

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Revision Date: 18/August/2016 Version: 1.0

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

1.1. Product identifier

Product form : Mixture

Product Name : ActivatorF PlateletMapping® 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 clotting activator in the PlateletMapping®Assay for the TEG® analyzer.

1.2.2. Uses advised against: No additional information available

1.3. Details of the supplier of the safety data sheet

Company Haemonetics

400 Wood Road Braintree, MA 02184

1.4. Emergency telephone number

Emergency number : Contact the Health, Safety, and Environment Department - (781) 848-7100

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)

GHS07

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

reathing.

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

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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	> 85	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Disodium EDTA	(CAS No) 139-33-3 (EC no) 205-358-3	< 5	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 STOT RE 2, H373
Trehalose dihydrate	(CAS No) 6138-23-4 (EC no) 612-140-5	< 5	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.

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 considered flammable but may burn at high temperatures. Contains

substances that are combustible dusts. If dried and allowed to accumulate, may form combustible dust concentrations in air that could ignite and cause an

explosion. Take appropriate precautions.

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.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid breathing dust. Avoid all contact with skin, eyes, or clothing.

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, 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 breathing dust. Avoid contact with skin, eyes and clothing. Avoid contact with eyes, skin and clothing.

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 clotting activator in the PlateletMapping® Assay for the TEG® analyzer.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

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.

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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 : No data available

Odour : None

Odour threshold : No data available рΗ : No data available : No data available **Evaporation rate** Melting point : No data available Freezing point No data available : No data available **Boiling point** Flash point : No data available Auto-ignition temperature : No data available Decomposition temperature : No data available Flammability (solid, gas) No data available : No data available Vapour pressure Relative vapour density at 20 °C : No data available Solubility : Soluble in water. Partition coefficient: n-octanol/water : No data available No data available Viscosity : No data available **Explosive properties** 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

Carbon oxides (CO, CO₂). Nitrogen oxides.

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	
Disodium EDTA (139-33-3)		
LD50 oral rat	2 g/kg	

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Disodium EDTA (139-33-3)		
ATE CLP (oral)	2.000,00 mg/kg bodyweight	
ATE CLP (dust,mist)	1,50 mg/l/4h	

Skin corrosion/irritation: Causes skin irritation.Serious eye damage/irritation: Causes serious eye irritation.

Respiratory or skin sensitisation: Not classifiedGerm cell mutagenicity: Not classifiedCarcinogenicity: Not classifiedReproductive 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

Potential adverse human health effects and : Based on available data, the classification criteria are not met.

symptoms

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Not classified.

Disodium EDTA (139-33-3)	
LC50 fish 1	320 mg/l (Exposure time: 96 h - Species: Poecilia reticulata [semi-static])

12.2. Persistence and degradability

ActivatorF PlateletMapping® Reagent	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

ActivatorF PlateletMapping® 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 : Container may remain hazardous when empty. Continue to observe all precautions.

Refer to local statutory requirements and the Biohazardous Waste Disposal

Guidelines for proper disposal instructions.

Ecology - waste materials : Avoid release to the environment.

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SECTION 14: Transport information

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued. In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN numbe	er		·	
Not regulated for tra	ansport			
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 gr	oup			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environme	ental hazards	1		I
Dangerous for the	Dangerous for the	Dangerous for the	Dangerous for the	Dangerous for the
environment : No	environment : No	environment : No	environment : No	environment : No
	Marine pollutant : 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

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

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SECTION 16: Other information

Revision date: : 18/August/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:

Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H373	May cause damage to organs through prolonged or repeated exposure

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.

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