

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
 Product Name : RapidTEG™ Reagent

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

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

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

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

Classification according to Regulation (EC) No. 1272/2008 [CLP]

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

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

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



Signal word (CLP) : Warning

Hazard statements (CLP) : H315 - Causes skin irritation
 H319 - Causes serious eye irritation
 H335 - May cause respiratory irritation

Precautionary statements (CLP) : 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 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.

2.3. Other hazards

Other hazards not contributing to the classification : Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (Tris Buffer)	(CAS No) 77-86-1 (EC no) 201-064-4	> 60	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Kaolin	(CAS No) 1332-58-7 (EC no) 310-194-1	20 - 30	Not classified
Tissue Factor	(CAS No) Not available	5 - 10	Not classified

Full text of H-statements: 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 after 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: Firefighting 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.

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 responders

Protective equipment : Equip cleanup crew with proper protection.

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 material 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, shovelling 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.

Incompatible materials : Sources of ignition. Direct sunlight.

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

Kaolin (1332-58-7)		
Belgium	Limit value (mg/m ³)	2 mg/m ³ (alveolar fraction)
Bulgaria	OEL TWA (mg/m ³)	3,0 mg/m ³ (containing <2% free Crystalline silicon dioxide in respirable fraction-respirable fraction) 6,0 mg/m ³ (containing <2% free Crystalline silicon dioxide in respirable fraction-inhalable fraction)
Croatia	GVI (granična vrijednost izloženosti) (mg/m ³)	2 mg/m ³ (respirable dust)
France	VME (mg/m ³)	10 mg/m ³
USA ACGIH	ACGIH TWA (mg/m ³)	2 mg/m ³ (particulate matter containing no asbestos and <1% crystalline silica, respirable fraction)

Kaolin (1332-58-7)		
Spain	VLA-ED (mg/m ³)	2 mg/m ³ (this value is for the particulate matter that is free from Asbestos and contains <1% of Crystalline silica-respirable fraction)
Switzerland	VME (mg/m ³)	3 mg/m ³ (respirable dust)
United Kingdom	WEL TWA (mg/m ³)	2 mg/m ³ (respirable dust)
United Kingdom	WEL STEL (mg/m ³)	6 mg/m ³ (calculated-respirable dust)
Denmark	Grænseværdie (langvarig) (mg/m ³)	2 mg/m ³ (respirable)
Finland	HTP-arvo (8h) (mg/m ³)	2 mg/m ³ (respirable)
Ireland	OEL (8 hours ref) (mg/m ³)	2 mg/m ³ (respirable dust)
Poland	NDS (mg/m ³)	10,0 mg/m ³ (<2% free crystalline silica and containing no asbestos-inhalable fraction)
Slovakia	NPHV (priemerná) (mg/m ³)	2 mg/m ³ 10 mg/m ³ (total aerosol)
Portugal	OEL TWA (mg/m ³)	2 mg/m ³ (respirable fraction, particulate matter containing no Asbestos and <1% Crystalline silica)
Portugal	OEL chemical category (PT)	A4 - Not Classifiable as a Human Carcinogen

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

: Chemically resistant materials and fabrics.

Hand protection

: Wear protective gloves.

Eye protection

: Chemical safety goggles.

Skin and body protection

: Wear suitable protective clothing.

Respiratory protection

: 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state

: Solid

Colour

: 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.

Odour

: None

Odour threshold

: No data available

pH

: No data available

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

Decomposition temperature

: No data available

Flammability (solid, gas)

: No data available

Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Solubility	: Water: Soluble
Partition coefficient: n-octanol/water	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: 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 sensitisation	: 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	: 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.
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information
12.1. Toxicity

Ecology - general : Not classified.

12.2. Persistence and degradability
RapidTEG™ Reagent

Persistence and degradability	Not established.
-------------------------------	------------------

12.3. Bioaccumulative potential
RapidTEG™ Reagent

Bioaccumulative potential	Not established.
---------------------------	------------------

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. 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

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated for transport				
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No

14.6. Special precautions for user

No additional information available

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3. Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008	1,3-Propanediol, 2-amino-2-(hydroxymethyl)-
3.b. Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	1,3-Propanediol, 2-amino-2-(hydroxymethyl)-

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Kaolin (1332-58-7)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Revision date: : 22/June/2016

Data sources : According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

EU GHS SDS

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.