Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Revision Date: 22/June/2016 Version: 1.0

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

: Heparinase I, recombinant

1.1. Product identifier

Product form Product Name : Mixture

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

HAEMONETIC

1.2.1. Relevant identified uses

Use of the substance/mixture : Use for reversal of heparin in samples that may contain heparin on the TEG[®] system.

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]Acute Tox. 4 (Oral)H302Aquatic Chronic 3H412Full 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)

	GH507
Signal word (CLP)	: Warning
Hazard statements (CLP)	: H302 - Harmful if swallowed
	H412 - Harmful to aquatic life with long lasting effects
Precautionary statements (CLP)	 P264 - Wash hands, forearms, and other exposed areas thoroughly after handling. P270 - Do not eat, drink or smoke when using this product.
	P273 - Avoid release to the environment. P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.
	P330 - Rinse mouth.
	P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.
EUH-statements	: EUH032 - Contact with acids liberates very toxic gas
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]
Trehalose dihydrate	(CAS No) 6138-23-4 (EC no) 612-140-5	80 - 90	Not classified
Ammonium sulfate	(CAS No) 7783-20-2 (EC no) 231-984-1	5 - 10	Not classified
Lyase, heparin (heparinase)	(CAS No) 9025-39-2	< 5	Not classified
Sodium azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 2	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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	 Using proper respiratory protection, move the exposed person to fresh air at once. Encourage exposed person to cough, spit out, and blow nose to remove dust. Immediately call a poison center, physician, or emergency medical service.
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	: Harmful if swallowed. May cause damage to organs through prolonged or repeated exposure.
Symptoms/injuries after inhalation	: Dust may be harmful or cause irritation.
Symptoms/injuries after skin contact	: Prolonged exposure may cause skin irritation.
Symptoms/injuries after eye contact	: May cause slight irritation to eyes.
Symptoms/injuries after ingestion	: This material is harmful orally and can cause adverse health effects or death in
	significant amounts.
Chronic symptoms	: May cause damage to organs through prolonged or repeated exposure.
4.3. Indication of any immediate	e medical attention and special treatment needed
If exposed or concerned, get medical ad	vice and attention. If medical advice is needed, have product container or label at hand.
SECTION 5: Firefighting mea	sures
5.1. Extinguishing media	
Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
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	
Fire hazard	: Combustible Dust.
Explosion hazard	: Dust explosion hazard in air.
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.
Other information	: Do not allow run-off from fire fighting to enter drains or water courses. Risk of dust explosion.
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	According to Regulation (EC) NO. 1907/2006 (REACH) with its amendment Regulation (EC) 2015/830
SECTION 6: Accidental relea	ase measures
6.1. Personal precautions, prote	ective equipment and emergency procedures
General measures	: Avoid breathing dust. Avoid all contact with skin, eyes, or clothing. Avoid generating dust. Remove ignition sources. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.
6.1.1. For non-emergency personne	I
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	5
Prevent entry to sewers and public wat	ers. Avoid release to the environment.
6.3. Methods and material for o	containment and cleaning up
For containment	: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Avoid generation of dust during clean-up of spills.
Methods for cleaning up	: Clean up spills immediately and dispose of waste safely. Contact competent authorities after a spill. Use explosion proof vacuum during cleanup, with appropriate filter. Do not mix with other materials. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Use only non-sparking tools.
6.4. Reference to other section	S
See Section 8 for exposure controls and	d personal protection and Section 13 for disposal considerations.
SECTION 7: Handling and st	orage
7.1. Precautions for safe handli	
Additional hazards when processed	: Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.
Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating,

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. Handle empty containers with care because they may still present a hazard. Do not get in eyes, on skin, or on clothing. Avoid contact with skin, eyes and clothing. Avoid creating or spreading dust. Keep away from heat, sparks, open flames, hot surfaces. – No
	smoking.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety procedures.
7.2. Conditions for safe storage	ge, including any incompatibilities
Technical measures	· Comply with applicable regulations. Avoid creating or spreading dust. Use

Technical measures	 Comply with applicable regulations. Avoid creating or spreading dust. Use explosion-proof electrical, ventilating, lighting equipment. Proper grounding procedures to avoid static electricity should be followed. 	
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 for reversal of heparin in samples that may contain heparin in testing on the TEG® system.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ammonium sulfate (7783-20-2)			
BulgariaOEL TWA (mg/m³)10,0 mg/m³			
Sodium azide (26628-22-8)			
EU IOELV TWA (mg/m³) 0,1 mg/m³			



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Sodium azide (26628-22-8)	
EU	IOELV STEL (mg/m ³)	0,3 mg/m³
Austria	MAK (mg/m³)	0,1 mg/m ³
Austria	MAK Short time value (mg/m³)	0,3 mg/m ³
Austria	OEL chemical category (AT)	Skin notation
Belgium	OEL chemical category (BE)	Skin, Skin notation
Bulgaria	OEL TWA (mg/m³)	0,1 mg/m ³
Bulgaria	OEL STEL (mg/m ³)	0,3 mg/m³
Croatia	GVI (granična vrijednost izloženosti) (mg/m ³)	0,1 mg/m ³
Croatia	KGVI (kratkotrajna granična vrijednost izloženosti) (mg/m ³)	0,3 mg/m ³
Croatia	OEL chemical category (HR)	Skin notation
Cyprus	OEL TWA (mg/m³)	0,1 mg/m³
Cyprus	OEL STEL (mg/m ³)	0,3 mg/m³
Cyprus	OEL chemical category (CY)	Skin-potential for cutaneous absorption
France	VLE (mg/m ³)	0,3 mg/m ³ (restrictive limit)
France	VME (mg/m ³)	0,1 mg/m ³ (restrictive limit)
France	OEL chemical category (FR)	Risk of cutaneous absorption
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	0,2 mg/m ³
Gibraltar	OEL TWA (mg/m ³)	0,1 mg/m ³
Gibraltar	OEL STEL (mg/m ³)	0,3 mg/m ³
Gibraltar	OEL chemical category (GI)	Skin notation
Greece	OEL TWA (mg/m³)	0,3 mg/m³
Greece	OEL TWA (ppm)	0,1 ppm
Greece	OEL STEL (mg/m ³)	0,3 mg/m ³
Greece	OEL STEL (ppm)	0,1 ppm
USA ACGIH	ACGIH Ceiling (mg/m ³)	0,29 mg/m ³
USA ACGIH	ACGIH Ceiling (ppm)	0,11 ppm (vapor)
Italy	OEL TWA (mg/m ³)	0,1 mg/m ³
Italy	OEL STEL (mg/m ³)	0,3 mg/m ³
, Italy	OEL chemical category (IT)	skin - potential for cutaneous absorption
Latvia	OEL TWA (mg/m ³)	0,1 mg/m ³
Latvia	OEL chemical category (LV)	skin - potential for cutaneous exposure
Spain	VLA-ED (mg/m ³)	0,1 mg/m ³ (indicative limit value)
Spain	VLA-EC (mg/m ³)	0,3 mg/m ³
Spain	OEL chemical category (ES)	skin - potential for cutaneous exposure
Switzerland	VLE (mg/m ³)	0,4 mg/m ³ (inhalable dust)
Switzerland	VME (mg/m ³)	0,2 mg/m ³ (inhalable dust)
Netherlands	Grenswaarde TGG 8H (mg/m ³)	0,1 mg/m ³
Netherlands	Grenswaarde TGG 15MIN (mg/m ³)	0,3 mg/m ³
United Kingdom	WEL TWA (mg/m ³)	0,1 mg/m ³
United Kingdom	WEL STEL (mg/m ³)	0,3 mg/m ³
United Kingdom	WEL STEE (Hg/H)	Potential for cutaneous absorption
Czech Republic	Expoziční limity (PEL) (mg/m ³)	0,1 mg/m ³
Czech Republic	OEL chemical category (CZ)	Potential for cutaneous absorption
Denmark	Grænseværdie (langvarig) (mg/m³)	0,1 mg/m ³
		ο,± (liβ/ lil



Heparinase I, recombinant (in cups and pins)

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Sodium azide (26628-22	-8)	
Estonia	OEL TWA (mg/m ³)	0,1 mg/m ³
Estonia	OEL STEL (mg/m ³)	0,3 mg/m ³
Estonia	OEL chemical category (ET)	Sensitizer, Skin notation
Finland	HTP-arvo (8h) (mg/m ³)	0,1 mg/m ³
Finland	HTP-arvo (15 min)	0,3 mg/m ³
Finland	OEL chemical category (FI)	Potential for cutaneous absorption
Hungary	AK-érték	0,1 mg/m ³
Hungary	CK-érték	0,3 mg/m³
Ireland	OEL (8 hours ref) (mg/m ³)	0,1 mg/m ³
Ireland	OEL (15 min ref) (mg/m3)	0,3 mg/m³
Ireland	OEL chemical category (IE)	Potential for cutaneous absorption
Lithuania	IPRV (mg/m ³)	0,1 mg/m³
Lithuania	TPRV (mg/m ³)	0,3 mg/m³
Lithuania	OEL chemical category (LT)	Skin notation
Malta	OEL TWA (mg/m³)	0,1 mg/m³
Malta	OEL STEL (mg/m ³)	0,3 mg/m ³
Malta	OEL chemical category (MT)	Possibility of significant uptake through the skin
Norway	Grenseverdier (AN) (mg/m ³)	0,1 mg/m³
Norway	Grenseverdier (Korttidsverdi) (mg/m3)	0,1 mg/m³
Poland	NDS (mg/m ³)	0,1 mg/m³
Poland	NDSCh (mg/m ³)	0,3 mg/m³
Romania	OEL TWA (mg/m³)	0,1 mg/m³
Romania	OEL STEL (mg/m ³)	0,3 mg/m³
Romania	OEL chemical category (RO)	Skin notation
Slovakia	NPHV (priemerná) (mg/m ³)	0,1 mg/m³
Slovakia	NPHV (Hraničná) (mg/m ³)	0,3 mg/m³
Slovakia	OEL chemical category (SK)	Potential for cutaneous absorption
Slovenia	OEL TWA (mg/m ³)	0,1 mg/m ³
Slovenia	OEL STEL (mg/m ³)	0,3 mg/m ³
Slovenia	OEL chemical category (SL)	Potential for cutaneous absorption
Sweden	nivågränsvärde (NVG) (mg/m ³)	0,1 mg/m ³
Sweden	kortidsvärde (KTV) (mg/m ³)	0,3 mg/m ³
Sweden	OEL chemical category (SE)	Skin notation
Portugal	OEL TWA (mg/m ³)	0,1 mg/m ³ (indicative limit value)
Portugal	OEL STEL (mg/m ³)	0,3 mg/m ³ (indicative limit value)
Portugal	OEL - Ceilings (mg/m ³)	0,29 mg/m ³
Portugal	OEL - Ceilings (ppm)	0,11 ppm (vapor)
Portugal	OEL chemical category (PT)	A4 - Not Classifiable as a Human Carcinogen, skin - potential for cutaneous exposure indicative limit value



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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. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.
Personal protective equipment	:	Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.
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	ch	emical properties
9.1. Information on basic pl	nysi	cal and chemical properties
Physical state		: Solid

Physical state	: Solid
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
рН	: 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 odditional information quallele	

No additional information available



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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. Sparks, heat, open flame and other sources of ignition. Dust accumulation (to minimize explosion hazard).

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizers. Heavy metals.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Oral: Harmful if swallowed.		
Heparinase I, recombinant			
ATE CLP (oral)	1.350,00 mg/kg bodyweight		
Ammonium sulfate (7783-20-2)	·		
LD50 oral rat	> 2000 mg/kg		
Sodium azide (26628-22-8)			
LD50 oral rat	27 mg/kg		
LD50 oral	45 mg/kg		
ATE CLP (oral)	27,00 mg/kg bodyweight		
Skin corrosion/irritation	: Not classified		
Serious eye damage/irritation	: Not classified		
Respiratory or skin sensitisation	: Not classified		
Germ cell mutagenicity	: Not classified		
Carcinogenicity	: Not classified		
Reproductive toxicity	: Not classified		
Specific target organ toxicity (single exposur	re) : Not classified		
Specific target organ toxicity (repeated expo	osure) : Not classified Causes damage to organs through prolonged or repeated exposure		
Aspiration hazard	: Not classified		
Symptoms/Injuries	: Dust may be harmful or cause irritation.		
Symptoms/Injuries After Skin Contact	: Prolonged exposure may cause skin irritation.		
Symptoms/Injuries After Eye Contact	: May cause slight irritation to eyes.		
Symptoms/Injuries After Ingestion	 This material is harmful orally and can cause adverse health effects or death in significant amounts. 		
Chronic Symptoms	: May cause damage to organs through prolonged or repeated exposure.		
Potential adverse human health effects and	: Based on available data, the classification criteria are not met. Harmful		
symptoms	if swallowed.		
SECTION 12: Ecological informa	ation		
12.1. Toxicity			
Ecology - general	: Harmful to aquatic life with long lasting effects.		
Ecology - water	: Harmful to aquatic life. Harmful to aquatic life with long lasting effects.		
Ammonium sulfate (7783-20-2)			
LC50 fish 1	5,2 (5,2 - 8,2) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])		
EC50 Daphnia 1	14 mg/l (Exposure time: 48 h - Species: Daphnia magna)		



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Ammonium sulfate (7783-20-2)			
LC50 fish 2	32,2 (32,2 - 41,9) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [flow-through])		
Sodium azide (26628-22-8)			
LC50 fish 1	0,8 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss)		
LC50 fish 2	0,7 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)		
ErC50 (algae)	0,348 mg/l		
12.2. Persistence and degradabili	ty		
Heparinase I, recombinant			
Persistence and degradability	May cause long-term adverse effects in the environment.		
12.3. Bioaccumulative potential			
Heparinase I, recombinant			
Bioaccumulative potential	Not established.		
Ammonium sulfate (7783-20-2)			
Log Pow	-5,1 (at 25 °C)		
12.4. Mobility in soil No additional information available			
12.5. Results of PBT and vPvB ass	essment		
No additional information available			
12.6. Other adverse effects			
Other information	: Avoid release to the environment.		
SECTION 13: Disposal consid	lerations		
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.		
Ecology - waste materials	: Avoid release to the environment. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.		
SECTION 14: Transport infor	mation		
In accordance with ADR / RID / IMDG / I	ATA / ADN		

ADR	IMDG	ΙΑΤΑ	ADN	RID
14.1. UN number				
Not regulated for trans	sport			
14.2. UN proper s	hipping name			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport ha	azard 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 grou	ıp			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmen	tal hazards			
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

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Ammonium sulfate (7783-20-2)

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

Sodium azide (26628-22-8)

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: Data sources

- : 22/June/2016
- : Accordir
 - : According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
- Full text of H- and EUH-statements:

Acute toxicity (oral), Category 2		
Acute toxicity (oral), Category 4		
Hazardous to the aquatic environment — Acute Hazard, Category 1		
Hazardous to the aquatic environment — Chronic Hazard, Category 1		
Hazardous to the aquatic environment — Chronic Hazard, Category 3		
Fatal if swallowed		
Harmful if swallowed		
Very toxic to aquatic life		
Very toxic to aquatic life with long lasting effects		
Harmful to aquatic life with long lasting effects		
Contact with acids liberates very toxic gas		

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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