

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

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

1.1 Product identifier

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

Id-N° 005400

Bio-Rad MSDS Number: 2039M

Article number: 05040

1.2 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.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

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

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

1.4 Emergency telephone number: CHEMTREC UK (London) +(44)-870-8200418

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



GHS02 flame

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

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



GHS02

Signal word Danger

Hazard statements

H225 Highly flammable liquid and vapour.

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/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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- **2.3 Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
 - **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 64-17-5 EINECS: 200-578-6 Index number: 603-002-00-5	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.

SECTION 4: First aid measures

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 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.
- **5.2 Special hazards arising from the substance or mixture**
No further relevant information available.
- **5.3 Advice for firefighters**
 - **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Keep away from ignition sources.
Wear protective equipment. Keep unprotected persons away.
- **6.2 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.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.

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See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **Handling:**
 - **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
 - **Ingredients with limit values that require monitoring at the workplace:**

64-17-5 ethanol	
WEL	Long-term value: 1920 mg/m ³ , 1000 ppm

 - **Additional information:** The lists valid during the making were used as basis.
- **8.2 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

SECTION 9: Physical and chemical properties

· 9.1 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 (ethanol)

· Flash point:

13 °C (ethanol)

Not applicable.

· Ignition temperature:

425 °C (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:

59hPa

· Density at 20 °C:

0.843g/cm³

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%
- **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **Primary irritant effect:**
 - **Skin corrosion/irritation**
Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation**
Based on available data, the classification criteria are not met.
 - **Respiratory or skin sensitisation**
Based on available data, the classification criteria are not met.
 - **Additional toxicological information:** No further relevant information available.
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **Germ cell mutagenicity**
Based on available data, the classification criteria are not met.
 - **Carcinogenicity** Based on available data, the classification criteria are not met.
 - **Reproductive toxicity**
Based on available data, the classification criteria are not met.
 - **STOT-single exposure** Based on available data, the classification criteria are not met.
 - **STOT-repeated exposure**
Based on available data, the classification criteria are not met.
 - **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.

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- **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.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.



SECTION 13: Disposal considerations

- **13.1 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.

SECTION 14: Transport information

- | | |
|---|--|
| · 14.1 UN-Number | UN1170 |
| · ADR, IMDG, IATA | |
| · 14.2 UN proper shipping name | 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) |
| · ADR | ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) |
| · IMDG | ETHANOL SOLUTION |
| · IATA | |
| · 14.3 Transport hazard class(es) | |
| · ADR | |
|  | |
| · Class | 3 (F1) Flammable liquids. |
| · Label | 3 |
| · IMDG, IATA | |
|  | |
| · Class | 3 Flammable liquids. |
| · Label | 3 |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | II |

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14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	
Danger code (Kemler):	Warning: Flammable liquids. 33
EMS Number:	F-E,S-D
Stowage Category	A
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	
Not applicable.	
Transport/Additional information:	
ADR	
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	

SECTION 15: Regulatory information

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

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



GHS02

Signal word Danger

Hazard statements

H225 Highly flammable liquid and vapour.

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.

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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.

· 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
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

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

SECTION 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:

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
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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.**

GB

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

1.1 Product identifier

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

- Id-N° 005400
- Bio-Rad MSDS Number: 2040M
- Article number: 05030

1.2 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.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

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

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

1.4 Emergency telephone number: CHEMTREC UK (London) +(44)-870-8200418

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



GHS02 flame

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



GHS05 corrosion

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

Eye Dam. 1 H318 Causes serious eye damage.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

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, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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

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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.

2.3 Other hazards

Results of PBT and vPvB assessment


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

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

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

Dangerous components:

CAS: 64-17-5 EINECS: 200-578-6 Index number: 603-002-00-5	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.

SECTION 4: First aid measures

4.1 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.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 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.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

- Protective equipment: No special measures required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

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Keep away from ignition sources.

Wear protective equipment. Keep unprotected persons away.

· **6.2 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.

· **6.3 Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Use neutralising agent.

· **6.4 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.

SECTION 7: Handling and storage

· **7.1 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.

· **7.2 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.

· **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

· **8.1 Control parameters**

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

64-17-5 ethanol

WEL Long-term value: 1920 mg/m³, 1000 ppm

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 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.

· **Protection of hands:**



Protective gloves

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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

SECTION 9: Physical and chemical properties

- **9.1 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:**

1.9

- **Change in condition**

- **Melting point/freezing point:**

Undetermined.

- **Initial boiling point and boiling range:**

78 °C (ethanol)

- **Flash point:**

13 °C (ethanol)

Not applicable.

- **Flammability (solid, gas):**

Not applicable.

- **Ignition temperature:**

425 °C (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:**

59hPa

- **Density at 20 °C:**

0.827g/cm³

Not determined.

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<ul style="list-style-type: none"> · Relative density · Vapour density · Evaporation rate 	<ul style="list-style-type: none"> Not determined. Not determined. Not determined.
<ul style="list-style-type: none"> · Solubility in / Miscibility with water: 	<ul style="list-style-type: none"> Fully miscible.
<ul style="list-style-type: none"> · Partition coefficient: n-octanol/water: 	<ul style="list-style-type: none"> Not determined.
<ul style="list-style-type: none"> · Viscosity: <ul style="list-style-type: none"> · Dynamic: · Kinematic: 	<ul style="list-style-type: none"> Not determined. Not determined.
<ul style="list-style-type: none"> · Solvent content: <ul style="list-style-type: none"> · Organic solvents: · Water: 	<ul style="list-style-type: none"> 80.5% 19.2%
<ul style="list-style-type: none"> · Solids content: 	<ul style="list-style-type: none"> 0.0%
<ul style="list-style-type: none"> · 9.2 Other information 	<ul style="list-style-type: none"> No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **Primary irritant effect:**
 - **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
 - **Serious eye damage/irritation**
Causes serious eye damage.
 - **Respiratory or skin sensitisation**
Based on available data, the classification criteria are not met.
 - **Additional toxicological information:** No further relevant information available.
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **Germ cell mutagenicity**
Based on available data, the classification criteria are not met.
 - **Carcinogenicity** Based on available data, the classification criteria are not met.
 - **Reproductive toxicity**
Based on available data, the classification criteria are not met.
 - **STOT-single exposure** Based on available data, the classification criteria are not met.
 - **STOT-repeated exposure**
Based on available data, the classification criteria are not met.
 - **Aspiration hazard** Based on available data, the classification criteria are not met.

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SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 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.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 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.

SECTION 14: Transport information

- | | |
|---------------------------------------|---|
| • 14.1 UN-Number | |
| • ADR, IMDG, IATA | UN2924 |
| • 14.2 UN proper shipping name | |
| • ADR | 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHANOL (ETHYL ALCOHOL), HYDROCHLORIC ACID) |
| • IMDG | FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHANOL (ETHYL ALCOHOL), HYDROCHLORIC ACID) |
| • IATA | FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHANOL, HYDROCHLORIC ACID) |

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14.3 Transport hazard class(es)

ADR



· Class
· Label

3 (FC) Flammable liquids.
3

IMDG, IATA



· Class
· Label

3 Flammable liquids.
3

14.4 Packing group

· ADR, IMDG, IATA

II

14.5 Environmental hazards:

· Marine pollutant:

No

14.6 Special precautions for user

Warning: Flammable liquids.

· Danger code (Kemler):
· EMS Number:
· Stowage Category
· Stowage Code

338
F-E,S-C
B
SW2 Clear of living quarters.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

Transport/Additional information:

ADR

· 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

· Transport category
· Tunnel restriction code

2
D/E

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 2924 FLAMMABLE LIQUID,
CORROSIVE, N.O.S. (ETHANOL (ETHYL
ALCOHOL), HYDROCHLORIC ACID), 3, II

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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
 - **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, 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/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
 - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

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

SECTION 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:**
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
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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

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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.**

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

1.1 Product identifier

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

Id-N° 005400

Bio-Rad MSDS Number: 2041M

Article number: 41711

1.2 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.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

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

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

1.4 Emergency telephone number: CHEMTREC UK (London) +(44)-870-8200418

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



GHS05 corrosion

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

Eye Dam. 1 H318 Causes serious eye damage.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

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.

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

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
 - **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 56-81-5 EINECS: 200-289-5	glycerol substance with a Community workplace exposure limit	15.0%
CAS: 7783-83-7 EINECS: 233-382-4	Ammonium iron (III) sulfate dodecahydrate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.3%
CAS: 7664-93-9 EINECS: 231-639-5 Index number: 016-020-00-8	sulphuric acid ⚠ Skin Corr. 1A, H314	1.0%

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

SECTION 4: First aid measures

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 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.
- **5.2 Special hazards arising from the substance or mixture**
No further relevant information available.
- **5.3 Advice for firefighters**
 - **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Do not allow to enter sewers/ surface or ground water.

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

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- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Use neutralising agent.
- **6.4 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.

SECTION 7: Handling and storage

- **Handling:**
 - **Information about fire - and explosion protection:** No special measures required.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
 - **Ingredients with limit values that require monitoring at the workplace:**

56-81-5 glycerol	
WEL	Long-term value: 10 mg/m ³
7664-93-9 sulphuric acid	
WEL	Long-term value: 0.05* mg/m ³ *mist: defined as thoracic fraction
- **Additional information:** The lists valid during the making were used as basis.

- **8.2 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**

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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

SECTION 9: Physical and chemical properties

· **9.1 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:**

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 (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:**

23hPa

· **Density:**

Not determined.

· **Relative density**

Not determined.

· **Vapour density**

Not determined.

· **Evaporation rate**

Not determined.

· **Solubility in / Miscibility with**

· **water:**

Fully miscible.

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· 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%
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **Primary irritant effect:**
 - **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
 - **Serious eye damage/irritation**
Causes serious eye damage.
 - **Respiratory or skin sensitisation**
Based on available data, the classification criteria are not met.
 - **Additional toxicological information:** No further relevant information available.
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **Germ cell mutagenicity**
Based on available data, the classification criteria are not met.
 - **Carcinogenicity** Based on available data, the classification criteria are not met.
 - **Reproductive toxicity**
Based on available data, the classification criteria are not met.
 - **STOT-single exposure** Based on available data, the classification criteria are not met.
 - **STOT-repeated exposure**
Based on available data, the classification criteria are not met.
 - **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.

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- **12.4 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.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 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.

SECTION 14: Transport information

- | | |
|---|------------------------------|
| • 14.1 UN-Number | |
| • ADR, IMDG, IATA | UN2796 |
| • 14.2 UN proper shipping name | |
| • ADR | 2796 SULPHURIC ACID mixture |
| • IMDG, IATA | SULPHURIC ACID mixture |
| • 14.3 Transport hazard class(es) | |
| • ADR | |
|  | |
| • Class | 8 (C1) Corrosive substances. |
| • Label | 8 |
| • IMDG, IATA | |
|  | |
| • Class | 8 Corrosive substances. |
| • Label | 8 |

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· 14.4 Packing group	II
· ADR, IMDG, IATA	
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Warning: Corrosive substances.
· Danger code (Kemler):	80
· EMS Number:	F-A,S-B
· Segregation groups	Acids
· Stowage Category	B
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· 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

SECTION 15: Regulatory information

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

· Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· 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.

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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** None of the ingredients is listed.
 - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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:**

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
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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. 2: Serious eye damage/eye irritation – Category 2

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

GB