

01/29/2018

Kit Components

Product code	Description
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005400	DiaMed HbF Screening Test
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Components:

34	DiaMed HbF Screening Test Fixation Solution
35	DiaMed HbF Screening Test Elution Solution
36	DiaMed HbF Screening Test Staining Solution

Material Safety Data Sheet

acc. to the Controlled Products Regulations (CPR)

Printing date 01/29/2018

Version 3

Reviewed on 01/29/2018

1 Identification

Product identifier

Trade name: **DiaMed HbF Screening Test Fixation Solution**

Id-N° 005400

Bio-Rad MSDS Number: 2039M

References and packagings 05040

Relevant identified uses of the substance or mixture and uses advised against
No further relevant information available.

Application of the substance / the mixture

In vitro diagnostic medical device or component.

Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Supplier

Bio-Rad Laboratories (Canada) Ltd.

2403, rue Guénette

Montréal (Québec) H4R 2E9

Tél: 1-800-361-1808

Manufacturer:

Diamed GmbH

Pra-Rond 23

CH-1785 Cressier FR

(Switzerland/Schweiz/Suisse/Svizzera)

Tel: +41 (0)26 674 51 11

Fax: + 41 (0)26 674 51 45

Information department: fds-msds.ch@bio-rad.com

Emergency telephone number:

Tel.: 145 oder/or/ou +41 442 51 51 51 (EU)

CHEMTREC Switzerland (Zurich): +(41) 43 508 20 11

2 Hazard(s) identification

Classification of the substance or mixture



Flame

Flammable Liquids - Category 2 H225 Highly flammable liquid and vapour.



Health hazard

Carcinogenicity - Category 1A H350 May cause cancer.

Label elements

GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms



GHS02 GHS08

Signal word Danger

Hazard-determining components of labeling:
ethanol

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Hazard statements

H225 Highly flammable liquid and vapour.

H350 May cause cancer.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P241 Use explosion-proof [electrical/ventilating/lighting] equipment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard description:
WHMIS-symbols:

B2 - Flammable liquid



3 Composition/information on ingredients

Chemical characterization: Mixtures
Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous components:

64-17-5	ethanol		Flammable Liquids - Category 2, H225 Carcinogenicity - Category 1A, H350	76.0% w/w
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4 First-aid measures

Description of first aid measures
After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Generally the product does not irritate the skin.

After eye contact: Rinse opened eye for several minutes under running water.

After swallowing: If symptoms persist consult doctor.

Information for doctor:
Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

Extinguishing media
Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire fighting measures that suit the environment.

Special hazards arising from the substance or mixture No further relevant information available.

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- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Keep away from ignition sources
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow product to reach sewage system or any water course.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
 - **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage:**
 - **Requirements to be met by storerooms and receptacles:** Store in a cool location.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
see related package insert.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

64-17-5 ethanol

EL	Short-term value: 1000 ppm
EV	Long-term value: 1,900 mg/m ³ , 1,000 ppm

- **Additional information:**
The lists that were valid during the creation were used as basis.
- **Exposure controls**
 - **Personal protective equipment:**
 - **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.

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Store protective clothing separately.

Protection of hands:


Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Safety glasses



Tightly sealed goggles

Body protection: Protective work clothing

9 Physical and chemical properties

Information on basic physical and chemical properties
General Information
Appearance:
Form:

Liquid

Color:

Colorless

Odor:

Alcohol-like

Odor threshold:

Not determined.

pH-value:

Not determined.

Change in condition
Melting point/Melting range:

unbekannt °C

Undetermined.

Boiling point/Boiling range:

78 °C (ethanol)

Flash point:

13 °C (ethanol)

Not applicable.

Ignition temperature:

425 °C (ethanol)

Decomposition temperature:

Not determined.

Auto igniting:

Product is not selfigniting.

Danger of explosion:

Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

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· Explosion limits:	
· Lower:	3.5Vol % (ethanol) Not determined.
· Upper:	15Vol % (ethanol) Not determined.
· Vapor pressure at 20 °C:	59hPa
· Density at 20 °C:	0.843g/cm ³ Not determined.
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Fully miscible.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· Dynamic:	Not determined.
· Kinematic:	Not determined.
· Solvent content:	
· Organic solvents:	75.9%
· Water:	24.1%
· Solids content:	0.0%
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
 - **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity:**
 - **Primary irritant effect:**
 - on the skin: No irritant effect.
 - on the eye: No irritating effect.
 - **Sensitization:** No sensitizing effects known.
 - **Additional toxicological information:** No further relevant information available.

12 Ecological information

- **Toxicity**
 - **Aquatic toxicity:** No further relevant information available.

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- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
 - **Bioaccumulative potential** No further relevant information available.
 - **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
 - **General notes:**

Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
 - **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.
 - **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- **UN-Number**
 - DOT, TDG, IMDG, IATA UN1170
- **UN proper shipping name**
 - DOT Ethanol solutions
 - TDG 1170 Ethanol solutions
 - IMDG ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
 - IATA ETHANOL SOLUTION
- **Transport hazard class(es)**
 - DOT

 - **Class** 3 Flammable liquids
 - **Label** 3
 - **TDG (Transport dangerous goods):**
 - **Class** 3 (F1) Flammable liquids

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· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids
· Label	3
· Packing group	
· DOT, TDG, IMDG, IATA	II
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids
· Danger code (Kemler):	33
· EMS Number:	F-E,S-D
· Stowage Category	A
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· TDG	
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1170 ETHANOL SOLUTIONS, 3, II

15 Regulatory information

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

· Canadian substance listings:

· Canadian Domestic Substances List (DSL)

All ingredients are listed.

· Canadian Ingredient Disclosure list (limit 0.1%)

64-17-5 ethanol

· Canadian Ingredient Disclosure list (limit 1%)

None of the ingredients is listed.

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

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· Hazard pictograms



GHS02 GHS08

· Signal word Danger

· Hazard-determining components of labeling:

ethanol

· Hazard statements

H225 Highly flammable liquid and vapour.

H350 May cause cancer.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P241 Use explosion-proof [electrical/ventilating/lighting] equipment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· National regulations:

· Additional classification according to Decree on Hazardous Materials:

Carcinogenic hazardous material group III (dangerous).

· Information about limitation of use:

Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Department issuing SDS:

DiaMed GmbH

Pra Rond 23

CH-1785 Cressier FR

(Switzerland/Schweiz/Suisse/Svizzera)

· Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

WHMIS: Workplace Hazardous Materials Information System (Canada)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· * Data compared to the previous version altered.

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1 Identification

Product identifier

- Trade name: **DiaMed HbF Screening Test Elution Solution**
- Id-N° 005400
- Bio-Rad MSDS Number: 2040M
- References and packagings 05030
- Relevant identified uses of the substance or mixture and uses advised against
No further relevant information available.
- Application of the substance / the mixture
In vitro diagnostic medical device or component.

Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Supplier
Bio-Rad Laboratories (Canada) Ltd.
2403, rue Guénette
Montréal (Québec) H4R 2E9
Tél: 1-800-361-1808

Manufacturer:
Diamed GmbH
Pra-Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Svizzera)
Tel: +41 (0)26 674 51 11
Fax: + 41 (0)26 674 51 45

Information department: fds-msds.ch@bio-rad.com

Emergency telephone number:

Tel.: 145 oder/or/ou +41 442 51 51 51 (EU)
CHEMTREC Switzerland (Zurich): +(41) 43 508 20 11

2 Hazard(s) identification

Classification of the substance or mixture



Flame

Flammable Liquids - Category 2 H225 Highly flammable liquid and vapour.



Health hazard

Carcinogenicity - Category 1A H350 May cause cancer.



Corrosion

Skin Corrosion - Category 1A H314 Causes severe skin burns and eye damage.

Serious Eye Damage - Category 1 H318 Causes serious eye damage.

Label elements

GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

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Hazard pictograms



GHS02 GHS05 GHS08

Signal word Danger

Hazard-determining components of labeling:

ethanol

Hazard statements

H225 Highly flammable liquid and vapour.

H314 Causes severe skin burns and eye damage.

H350 May cause cancer.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard description:

WHMIS-symbols:

B2 - Flammable liquid

D2B - Toxic material causing other toxic effects

E - Corrosive material



3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous components:

64-17-5	ethanol	Flammable Liquids - Category 2, H225 Carcinogenicity - Category 1A, H350	80.0% w/w
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4 First-aid measures

Description of first aid measures

General information: Immediately remove any clothing soiled by the product.

After inhalation:

In case of unconsciousness place patient stably in side position for transportation.

After eye contact:

Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing:

Drink copious amounts of water and provide fresh air. Immediately call a doctor.

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- **Information for doctor:**
 - **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Keep away from ignition sources
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow product to reach sewage system or any water course.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Use neutralizing agent.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
 - **Precautions for safe handling** No special precautions are necessary if used correctly.
 - **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage:**
 - **Requirements to be met by storerooms and receptacles:** Store in a cool location.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
see related package insert.
- **Specific end use(s)** No further relevant information available.

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8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· Components with limit values that require monitoring at the workplace:

64-17-5 ethanol

EL	Short-term value: 1000 ppm
EV	Long-term value: 1,900 mg/m ³ , 1,000 ppm

· Additional information:

The lists that were valid during the creation were used as basis.

· Exposure controls

· Personal protective equipment:

· General protective and hygienic measures:

Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Store protective clothing separately.
Avoid contact with the eyes and skin.

· Breathing equipment: Not required.

· Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:

Safety glasses



Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:

Liquid

· Color:

Colorless

· Odor:

Alcohol-like

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· Odor threshold:	Not determined.
· pH-value at 20 °C:	1.9
· Change in condition	
· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	78 °C (ethanol)
· Flash point:	13 °C (ethanol) Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· Ignition temperature:	425 °C (ethanol)
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· Explosion limits:	
· Lower:	3.5Vol % (ethanol) Not determined.
· Upper:	15Vol % (ethanol) Not determined.
· Vapor pressure at 20 °C:	59hPa
· Density at 20 °C:	0.827g/cm ³ Not determined.
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Fully miscible.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· Dynamic:	Not determined.
· Kinematic:	Not determined.
· Solvent content:	
· Organic solvents:	80.5%
· Water:	19.2%
· Solids content:	0.0%
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
 - **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.

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- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity:**
 - **Primary irritant effect:**
 - **on the skin:** Strong caustic effect on skin and mucous membranes.
 - **on the eye:**
 - Strong caustic effect.
 - Strong irritant with the danger of severe eye injury.
 - **Sensitization:** No sensitizing effects known.
 - **Additional toxicological information:** No further relevant information available.

12 Ecological information

- **Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
 - **Bioaccumulative potential** No further relevant information available.
 - **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
 - **General notes:**
 - Water hazard class 1 (Self-assessment): slightly hazardous for water
 - Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
 - Must not reach bodies of water or drainage ditch undiluted or unneutralized.
 - Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
 - **Recommendation:**
 - Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.
 - **Recommended cleansing agent:** Water, if necessary with cleansing agents.

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14 Transport information

<ul style="list-style-type: none"> UN-Number DOT, TDG, IMDG, IATA 	UN2924
<ul style="list-style-type: none"> UN proper shipping name DOT TDG IMDG IATA 	Flammable liquids, corrosive, n.o.s. (Ethanol, Hydrochloric acid) 2924 Flammable liquids, corrosive, n.o.s. (Ethanol, Hydrochloric acid) FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHANOL (ETHYL ALCOHOL), HYDROCHLORIC ACID) FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHANOL, HYDROCHLORIC ACID)
<ul style="list-style-type: none"> Transport hazard class(es) DOT 	<div>  <ul style="list-style-type: none"> Class Label </div> 3 Flammable liquids 3
<ul style="list-style-type: none"> TDG (Transport dangerous goods): 	<div>  <ul style="list-style-type: none"> Class Label </div> 3 (FC) Flammable liquids 3
<ul style="list-style-type: none"> IMDG, IATA 	<div>  <ul style="list-style-type: none"> Class Label </div> 3 Flammable liquids 3
<ul style="list-style-type: none"> Packing group DOT, TDG, IMDG, IATA 	II
<ul style="list-style-type: none"> Environmental hazards: Marine pollutant: 	No
<ul style="list-style-type: none"> Special precautions for user Danger code (Kemler): EMS Number: Stowage Category Stowage Code 	Warning: Flammable liquids 338 F-E,S-C B SW2 Clear of living quarters.
<ul style="list-style-type: none"> Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code 	Not applicable.

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Trade name: **DiaMed HbF Screening Test Elution Solution**

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Transport/Additional information:

TDG

Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

IMDG

Limited quantities (LQ)

1L

Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

UN "Model Regulation":

UN 2924 FLAMMABLE LIQUIDS, CORROSIVE, N.O.S. (ETHANOL, HYDROCHLORIC ACID), 3, II

15 Regulatory information

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

Canadian substance listings:

Canadian Domestic Substances List (DSL)

All ingredients are listed.

Canadian Ingredient Disclosure list (limit 0.1%)

64-17-5 ethanol

Canadian Ingredient Disclosure list (limit 1%)

None of the ingredients is listed.

GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms



GHS02 GHS05 GHS08

Signal word Danger

Hazard-determining components of labeling:

ethanol

Hazard statements

H225 Highly flammable liquid and vapour.

H314 Causes severe skin burns and eye damage.

H350 May cause cancer.

Precautionary statements

P210

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

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Trade name: DiaMed HbF Screening Test Elution Solution

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P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **National regulations:**

· **Additional classification according to Decree on Hazardous Materials:**

Carcinogenic hazardous material group III (dangerous).

· **Information about limitation of use:**

Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:**

DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Svizzera)

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
WHMIS: Workplace Hazardous Materials Information System (Canada)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

· *** Data compared to the previous version altered.**

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1 Identification

Product identifier

Trade name: **DiaMed HbF Screening Test Staining Solution**

Id-N° 005400

Bio-Rad MSDS Number: 2041M

References and packagings 41711

Relevant identified uses of the substance or mixture and uses advised against
No further relevant information available.

Application of the substance / the mixture

In vitro diagnostic medical device or component.

Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Supplier

Bio-Rad Laboratories (Canada) Ltd.

2403, rue Guénette

Montréal (Québec) H4R 2E9

Tél: 1-800-361-1808

Manufacturer:

Diamed GmbH

Pra-Rond 23

CH-1785 Cressier FR

(Switzerland/Schweiz/Suisse/Svizzera)

Tel: +41 (0)26 674 51 11

Fax: + 41 (0)26 674 51 45

Information department: fds-msds.ch@bio-rad.com

Emergency telephone number:

Tel.: 145 oder/or/ou +41 442 51 51 51 (EU)

CHEMTREC Switzerland (Zurich): +(41) 43 508 20 11

2 Hazard(s) identification

Classification of the substance or mixture



Health hazard

Carcinogenicity - Category 1A

H350 May cause cancer.



Corrosion

Skin Corrosion - Category 1A

H314 Causes severe skin burns and eye damage.

Serious Eye Damage - Category 1 H318 Causes serious eye damage.

Label elements

GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms



GHS05 GHS08

Signal word Danger

(Contd. on page 2)

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Trade name: DiaMed HbF Screening Test Staining Solution

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- **Hazard-determining components of labeling:**
sulphuric acid
- **Hazard statements**
H314 Causes severe skin burns and eye damage.
H350 May cause cancer.
- **Precautionary statements**
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Hazard description:**

- **WHMIS-symbols:**

- D2B - Toxic material causing other toxic effects
 - E - Corrosive material



3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

56-81-5	glycerol	15.0% w/w
7783-83-7	Ammonium iron (III) sulfate dodecahydrate	2.3% w/w
	⚠ Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319	
7664-93-9	sulphuric acid	1.0% w/w
	⚠ Carcinogenicity - Category 1A, H350	
	⚠ Skin Corrosion - Category 1A, H314	

4 First-aid measures

- **Description of first aid measures**

- **General information:** Immediately remove any clothing soiled by the product.
 - **After inhalation:**
In case of unconsciousness place patient stably in side position for transportation.
 - **After eye contact:**
Rinse opened eye for several minutes under running water. Then consult a doctor.
 - **After swallowing:**
Drink copious amounts of water and provide fresh air. Immediately call a doctor.
 - **Information for doctor:**
 - **Most important symptoms and effects, both acute and delayed**
No further relevant information available.

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Trade name: **DiaMed HbF Screening Test Staining Solution**

(Contd. of page 2)

- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Use neutralizing agent.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
 - **Information about protection against explosions and fires:**
No special measures required.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage:**
 - **Requirements to be met by storerooms and receptacles:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:**
Keep receptacle tightly sealed.
see related package insert.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

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· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

56-81-5 glycerol

EL Long-term value: 10* 3** mg/m³
*mist; **mist, respirable

EV Long-term value: 10 mg/m³

7664-93-9 sulphuric acid

EL Long-term value: 0.2 mg/m³
ACGIH A2; IARC 1

EV Long-term value: 0.2 mg/m³

· **Additional information:**

The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Store protective clothing separately.
Avoid contact with the eyes and skin.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**

Safety glasses



Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:**

Liquid

· **Color:**

Blue

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· Odor:	Odorless
· Odor threshold:	Not determined.
· pH-value at 20 °C:	1.1
· Change in condition	
· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· Ignition temperature:	400 °C (glycerol)
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
· Lower:	0,9Vol %
	Not determined.
· Upper:	0,0Vol %
	Not determined.
· Vapor pressure at 20 °C:	23hPa
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Fully miscible.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· Dynamic:	Not determined.
· Kinematic:	Not determined.
· Solvent content:	
· Organic solvents:	14.6%
· Water:	81.0%
· Solids content:	0.0%
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
 - **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.

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- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity:**
 - **Primary irritant effect:**
 - **on the skin:** Strong caustic effect on skin and mucous membranes.
 - **on the eye:**
 - Strong caustic effect.
 - Strong irritant with the danger of severe eye injury.
 - **Sensitization:** No sensitizing effects known.
 - **Additional toxicological information:** No further relevant information available.

12 Ecological information

- **Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
 - **Bioaccumulative potential** No further relevant information available.
 - **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
 - **General notes:**
 - Water hazard class 1 (Self-assessment): slightly hazardous for water
 - Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
 - Must not reach bodies of water or drainage ditch undiluted or unneutralized.
 - Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
 - **Recommendation:**
 - Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT** UN3264

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· TDG, IMDG, IATA	UN2796
· UN proper shipping name	
· DOT	Corrosive liquid, acidic, inorganic, n.o.s. (Sulfuric acid)
· TDG	2796 Sulfuric acid mixture
· IMDG, IATA	SULPHURIC ACID mixture
· Transport hazard class(es)	
· DOT	
	
· Class	8 Corrosive substances
· Label	8
· TDG (Transport dangerous goods):	
	
· Class	8 (C1) Corrosive substances
· Label	8
· IMDG, IATA	
	
· Class	8 Corrosive substances
· Label	8
· Packing group	
· DOT	III
· TDG, IMDG, IATA	II
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Corrosive substances
· Danger code (Kemler):	80
· EMS Number:	F-A,S-B
· Segregation groups	Acids
· Stowage Category	B
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· TDG	
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml

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· IMDG

- Limited quantities (LQ)
- Excepted quantities (EQ)

1L
Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml

· UN "Model Regulation":

UN 2796 SULFURIC ACID MIXTURE, 8, II

15 Regulatory information

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

· Canadian substance listings:
· Canadian Domestic Substances List (DSL)

56-81-5	glycerol
7664-93-9	sulphuric acid
3244-88-0	Fuchsin Acid
7732-18-5	water, distilled, conductivity or of similar purity

· Canadian Ingredient Disclosure list (limit 0.1%)

None of the ingredients is listed.

· Canadian Ingredient Disclosure list (limit 1%)

7664-93-9	sulphuric acid
-----------	----------------

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms


GHS05 GHS08

· Signal word Danger

· Hazard-determining components of labeling:

sulphuric acid

· Hazard statements

H314 Causes severe skin burns and eye damage.

H350 May cause cancer.

· Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.

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

P310 Immediately call a POISON CENTER/doctor.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **National regulations:**
 - **Additional classification according to Decree on Hazardous Materials:**
Carcinogenic hazardous material group III (dangerous).
 - **Information about limitation of use:**
Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Svizzera)
- **Abbreviations and acronyms:**
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
WHMIS: Workplace Hazardous Materials Information System (Canada)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
- *** Data compared to the previous version altered.**

CA