

29.01.2018

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

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 29.01.2018

Version number 3

Revision: 29.01.2018

Hazardous according to criteria of Australian Safety and Compensation Council.

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

Product identifier

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

Id-N° 005400

Bio-Rad MSDS Number: 2039M

Article number: 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:

Bio-Rad Laboratories Pty., Ltd.

Level 5, 446 Victoria Road

Gladesville, New South Wales 2111

(Australia)

Phone: +61 (2) 9914-2800

Fax: +61 (2) 9914-2888

Further information obtainable from: fds-msds.ch@bio-rad.com

Emergency telephone number:

CHEMTREC Australia (Sydney): +(61)-290372994

or 1-800-039-008 or 61 2 9186 1132

2 Hazards identification

Classification of the substance or mixture



flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Label elements

GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

Hazard pictograms



GHS02

Signal word Danger

Hazard statements

H225 Highly flammable liquid and vapour.

Precautionary statements

P210 Keep away from heat/sparks/open flames/hot surfaces. 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/shower.

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P403+P235
P501

Store in a well-ventilated place. Keep cool.
Dispose of contents/container in accordance with local/regional/
national/international regulations.


- **Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition/information on ingredients

· Chemical characterisation: Mixtures

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

· **Dangerous components:**

64-17-5	ethanol	 Flam. Liq. 2, H225	76.0%
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- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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 Firefighting measures

· Extinguishing media

· Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.

- **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).

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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 fire - and explosion protection:

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 container 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 facilities: No further data; see item 7.

Control parameters

Ingredients with limit values that require monitoring at the workplace:

64-17-5 ethanol

WES | Long-term value: 1880 mg/m³, 1000 ppm

· **Additional information:** The lists valid during the making 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.

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.

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- **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

· Colour:

Colourless

· Odour:

Alcohol-like

· Odour threshold:

Not determined.

· pH-value:

Not determined.

· Change in condition

· Melting point/freezing point:

unbekannt °C

Undetermined.

· Initial boiling point and boiling range:

78 °C (172.4 °F) (ethanol)

· Flash point:

13 °C (55.4 °F) (ethanol)

Not applicable.

· Ignition temperature:

425 °C (797 °F) (ethanol)

· Decomposition temperature:

Not determined.

· Auto-ignition temperature:

Product is not selfigniting.

· Explosive properties:

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

· Explosion limits:

· Lower:

3.5Vol % (ethanol)

Not determined.

· Upper:

15Vol % (ethanol)

Not determined.

· Vapour pressure at 20 °C (68 °F):

59hPa (44.3 mm Hg)

· Density at 20 °C (68 °F):

0.843g/cm³ (7.03484 lbs/gal)

Not determined.

· Relative density

Not determined.

· Vapour 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.

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- **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:**
 - **Skin corrosion/irritation** No irritant effect.
 - **Serious eye damage/irritation** No irritating effect.
 - **Respiratory or skin sensitisation** No sensitising 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.
- **Behaviour 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 (German Regulation) (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.

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13 Disposal considerations

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

14 Transport information

- | | |
|---|--|
| · UN-Number | UN1170 |
| · ADG, IMDG, IATA | |
| · UN proper shipping name | 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) |
| · ADG | ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) |
| · IMDG | ETHANOL SOLUTION |
| · IATA | |
| · Transport hazard class(es) | |
| · ADG | |
|  | |
| · Class | 3 (F1) Flammable liquids. |
| · Label | 3 |
| · IMDG, IATA | |
|  | |
| · Class | 3 Flammable liquids. |
| · Label | 3 |
| · Packing group | II |
| · ADG, IMDG, IATA | |
| · Environmental hazards: | No |
| · Marine pollutant: | |
| · 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 Marpol and the IBC Code | Not applicable. |

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· Transport/Additional information:

· ADG

- 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
- Transport category 2
- Tunnel restriction code D/E

· 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 SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II

15 Regulatory information

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

· Australian Inventory of Chemical Substances

All ingredients are listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



GHS02

· Signal word Danger

· Hazard statements

H225 Highly flammable liquid and vapour.

· Precautionary statements

- P210 Keep away from heat/sparks/open flames/hot surfaces. 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/shower.
- P403+P235 Store in a well-ventilated place. Keep cool.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **Directive 2012/18/EU**
 - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
 - **Seveso category P5c FLAMMABLE LIQUIDS**
 - **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
 - **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
- **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)
- **Contact:**
Bio-Rad Laboratories Pty., Ltd.
Level 5, 446 Victoria Road
Gladesville, New South Wales 2111
(Australia)
Phone: +61 (2) 9914-2800
Fax: +61 (2) 9914-2888
- **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
- *** Data compared to the previous version altered.**

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Version number 3

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Hazardous according to criteria of Australian Safety and Compensation Council.

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

Product identifier

- Trade name: **DiaMed HbF Screening Test Elution Solution**
 - Id-N° 005400
 - Bio-Rad MSDS Number: 2040M
 - Article number: 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:
 - Bio-Rad Laboratories Pty., Ltd.
 - Level 5, 446 Victoria Road
 - Gladesville, New South Wales 2111 (Australia)
 - Phone: +61 (2) 9914-2800
 - Fax: +61 (2) 9914-2888
- Further information obtainable from: fds-msds.ch@bio-rad.com
- Emergency telephone number:
 - CHEMTREC Australia (Sydney): +(61)-290372994
 - or 1-800-039-008 or 61 2 9186 1132

2 Hazards identification

Classification of the substance or mixture



flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.



corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.

Label elements

GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

Hazard pictograms



GHS02 GHS05

Signal word Danger

Hazard statements

H225 Highly flammable liquid and vapour.

H314 Causes severe skin burns and eye damage.

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Precautionary statements

- P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/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.

Other hazards

Results of PBT and vPvB assessment


- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

Chemical characterisation: Mixtures

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

Dangerous components:

64-17-5	ethanol	 Flam. Liq. 2, H225	80.0%
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- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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 plenty of water and provide fresh air. Call for a doctor immediately.
- **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 Firefighting measures

Extinguishing media

Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire extinguishing methods suitable to surrounding conditions.

- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.

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

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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 neutralising 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 fire - and explosion protection:**
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 container 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 facilities:** No further data; see item 7.
- **Control parameters**

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

64-17-5 ethanol

WES Long-term value: 1880 mg/m³, 1000 ppm

· **Additional information:** The lists valid during the making 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.
Avoid contact with the eyes and skin.
 - **Respiratory protection:** Not required.

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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

Colour:

Colourless

Odour:

Alcohol-like

Odour threshold:

Not determined.

pH-value at 20°C (68 °F):

1.9

Change in condition

Melting point/freezing point:

Undetermined.

Initial boiling point and boiling range:

78°C (172.4 °F) (ethanol)

Flash point:

13°C (55.4 °F) (ethanol)

Not applicable.

Flammability (solid, gas):

Not applicable.

Ignition temperature:

425°C (797 °F) (ethanol)

Decomposition temperature:

Not determined.

Auto-ignition temperature:

Product is not selfigniting.

Explosive properties:

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

Explosion limits:

Lower:

3.5Vol % (ethanol)

Not determined.

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· Upper:	15Vol % (ethanol) Not determined.
· Vapour pressure at 20°C (68 °F):	59hPa (44.3 mm Hg)
· Density at 20°C (68 °F):	0.827g/cm ³ (6.90132 lbs/gal) Not determined.
· Relative density	Not determined.
· Vapour 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.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity**
 - **Primary irritant effect:**
 - **Skin corrosion/irritation**
Strong caustic effect on skin and mucous membranes.
 - **Serious eye damage/irritation**
Strong caustic effect.
Strong irritant with the danger of severe eye injury.
 - **Respiratory or skin sensitisation** No sensitising 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.
- **Behaviour 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 (German Regulation) (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 sewage water or drainage ditch undiluted or unneutralised.
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 together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.
 - **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

- | | |
|---|---|
| · UN-Number | UN2924 |
| · ADG, IMDG, IATA | |
| · UN proper shipping name | 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHANOL (ETHYL ALCOHOL), HYDROCHLORIC ACID) |
| · ADG | |
| · IMDG | FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHANOL (ETHYL ALCOHOL), HYDROCHLORIC ACID) |
| · IATA | FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHANOL, HYDROCHLORIC ACID) |
| · Transport hazard class(es) | |
| · ADG | |
|  | |
| · Class | 3 (FC) Flammable liquids. |

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· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· Packing group	
· ADG, IMDG, IATA	II
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids.
· Danger code (Kemler):	338
· EMS Number:	F-E,S-C
· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADG	
· 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
· Transport category	2
· Tunnel restriction code	D/E
· 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 LIQUID, CORROSIVE, N.O.S. (ETHANOL (ETHYL ALCOHOL), HYDROCHLORIC ACID), 3, II

15 Regulatory information

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

· Australian Inventory of Chemical Substances

All ingredients are listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

7647-01-0 hydrogen chloride

S5, S6

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Trade name: DiaMed HbF Screening Test Elution Solution

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· GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



GHS02 GHS05

· Signal word Danger

· Hazard statements

H225 Highly flammable liquid and vapour.

H314 Causes severe skin burns and eye damage.

· Precautionary statements

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.

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

· Directive 2012/18/EU

· **Named dangerous substances - ANNEX I** hydrogen chloride

· **Seveso category** P5c FLAMMABLE LIQUIDS

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t

· **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)

· Contact:

Bio-Rad Laboratories Pty., Ltd.
Level 5, 446 Victoria Road
Gladesville, New South Wales 2111
(Australia)
Phone: +61 (2) 9914-2800
Fax: +61 (2) 9914-2888

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

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)

PBT: Persistent, Bioaccumulative and Toxic

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vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

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

—AU—

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Hazardous according to criteria of Australian Safety and Compensation Council.

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

Product identifier

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

Id-N° 005400

Bio-Rad MSDS Number: 2041M

Article number: 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:

Bio-Rad Laboratories Pty., Ltd.

Level 5, 446 Victoria Road

Gladesville, New South Wales 2111

(Australia)

Phone: +61 (2) 9914-2800

Fax: +61 (2) 9914-2888

Further information obtainable from: fds-msds.ch@bio-rad.com

Emergency telephone number:

CHEMTREC Australia (Sydney): +(61)-290372994

or 1-800-039-008 or 61 2 9186 1132

2 Hazards identification

Classification of the substance or mixture



corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.

Label elements

GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

Hazard pictograms



GHS05

Signal word Danger

Hazard statements

H314 Causes severe skin burns and eye damage.

Precautionary statements

P260 Do not breathe dusts or mists.

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

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

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P405

Store locked up.

P501

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

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterisation: Mixtures**

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

· **Dangerous components:**

56-81-5	glycerol	15.0%
7783-83-7	Ammonium iron (III) sulfate dodecahydrate	2.3%
	⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319	
7664-93-9	sulphuric acid	1.0%
	⚠ Skin Corr. 1A, H314	

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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 plenty of water and provide fresh air. Call for a doctor immediately.

· **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 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

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

Use fire extinguishing methods suitable to surrounding conditions.

· **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.

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

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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 neutralising 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 fire - and explosion protection:** 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 container 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 facilities:** No further data; see item 7.

• **Control parameters**

• **Ingredients with limit values that require monitoring at the workplace:**

56-81-5 glycerol

WES Long-term value: 10 mg/m³

7664-93-9 sulphuric acid

WES Short-term value: 3 mg/m³

Long-term value: 1 mg/m³

• **Additional information:** The lists valid during the making 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.

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

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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

· Colour:

Blue

· Odour:

Odourless

· Odour threshold:

Not determined.

· pH-value at 20 °C (68 °F): 1.1

· Change in condition
· Melting point/freezing point: Undetermined.

· Initial boiling point and boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gas): Not applicable.

· Ignition temperature: 400 °C (752 °F) (glycerol)

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Explosion limits:
· Lower: 0,9Vol %
Not determined.

· Upper: 0,0Vol %
Not determined.

· Vapour pressure at 20 °C (68 °F): 23hPa (17.3 mm Hg)

· Density: Not determined.

· Relative density Not determined.

· Vapour 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.

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

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

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity**
 - **Primary irritant effect:**
 - **Skin corrosion/irritation**
Strong caustic effect on skin and mucous membranes.
 - **Serious eye damage/irritation**
Strong caustic effect.
Strong irritant with the danger of severe eye injury.
 - **Respiratory or skin sensitisation** No sensitising 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.
- **Behaviour 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 (German Regulation) (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 sewage water or drainage ditch undiluted or unneutralised.
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.

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Trade name: DiaMed HbF Screening Test Staining Solution


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- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

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

14 Transport information

- | | |
|---|---|
| <ul style="list-style-type: none"> · UN-Number · ADG, IMDG, IATA | UN2796 |
| <ul style="list-style-type: none"> · UN proper shipping name · ADG · IMDG, IATA | 2796 SULPHURIC ACID mixture
SULPHURIC ACID mixture |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADG | 

<ul style="list-style-type: none"> · Class · Label |
| <ul style="list-style-type: none"> · IMDG, IATA | 

<ul style="list-style-type: none"> · Class · Label |
| <ul style="list-style-type: none"> · Packing group · ADG, 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: · Segregation groups · Stowage Category | Warning: Corrosive substances.
80
F-A,S-B
Acids
B |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |

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according to 1907/2006/EC, Article 31

Printing date 29.01.2018

Version number 3

Revision: 29.01.2018

Trade name: DiaMed HbF Screening Test Staining Solution

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· Transport/Additional information:

· ADG

- 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
- Transport category 2
- Tunnel restriction code E

· 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 2796 SULPHURIC ACID MIXTURE, 8, II

15 Regulatory information

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

· Australian Inventory of Chemical Substances

56-81-5	glycerol
7783-83-7	Ammonium iron (III) sulfate dodecahydrate
7664-93-9	sulphuric acid
3244-88-0	Fuchsin Acid
7732-18-5	water, distilled, conductivity or of similar purity

· Standard for the Uniform Scheduling of Medicines and Poisons

7664-93-9	sulphuric acid	S6
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· GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



GHS05

· Signal word Danger

· Hazard statements

H314 Causes severe skin burns and eye damage.

· Precautionary statements

- P260 Do not breathe dusts or mists.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/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.

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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 29.01.2018

Version number 3

Revision: 29.01.2018

Trade name: DiaMed HbF Screening Test Staining Solution

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P405

Store locked up.

P501

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

- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **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)

· Contact:

Bio-Rad Laboratories Pty., Ltd.
Level 5, 446 Victoria Road
Gladesville, New South Wales 2111
(Australia)
Phone: +61 (2) 9914-2800
Fax: +61 (2) 9914-2888

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

· * Data compared to the previous version altered.

AU