

## MATERIAL SAFETY DATA SHEET

### 1. PRODUCT IDENTIFICATION

- 1.1 Product Name:** HEPTTEST®  
**1.2 Product REF:** 830  
**1.3 Configuration:** Twelve (12) vial set of reagents  
**1.4 Use of Product:** For In Vitro Diagnostic Use  
**1.5 Company**
- |                      |  |                        |  |
|----------------------|--|------------------------|--|
| <b>Manufacturer:</b> | Sekisui Diagnostics, LLC<br>500 West Avenue<br>Stamford, CT 06902 USA<br>Tel: (203) 602 7777<br>Fax: (203) 602 2221<br>Email: <a href="mailto:linus@amdiag.com">linus@amdiag.com</a> | <b>Distributor EU:</b> | American Diagnostica GmbH<br>Kaplangasse 35<br>Pfungstadt 64319 Germany<br>Tel: +49 6157 990899<br>Fax: +49 6157 990808<br>Email: <a href="mailto:info@amdiag.de">info@amdiag.de</a> |
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### 2. HAZARDS IDENTIFICATION

- 2.1 Classification:** Xi, Irritant, R21/22, R50/53  
**2.2 Potential Health and Environmental Effects**
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|-------------------------|---|
| Skin Exposure:          | May be harmful.                                 |
| Eye Exposure:           | May cause eye irritation.                       |
| 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./ EC No.	Concentration, w/v, %
Recalmix®	Calcium Chloride	10043-52-4	233-140-8	< 10.0%
	Rabbit Brain Cephalin	NA	NA	< 10.0%
	Bovine Plasma	NA	NA	100%
Bovine Factor Xa	Bovine Factor Xa	9002-05-5	3.4.21.6	< 1.0%
	Tris-Maleate	72200-76-1	276-455-6	6.0%
	Sodium Chloride	7647-14-5	231-598-3	1.0%
	Polyethylene Glycol	25322-68-3	NA	1.0%
	Glycine	56-40-6	200-272-2	< 1.0%
	D-Mannitol	69-65-8	200-711-8	1.8%

### 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 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

TWA:	10 mg/m <sup>3</sup> for Polyethylene Glycol per WEEL
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## 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	Recalmix	Bovine Factor Xa
Appearance	white power	white power
Odor	None	None
pH	NA	NA
Freezing Point	NA	NA
Vapor Pressure	NA	NA
Specific Gravity	NA	NA
Solubility	water soluble	water soluble
Evaporation Rate	NA	NA
Viscosity	NA	NA
Surface Tension	NA	NA
Boiling Point	NA	NA
Melting Point	NA	NA
Flash Point	NA	NA
Lower Explosive Limit	NA	NA
Upper Explosive Limit	NA	NA
Flammability	NA	NA
Autoignition Temp.	NA	NA

NA = not available

## 10. STABILITY AND REACTIVITY

10.1 <b>Stability:</b>	The product is stable until the expiration date stated on its label when properly stored at 2°-8°C.
10.2 <b>Conditions To Avoid:</b>	Keep away from heat.
10.3 <b>Materials To Avoid:</b>	Strong acids, strong reducing agents, strong oxidizing reagents.
10.4 <b>Hazardous Decomposition Products:</b>	Hazardous decomposition products due to combustion may include carbon monoxide, carbon dioxide, and nitrogen oxides.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Acute Toxicity

Reagent/ Component	Chemical Name	Oral LD <sub>50</sub>	Inhalation LC <sub>50</sub>	Dermal LD <sub>50</sub>
Recalmix	Calcium Chloride	rat, 1,000 mg/kg	No Data Available	No Data Available
	Rabbit Brain Cephalin	No Data Available	No Data Available	No Data Available
	Bovine Plasma	No Data Available	No Data Available	No Data Available
Bovine Factor Xa	Bovine Factor Xa	No Data Available	No Data Available	No Data Available
	Tris-Maleate	No Data Available	No Data Available	No Data Available
	Sodium Chloride	No Data Available	rat, 1 hr, >42,000 mg/m <sup>3</sup>	rabbit, >10,000 mg/kg
	Polyethylene Glycol	rat, > 50,000 mg/kg	No Data Available	rabbit, > 20,000 mg/kg
	Glycine	rat, 7,930 mg/kg	No Data Available	No Data Available
	D-Mannitol	rat, 13,500 mg/kg	No Data Available	No Data Available

NA – Not Available

### 11.2 Irritation

Skin: No Data Available  
 Eye: Severe eye irritation in rat (from Calcium Chloride)  
 Inhalation: No Data Available

### 11.3 Sensitization

Skin: No Data Available  
 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 (Calcium Chloride)	LC50, <i>Lepomis macrochirus</i> – 10,650 mg/L, 96 hours
Toxicity to daphnia (Calcium Chloride)	EC50, <i>Daphnia magna</i> (water flea) – 52 mg/L, 48 hours
Toxicity to daphnia (Sodium Chloride)	EC50, <i>Daphnia magna</i> (water flea) – 1,661 mg/L, 48 hours
Toxicity to daphnia (Sodium Chloride)	Mortality NOEC, <i>daphnia</i> – 1,500 mg/L, 7 days

**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: Not classified as dangerous goods
- IMDG: 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: Xi
- Indication of Danger: Irritant
- Risk Code: R21/22, R51/53
- Safety Code: S24/25, S26, S37/39, S46
- Hazard Code: H302, H303, H316, H318, H319, H401, H402

- OSHA Hazards: Calcium Chloride is harmful by ingestion.
- SARA 302 Components: No chemicals in this product are subject to the reporting requirements of SARA Title III, Section 302.
- SARA 313 Components: This product does not contain any chemical components with known CAS numbers that exceed the threshold reporting levels by SARA Title III, Section 313.
- SARA 311/312 Hazards: Acute Health Hazard (Calcium Chloride).
- 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.