TEG® 6s QC; Level 1, Level 2, and Abnormal QC

Safety Data Sheet

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

Revision date: 15/April/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 : TEG 6s QC; Level 1, Level 2, and Abnormal QC

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 quality control 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

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]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

EUH-statements : EUH032 - Contact with acids liberates very toxic gas

2.3. Other hazards

Other hazards not contributing to the classification : Exposure may aggravate pre-existing eye, skin, or respiratory conditions. The product contains animal source material, therefore should be treated as potentially infectious. This product also contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

SECTION 3: Composition/information on ingredients

3.1. Substance Not applicable

3.2. Mixture Vial 1:

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Citrated Bovine Plasma	(CAS No) Not available	30 - 70	Not classified
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)- (Hepes Buffer)	(CAS No) 7365-45-9 (EC no) 230-907-9	15 - 65	Not classified
Blood-coagulation factor III (Tissue Factor)	(CAS No) 9035-58-9 (EC no) 232-903-2	5 - 15	Not classified
Sodium azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0,01	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Vial 2:

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Water	(CAS No) 7732-18-5 (EC no) 231-791-2	100	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 : 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 : Not expected to present a significant hazard under anticipated conditions of normal use.

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 : Ingestion may cause adverse effects.

Chronic symptoms : None known.

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 : 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 the substance or mixture

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 : Risk of dust explosion.

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. 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 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. 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 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

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, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing dust. 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, including any incompatibilities

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.

7.3. Specific end use(s)

Use as quality control for the TEG® analyzer.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium azide (26628-22-8)		
EU	IOELV TWA (mg/m³)	0,1 mg/m³
EU	IOELV STEL (mg/m³)	0,3 mg/m³
Austria	MAK (mg/m³)	0,1 mg/m³
Austria	MAK Short time value (mg/m³)	0,3 mg/m³
Austria	OEL chemical category (AT)	Skin notation
Belgium	OEL chemical category (BE)	Skin, Skin notation
Bulgaria	OEL TWA (mg/m³)	0,1 mg/m³
Bulgaria	OEL STEL (mg/m³)	0,3 mg/m³
Croatia	GVI (granična vrijednost izloženosti) (mg/m³)	0,1 mg/m³
Croatia	KGVI (kratkotrajna granična vrijednost izloženosti) (mg/m³)	0,3 mg/m³
Croatia	OEL chemical category (HR)	Skin notation

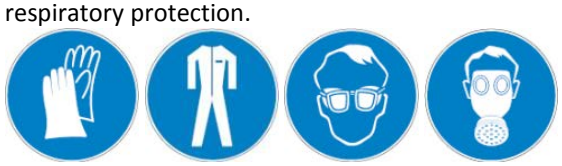
Sodium azide (26628-22-8)		
Cyprus	OEL TWA (mg/m³)	0,1 mg/m³
Cyprus	OEL STEL (mg/m³)	0,3 mg/m³
Cyprus	OEL chemical category (CY)	Skin-potential for cutaneous absorption
France	VLE (mg/m³)	0,3 mg/m³ (restrictive limit)
France	VME (mg/m³)	0,1 mg/m³ (restrictive limit)
France	OEL chemical category (FR)	Risk of cutaneous absorption
Germany	TRGS 900 Occupational exposure limit value (mg/m³)	0,2 mg/m³
Gibraltar	OEL TWA (mg/m³)	0,1 mg/m³
Gibraltar	OEL STEL (mg/m³)	0,3 mg/m³
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/m³)	0,3 mg/m³
Greece	OEL STEL (ppm)	0,1 ppm
USA ACGIH	ACGIH Ceiling (mg/m³)	0,29 mg/m³
USA ACGIH	ACGIH Ceiling (ppm)	0,11 ppm (vapor)
Italy	OEL TWA (mg/m³)	0,1 mg/m³
Italy	OEL STEL (mg/m³)	0,3 mg/m³
Italy	OEL chemical category (IT)	skin - potential for cutaneous absorption
Latvia	OEL TWA (mg/m³)	0,1 mg/m³
Latvia	OEL chemical category (LV)	skin - potential for cutaneous exposure
Spain	VLA-ED (mg/m³)	0,1 mg/m³ (indicative limit value)
Spain	VLA-EC (mg/m³)	0,3 mg/m³
Spain	OEL chemical category (ES)	skin - potential for cutaneous exposure
Switzerland	VLE (mg/m³)	0,4 mg/m³ (inhalable dust)
Switzerland	VME (mg/m³)	0,2 mg/m³ (inhalable dust)
Netherlands	Grenswaarde TGG 8H (mg/m³)	0,1 mg/m³
Netherlands	Grenswaarde TGG 15MIN (mg/m³)	0,3 mg/m³
United Kingdom	WEL TWA (mg/m³)	0,1 mg/m³
United Kingdom	WEL STEL (mg/m³)	0,3 mg/m³
United Kingdom	WEL chemical category	Potential for cutaneous absorption
Czech Republic	Expoziční limity (PEL) (mg/m³)	0,1 mg/m³
Czech Republic	OEL chemical category (CZ)	Potential for cutaneous absorption
Denmark	Grænseværdie (langvarig) (mg/m³)	0,1 mg/m³
Estonia	OEL TWA (mg/m³)	0,1 mg/m³
Estonia	OEL STEL (mg/m³)	0,3 mg/m³
Estonia	OEL chemical category (ET)	Sensitizer, Skin notation
Finland	HTP-arvo (8h) (mg/m³)	0,1 mg/m³
Finland	HTP-arvo (15 min)	0,3 mg/m³
Finland	OEL chemical category (FI)	Potential for cutaneous absorption
Hungary	AK-érték	0,1 mg/m³
Hungary	CK-érték	0,3 mg/m³
Ireland	OEL (8 hours ref) (mg/m³)	0,1 mg/m³
Ireland	OEL (15 min ref) (mg/m3)	0,3 mg/m³
Ireland	OEL chemical category (IE)	Potential for cutaneous absorption

Sodium azide (26628-22-8)		
Lithuania	IPRV (mg/m³)	0,1 mg/m³
Lithuania	TPRV (mg/m³)	0,3 mg/m³
Lithuania	OEL chemical category (LT)	Skin notation
Malta	OEL TWA (mg/m³)	0,1 mg/m³
Malta	OEL STEL (mg/m³)	0,3 mg/m³
Malta	OEL chemical category (MT)	Possibility of significant uptake through the skin
Norway	Grenseverdier (AN) (mg/m³)	0,1 mg/m³
Norway	Grenseverdier (Korttidsverdi) (mg/m3)	0,1 mg/m³
Poland	NDS (mg/m³)	0,1 mg/m³
Poland	NDSCh (mg/m³)	0,3 mg/m³
Romania	OEL TWA (mg/m³)	0,1 mg/m³
Romania	OEL STEL (mg/m³)	0,3 mg/m³
Romania	OEL chemical category (RO)	Skin notation
Slovakia	NPHV (priemerná) (mg/m³)	0,1 mg/m³
Slovakia	NPHV (Hraničná) (mg/m³)	0,3 mg/m³
Slovakia	OEL chemical category (SK)	Potential for cutaneous absorption
Slovenia	OEL TWA (mg/m³)	0,1 mg/m³
Slovenia	OEL STEL (mg/m³)	0,3 mg/m³
Slovenia	OEL chemical category (SL)	Potential for cutaneous absorption
Sweden	nivågränsvärde (NVG) (mg/m³)	0,1 mg/m³
Sweden	kortidsvärde (KTV) (mg/m³)	0,3 mg/m³
Sweden	OEL chemical category (SE)	Skin notation
Portugal	OEL TWA (mg/m³)	0,1 mg/m³ (indicative limit value)
Portugal	OEL STEL (mg/m³)	0,3 mg/m³ (indicative limit value)
Portugal	OEL - Ceilings (mg/m³)	0,29 mg/m³
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

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 chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	Vial 1: Yellowish to light amber lyophilized powder Vial 2: Clear diluent
Odour	:	No data available
Odour threshold	:	No data available
pH	:	6,9 - 7,9
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	:	Soluble in water.
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. 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.

10.6. Hazardous decomposition products

Thermal decomposition generates: Toxic gases may be formed. Nitrogen oxides. Sodium oxides. Hydrazoic acid.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)- (7365-45-9)	
LD50 oral rat	> 2000 mg/kg
LD50 dermal rat	> 2000 mg/kg

Sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg
LD50 oral	45 mg/kg

Skin corrosion/irritation : Not classified pH: 6,9 - 7,9
Serious eye damage/irritation : Not classified pH: 6,9 - 7,9
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
Specific target organ toxicity (single exposure) : Not classified
Specific target organ toxicity (repeated exposure) : Not classified
Aspiration hazard : Not classified
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 : Ingestion may cause adverse effects.
Chronic Symptoms : None known.
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.

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)- (7365-45-9)	
LC50 fish 1	> 100 mg/l (Exposure Time: 96 h - Species: Brachydanio rerio)
EC50 Daphnia 1	> 100 mg/l (Exposure Time: 48 h - Species:Daphnia magna)
NOEC chronic fish	>= 100 mg/l (Test Duration: 96 h - Species: Brachydanio rerio)
NOEC chronic crustacea	0,0178 g/l (Daphnia magna)
NOEC chronic algae	> 100 mg/l

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 degradability

TEG 6s QC; Level 1, Level 2, and Abnormal QC	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

TEG 6s QC; Level 1, Level 2, and Abnormal QC	
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.

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

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Blood-coagulation factor III (9035-58-9)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)- (7365-45-9)
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)

Water (7732-18-5)
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 : 15/April/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. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
H300	Fatal if swallowed
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
EUH032	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.