

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations Revision Date: 22/June/2016

Version: 1.0

SECTION 1: IDENTIFICATION

Product Identifier 1.1. **Product Form:** Mixture

Product Name: RapidTEG™ Reagent **Intended Use of the Product**

Use of the Substance/Mixture: Use as an activator for blood samples to be tested on the TEG® analyzer.

Name, Address, and Telephone of the Responsible Party 1.3.

Haemonetics 400 Wood Road Braintree, MA 02184

1.4. **Emergency Telephone Number**

Emergency Number : (800) 438-2834

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Skin Irrit. 2 H315 Eye Irrit. 2A H319 STOT SE 3 H335

Full text of hazard classes and H-statements: see section 16

2.2. **Label Elements**

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H315 - Causes skin irritation.

> H319 - Causes serious eye irritation. H335 - May cause respiratory irritation.

Precautionary Statements (GHS-US)

: P261 - Avoid breathing vapors, mist, or spray.

P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear protective gloves, protective clothing, and eye protection.

P302+P352 - If on skin: Wash with plenty of water.

P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position

comfortable for breathing.

P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P312 - Call a poison center or doctor if you feel unwell. P321 - Specific treatment (see section 4 on this SDS).

P332+P313 - If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse. P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local, regional, national,

and international regulations.

Other Hazards 2.3.

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

Hazards Not Otherwise Classified (HNOC): Safety data sheet available on request

Unknown Acute Toxicity (GHS-US) 2.4.

No data available

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-	(CAS No) 77-86-1	> 60	Skin Irrit. 2, H315
(Tris Buffer)			Eye Irrit. 2A, H319
			STOT SE 3, H335
Kaolin	(CAS No) 1332-58-7	20 - 30	Not classified
Tissue Factor	(CAS No) Not available	5 - 10	Not classified

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Causes serious eye irritation. Causes skin irritation. May cause respiratory irritation.

Symptoms/Injuries After Inhalation: Irritation of the respiratory tract and the other mucous membranes.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis. **Symptoms/Injuries After Eye Contact:** Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use. Exposure may produce an allergic reaction.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire. **Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing dust.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

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Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. **Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing dust.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight,

extremely high or low temperatures and incompatible materials. **Incompatible Products:** Strong acids, strong bases, strong oxidizers.

Storage Temperature: 2 - 8 °C 7.3. Specific End Use(s)

Use as an activator for blood samples to be tested on the TEG® analyzer.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Kaolin (1332-58-7)			
USA ACGIH	ACGIH TWA (mg/m³)	2 mg/m³ (particulate matter containing no asbestos and <1%	
		crystalline silica, respirable fraction)	
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen	
USA NIOSH	NIOSH REL (TWA) (mg/m³)	10 mg/m³ (total dust)	
		5 mg/m³ (respirable dust)	
USA OSHA	OSHA PEL (TWA) (mg/m³)	15 mg/m³ (total dust)	
		5 mg/m³ (respirable fraction)	

8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles.







Materials for Protective Clothing

Hand Protection Eye Protection

Skin and Body Protection Respiratory Protection

: Chemically resistant materials and fabrics.

- : Wear protective gloves.
- : Chemical safety goggles.
- : Wear suitable protective clothing.

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Solid

Appearance : Lyophilized white powder in clear glass vial with rubber stopper and white seal.

Vial has a pink and white label with lot number & expiration date.

Odor : None

No data available Odor Threshold No data available pН **Evaporation Rate** No data available **Melting Point** No data available **Freezing Point** No data available **Boiling Point** No data available **Flash Point** No data available **Auto-ignition Temperature** No data available No data available **Decomposition Temperature** Flammability (solid, gas) No data available No data available Vapor Pressure Relative Vapor Density at 20°C No data available **Relative Density** No data available Solubility Water: Soluble

Partition Coefficient: N-Octanol/Water: No data availableViscosity: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- **10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- **10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- **10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials.
- **10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products: None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)		
LD50 Oral Rat	> 5000 mg/kg	
LD50 Dermal Rat	> 5000 mg/kg	
Kaolin (1332-58-7)		
LD50 Oral Rat	> 5000 mg/kg	
LD50 Dermal Rabbit	> 5000 mg/kg	

Skin Corrosion/Irritation: Causes skin irritation.

Serious Eye Damage/Irritation: Causes serious eye irritation.

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): May cause respiratory irritation.

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Irritation of the respiratory tract and the other mucous membranes. **Symptoms/Injuries After Skin Contact:** Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

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Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use. Exposure may produce an allergic reaction.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

12.2. Persistence and Degradability

Persistence and Degradability Not established.

12.3. Bioaccumulative Potential

Bioaccumulative Potential Not established.

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Refer to local statutory requirements and the Biohazardous Waste Disposal Guidelines for proper disposal instructions.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

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RapidTEG™ Reagent		
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard	
1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)		
Listed on the United States TSCA (Toxic Substances Control Act) inventory		
Kaolin (1332-58-7) Listed on the United States TSCA (Toxic Substances Control Act) inventory		

15.2. US State Regulations

Kaolin (1332-58-7)

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 22/June/2016

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard

Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)

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