 1.5 Company**
- | | |
|---|---|
| Manufacturer: Sekisui Diagnostics, LLC
500 West Avenue
Stamford, CT 06902 USA
Tel: (203) 602 7777
Fax: (203) 602 2221
Email: linus@amdiag.com | Distributor EU: American Diagnostica GmbH
Kaplangasse 35
Pfungstadt 64319 Germany
Tel: +49 6157 990899
Fax: +49 6157 990808
Email: info@amdiag.de |
|---|---|

2. HAZARDS IDENTIFICATION

- 2.1 Classification:** Xn (Harmful), R21/22, R50/53
- 2.2 Potential Health and Environmental Effects**
- | | |
|-------------------------|---|
| Skin Exposure: | May cause irritation. |
| Eye Exposure: | May be harmful. |
| Inhalation Exposure: | May be harmful. |
| Ingestion: | Very harmful if swallowed. |
| Environmental Exposure: | Might cause adverse effects to the environment. |

3. COMPOSITION/INFORMATION ON INGREDIENTS

Reagent/Component	Chemical Name	CAS No.	EINECS No.	Concentration, w/v, %
Latex Reagent	Latex Particle	NA	NA	0.83%
	Monoclonal Anti-Human D-dimer IgG	NA	NA	NA
	Disodium Phosphate	7558-79-4	231-448-7	0.115%
	Potassium Phosphate	7778-77-0	231-913-4	0.02%
	Sodium Chloride	7647-14-5	231-598-3	2.4%
	Potassium Chloride	7447-40-7	231-211-8	0.02%
	Bovine Serum Albumin	9048-46-8	232-936-2	1.0%
	Sodium Azide	26628-22-8	247-852-1	0.1%
Positive Control	Human Fibrin Fragment (D-dimer)	9001-31-4	232-590-7	< 0.01%
	Disodium Phosphate	7558-79-4	231-448-7	0.144%
	Potassium Phosphate	7778-77-0	231-913-4	0.024%
	Sodium Chloride	7647-14-5	231-598-3	0.8%
	Potassium Chloride	7447-40-7	231-211-8	0.02%
	Bovine Serum Albumin	9048-46-8	232-936-2	0.5%
	Sodium Azide	26628-22-8	247-852-1	0.1%

Negative Control	Disodium Phosphate	7558-79-4	231-448-7	0.144%
	Potassium Phosphate	7778-77-0	231-913-4	0.024%
	Sodium Chloride	7647-14-5	231-598-3	0.8%
	Potassium Chloride	7447-40-7	231-211-8	0.02%
	Bovine Serum Albumin	9048-46-8	232-936-2	0.5%
	Sodium Azide	26628-22-8	247-852-1	0.1%
Buffer	Disodium Phosphate, monobasic	7558-79-4	231-448-7	0.144%
	Potassium Phosphate, monobasic	7778-77-0	231-913-4	0.024%
	Sodium Chloride	7647-14-5	231-598-3	0.8%
	Potassium Chloride	7447-40-7	231-211-8	0.02%
	Sodium Azide	26628-22-8	247-852-1	0.1%

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 medical attention if adverse symptoms appear.

5. FIRE FIGHTING MEASURES

Flammability:	Solutions are non-flammable. Boxing and instruction papers 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.
Unsuitable Extinguishing Media:	None known.
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:	Soak up with inert absorbent material, place in a bag and hold for waste disposal. 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: 0.1 mg/m³ for Sodium Azide¹
TLV/STEL: 0.3 mg/m³ for Sodium Azide
TLV/Ceiling: 0.29 mg/m³ for Sodium Azide, 0.11 ppm for Hydrazoic acid vapor per ACGIH
EU IOELV: 0.1 mg/m³ (TWA) for Sodium Azide, 0.3 mg/m³ (STEL) for Sodium Azide

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	Latex Reagent	Positive Control	Negative Control	Buffer
Appearance	milky white Suspension	clear, pale yellow liquid	clear, pale yellow liquid	clear, colorless liquid
Odor	None	None	None	None
pH	7.0	7.4	7.4	7.4
Freezing Point	N/A	N/A	N/A	N/A
Vapor Pressure	N/A	N/A	N/A	N/A
Specific Gravity	N/A	N/A	N/A	N/A
Solubility	water soluble	water soluble	water soluble	water soluble
Evaporation Rate	N/A	N/A	N/A	N/A
Viscosity	N/A	N/A	N/A	N/A
Surface Tension	N/A	N/A	N/A	N/A
Boiling Point	N/A	N/A	N/A	N/A
Melting Point	N/A	N/A	N/A	N/A
Flash Point	N/A	N/A	N/A	N/A
Lower Explosive Limit	N/A	N/A	N/A	N/A
Upper Explosive Limit	N/A	N/A	N/A	N/A
Flammability	N/A	N/A	N/A	N/A
Autoignition Temp.	N/A	N/A	N/A	N/A

N/A = not available

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, and nitrogen oxides.
Warning: Sodium Azide may form explosive compounds, copper azide or lead azide, when in contact with laboratory plumbing.

11. TOXICOLOGICAL INFORMATION

11.1 Acute Toxicity

Reagent/ Component	Chemical Name	Oral LD ₅₀	Inhalation LC ₅₀	Dermal LD ₅₀
Latex Reagent	Latex Particle	NA	NA	NA
	Monoclonal Anti-Human D-dimer IgG	NA	NA	NA
	Disodium Phosphate	NA	NA	NA
	Potassium Phosphate	NA	NA	rabbit, >4,640 mg/kg
	Sodium Chloride	NA	rat, 1 hr >42,000 mg/m ³	rabbit, >10,000 mg/kg
	Potassium Chloride	NA	NA	NA
	Bovine Serum Albumin	NA	NA	NA
	Sodium Azide	NA	rat, 37 mg/m ³	rabbit, 20 mg/kg
Positive Control	Human Fibrin Fragment (D-dimer)	NA	NA	NA
	Disodium Phosphate	NA	NA	NA
	Potassium Phosphate	NA	NA	rabbit, >4,640 mg/kg
	Sodium Chloride	NA	rat, 1 hr >42,000 mg/m ³	rabbit, >10,000 mg/kg
	Potassium Chloride	NA	NA	NA
	Bovine Serum Albumin	NA	NA	NA
	Sodium Azide	NA	rat, 37 mg/m ³	rabbit, 20 mg/kg
Negative Control	Disodium Phosphate	NA	NA	NA
	Potassium Phosphate	NA	NA	rabbit, >4,640 mg/kg
	Sodium Chloride	NA	rat, 1 hr >42,000 mg/m ³	rabbit, >10,000 mg/kg
	Potassium Chloride	NA	NA	NA
	Bovine Serum Albumin	NA	NA	NA
	Sodium Azide	NA	rat, 37 mg/m ³	rabbit, 20 mg/kg
Buffer	Disodium Phosphate	NA	NA	NA
	Potassium Phosphate,	NA	NA	rabbit, >4,640 mg/kg
	Sodium Chloride	NA	rat, 1 hr >42,000 mg/m ³	rabbit, >10,000 mg/kg
	Potassium Chloride	NA	NA	NA
	Sodium Azide	NA	rat, 37 mg/m ³	rabbit, 20 mg/kg

NA – Not Available

11.2 Irritation

Skin: Mild skin irritation in rabbit over 24 hours (from Disodium Phosphate)
 Eye: Mild eye irritation in rabbit over 24 hours (from Disodium Phosphate, Potassium Chloride)
 Inhalation: No Data Available

11.3 Sensitization

Skin: May cause an allergic skin reaction (from Latex Particles)
 Inhalation: No Data Available

11.4 Carcinogenicity

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen.

11.4 Mutagenicity

No data available

11.4 Teratogenicity

No data available

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:

Toxicity to fish (Potassium Chloride)	LC50, pimephales promelas (fathead minnow) – 880 mg/L, 96 hours Mortality NOEC, pimephales promelas (fathead minnow) – 500 mg/L, 7 days Mortality LOEC, pimephales promelas (fathead minnow) – 1,000 mg/L, 7 days
Toxicity to daphnia (Potassium Chloride)	EC50, daphnia magna (water flea) – 83 mg/L, 48 hours
Toxicity to daphnia (Sodium Chloride)	EC50, daphnia magna (water flea) – 1,661 mg/L, 48 hours
Toxicity to daphnia (Sodium Chloride)	Mortality NOEC, daphnia – 1,500 mg/L, 7 days
Toxicity to daphnia (Sodium Azide)	EC50, daphnia pulex (water flea) – 4.2 mg/L, 48 hours

12.2 Mobility: No Data Available

12.3 Persistence and degradability No Data Available
degradability:

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):	Not classified as dangerous goods
IATA:/ICAO	Not classified as dangerous goods
ADR (road):	Not classified as dangerous goods
RID (rail):	Not classified as dangerous goods

15. REGULATORY INFORMATION

This product is classified and labeled in accordance with Directives 1999/45/EC and 67/548/EEC. 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:	Xn
Indication of Danger:	Harmful.
Risk Code:	R21/22, R28, R32, R50/53
Safety Code:	S24/25, S26, S37/39, S46, S29/56
Hazard Code:	H300, H302, H313, H317, H400, H410

OSHA Hazards:	Sodium Azide is highly toxic by ingestion. Target organs are primarily the central nervous system and the brain.
SARA 302 Components:	Sodium Azide in this product, however it's level does not exceed the threshold reporting levels subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 Components:	Sodium Azide in this product, however it's level does not exceed the threshold reporting levels by SARA Title III, Section 313.
SARA 311/312 Hazards:	No SARA hazards.
California Prop 65 Components:	This product does not contain any chemicals known to the State of California to cause cancer, birth defects or any other reproductive harm.

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.