

**Safety Data Sheet**  
**HELICO\*STAT RAPID HELICOBACTER STAIN KIT EU**



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

**1.1 Product identifier**

Product name	HELICO*STAT RAPID HELICOBACTER STAIN KIT
Product number	KT019
Brand	HELICO*STAT RAPID HELICOBACTER STAIN KIT

**Other means of identification**

- Component 1: Periodic Acid Solution
- Component 2: Sodium metabisulfate Solution
- Component 3: Alcian Yellow Solution
- Component 4: Toluidine Blue
- Component 5: Sodium Hydroxide

**1.2 Relevant identified uses of the substance or mixture and uses advised against**  
In Vitro Diagnostic Use

**1.3 Details of the supplier of the safety data sheet**

Name	Diagnostic Biosystems
Address	6616 Owens Drive Pleasanton CA 94588 USA
Telephone	(888) 896-3350
email	customersupport@dbiosys.com

**1.4 Emergency telephone number**

(925) 484-3350 (9AM-6PM, Monday - Friday, Pacific Standard Time)

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**SECTION 2: Hazards identification**

**2.1 Classification of the substance or mixture**

**Classification according to Regulation (EC) No 1272/2008 (CLP)**

- Serious eye damage/eye irritation (chapter 3.3), Cat. 1, H318
- Skin corrosion/irritation (chapter 3.2), Cat. 1A, H314

For the full text corresponding to the "H"-codes displayed in this section, refer to Section 16.

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### 2.2 Label elements

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

#### Hazard pictograms



1. Exclamation mark; 2. Corrosion

#### Signal word

**Danger**

#### Hazard statements

H314

Causes severe skin burns and eye damage

H317

May cause an allergic skin reaction

H318

Causes serious eye damage

H332

Harmful if inhaled

#### Precautionary statements

P260

Do not breathe dust/fume/gas/mist/vapors/spray.

P264

Wash hands thoroughly after handling.

P271

Use only outdoors or in a well-ventilated area.

P272

Contaminated work clothing should not be allowed out of the workplace.

P280

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

P301+P330+P331

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303+P361+P353

IF ON SKIN: Take off immediately all contaminated clothing. Rinse skin with water.

P304+P340

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338

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

P312

Call a POISON CENTER/doctor if you feel unwell.

P333+P313

If skin irritation or rash occurs: Get medical advice/attention.

P362+P364

Take off contaminated clothing and wash it before reuse.

P405

Store locked up.

P501

Dispose of contents/container to a licensed disposal company.

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## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Component 1: Periodic Acid

##### 1. Periodic acid

Concentration 1% (volume)

Other names / synonyms Periodic acid (H5IO6)  
CAS no. 10450-60-9

#### Component 2: Sodium metabisulfite

##### 1. Sodium metabisulfite

Concentration 5 % (weight)

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Other names / synonyms Disodium disulphite; Disulfurous acid, sodium salt (1:2); Sodium disulfite; sodium metabisulphite; Sodium pyrosulfite

EC no. 231-673-0

CAS no. 7681-57-4

Index no. 016-063-00-2

- Acute toxicity, oral (chapter 3.1), Cat. 4
- Eye damage/irritation (chapter 3.3), Cat. 1

H302 Harmful if swallowed

H318 Causes serious eye damage

### Component 3. Alcian Yellow Solution

#### 1. Alcohol

Concentration 50 % (volume)

Other names / synonyms ABSOLUTE ETHANOL; ALCOHOL DEHYDRATED; ALCOHOL, ANHYDROUS; Alcoholum / ethanolum; ALGRAIN; ANHYDROL; COLOGNE SPIRIT; COLOGNE SPIRITS (ALCOHOL); Ethanol; ETHANOL 200 PROOF; ETHANOL SOLUTION; ETHYL ALCOHOL; ETHYL ALCOHOL ANHYDROUS; ETHYL HYDRATE; ETHYL HYDROXIDE; FERMENTATION ALCOHOL; GRAIN ALCOHOL; JAYSOL; JAYSOL S; METHYLCARBINOL; MOLASSES ALCOHOL; NCI-C03134; POTATO ALCOHOL; SD ALCOHOL 23-HYDROGEN; SPIRIT; SPIRITS OF WINE; TECSOL; UN 1170

EC no. 200-578-6

CAS no. 64-17-5

Index no. 603-002-00-5

- Flammable liquids (chapter 2.6), Cat. 2

H225 Highly flammable liquid and vapor

#### 2. Acetic acid

Concentration 3% (volume)

Other names / synonyms acetic acid; ACETIC ACID; ACETIC ACID, GLACIAL; ACETICACID; Acidum aceticum; ETHANOIC ACID; ETHYLIC ACID; GLACIAL ACETIC ACID; METHANECARBOXYLIC ACID; UN 2789; UN 2790; VINEGAR ACID

EC no. 200-580-7

CAS no. 64-19-7

Index no. 607-002-00-6

- Flammable liquids (chapter 2.6), Cat. 3
- Skin corrosion/irritation (chapter 3.2), Cat. 1A

H226 Flammable liquid and vapor

H314 Causes severe skin burns and eye damage

SCLs/M-factors/ATEs Skin Corr. 1A; H314: C ≥ 90 %

Skin Corr. 1B; H314: 25 % ≤ C < 90 %

Skin Irrit. 2; H315: 10 % ≤ C < 25 %

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Eye Irrit. 2; H319: 10 % ≤ C < 25 %

### 3. Alcian Yellow

Concentration 1 % (weight)  
CAS no. 61968-76-1

### Component 4. Toluidine Blue

#### 1. Toluidine Blue O

Concentration 1 % (weight)

Other names / synonyms Phenothiazin-5-ium, 3-amino-7-(dimethylamino)-2-methyl-, chloride;  
CAS no. 92-31-9

### Component 5. Sodium hydroxide

#### 1. Sodium hydroxide

Concentration 3 % (weight)

Other names / synonyms Caustic soda; Natrii hydroxidum; Sodium hydroxide ; Sodium hydroxide (Na(OH));

EC no. 215-185-5

CAS no. 1310-73-2

Index no. 011-002-00-6

- Skin corrosion/irritation (chapter 3.2), Cat. 1A

H314 Causes severe skin burns and eye damage

SCLs/M-factors/ATEs Skin Corr. 1A; H314: C ≥ 5 %

Skin Corr. 1B; H314: 2 % ≤ C < 5 %

Skin Irrit. 2; H315: 0,5 % ≤ C < 2 %

Eye Irrit. 2; H319: 0,5 % ≤ C < 2 %

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## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General notes Consult a physician. Show this safety data sheet to the doctor in attendance.

Following inhalation If breathed in, move person into fresh air. If not breathing, give artificial respiration.

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Following skin contact Rinse with plenty of water. Get medical attention if irritation develops and persists.

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Following eye contact	Rinse thoroughly with plenty of water for at least 15 minutes. Get medical attention if symptoms occur.
Following ingestion	Call a poison center or doctor if you feel unwell. If vomiting occurs naturally, have victim lean forward to reduce the risk of aspiration. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.  Acute and delayed symptoms and effects: May cause gastrointestinal irritation. Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.
Self-protection of the first aider	Ensure adequate ventilation. Use personal protective equipment. For personal protection see section 8.

#### 4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

#### 4.3 Indication of any immediate medical attention and special treatment needed

No data available

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Use extinguishing media appropriate for surrounding fire.

### 5.2 Special hazards arising from the substance or mixture

Ethanol: Carbon oxides

### 5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

#### Further information

No data available.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas. For personal protection see section 8.

Ensure adequate ventilation. Use personal protective equipment. For personal protection see section 8.

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas. For personal protection see section 8.

### 6.2 Environmental precautions

Should not be released into the environment. See Section 12 for additional ecological information.

### 6.3 Methods and material for containment and cleaning up

Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

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### 6.4 Reference to other sections

For disposal see section 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

### 7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

### 7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### CAS: 1310-73-2

Sodium hydroxide

ACGIH (USA): (C) 2 mg/m<sup>3</sup> TLV® inhalation; Cal/OSHA (USA): (C) 2 mg/m<sup>3</sup> PEL inhalation; NIOSH (USA): (C) 2 mg/m<sup>3</sup> REL inhalation; OSHA (USA): 2 mg/m<sup>3</sup> PEL inhalation

#### CAS: 64-17-5

Alcohol

ACGIH (USA): (ST) 1000 ppm TLV® inhalation; Cal/OSHA: 1000 ppm PEL inhalation; NIOSH: 1000 ppm REL inhalation; OSHA: 1000 ppm PEL inhalation; 1900 mg/m<sup>3</sup> PEL inhalation

#### CAS: 64-19-7 (EC: 200-580-7)

Acetic acid

ACGIH (USA): 15 ppm STEL inhalation; 10 ppm, (ST) 15 ppm TLV® inhalation; 10 ppm TWA inhalation; Cal/OSHA (USA): 40 ppm C inhalation; 10 ppm, (ST) 15 ppm, (C) 40 ppm PEL inhalation; 10 ppm, 25 mg/m<sup>3</sup> PEL inhalation; 15 ppm, 37 mg/m<sup>3</sup> STEL inhalation; NIOSH (USA): 10 ppm, (ST) 15 ppm REL inhalation; 15 ppm, 37 mg/m<sup>3</sup> ST inhalation; 10 ppm, 25 mg/m<sup>3</sup> TWA inhalation; OSHA (USA): 25 mg/m<sup>3</sup> PEL inhalation; 10 ppm PEL inhalation; 10 ppm, 25 mg/m<sup>3</sup> TWA inhalation

#### CAS: 7681-57-4 (EC: 231-673-0)

Sodium metabisulfite

ACGIH: 5 mg/m<sup>3</sup> (STEL) STEL inhalation; NIOSH: 5 mg/m<sup>3</sup> REL-TWA inhalation

### 8.2 Exposure controls

#### Appropriate engineering controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

#### Individual protection measures, such as personal protective equipment

#### Pictograms



#### Eye and face protection

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Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

### Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

### Body protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

### Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

### Thermal hazards

No data available

### Control banding approach

No data available.

### Environmental exposure controls

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Various dyes
Colour	Various dyes
Odour	Alcohol, Acetic Acid
Odour threshold	No data available.
pH	Various
Melting point/freezing point	No data available.
Boiling point or initial boiling point and boiling range	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability	No data available.
Lower and upper explosion limit/flammability limit	No data available.
Vapor pressure	No data available.
Relative vapor density	No data available.
Density and/or relative density	No data available.
Solubility	No data available.
Partition coefficient n-octanol/water (log value)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Kinematic viscosity	No data available.
Explosive properties	No data available.
Oxidizing properties	No data available.

### Particle characteristics

No data available.

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### 9.2 Other information

#### 9.2.1 Information with regard to physical hazard classes

No data available.

#### 9.2.2 Other safety characteristics

No data available.

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

None under normal use conditions.

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

None under normal use conditions.

### 10.4 Conditions to avoid

Exposure to moisture.

Avoid storing in direct sunlight and avoid extremes of temperature.

Heat, flames and sparks.

### 10.5 Incompatible materials

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Ethanol: Alkali metals, Oxidizing agents, Peroxides

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Acetic acid: Oxidizing agents, Soluble carbonates and phosphates, Hydroxides, Metals, Peroxides, permanganates, e.g. potassium permanganate, Amines, Alcohols, Nitric acid

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Sodium hydroxide : Caustic soda reacts with all the mineral acids to form the corresponding salts. It also reacts with weak-acid gases, such as hydrogen sulfide, sulfur dioxide, and carbon dioxide. Caustic soda reacts with amphoteric metals (Al, Zn, Sn) and their oxides to form complex anions such as  $AlO_2(-)$ ,  $ZnO_2(-2)$ ,  $SNO_2(-2)$ , and  $H_2$  (or  $H_2O$  with oxides). All organic acids also react with sodium hydroxide to form soluble salts. Another common reaction of caustic soda is dehydrochlorination.

### 10.6 Hazardous decomposition products

Other decomposition products - No data available In the event of fire: see section 5

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Acetic acid: Hazardous decomposition products formed under fire conditions. - Carbon oxides

Other decomposition products - No data available

In the event of fire: see section 5

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Sodium hydroxide : Sodium oxides



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### SECTION 11: Toxicological information

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

##### Acute toxicity

Ethanol: ACGIH: A3 Confirmed animal carcinogen with unknown relevance to humans.

##### Skin corrosion/irritation

Acetic acid

LD50 Skin - Rat - 1,112 mg/kg

ETHANOL

LD50 Skin - Rabbit - 15,800 mg/kg

ETHANOL

OECD Test Guideline 404 Skin - Rabbit - 24 h

Result: No skin irritation

Sodium metabisulfite

LD50 Skin - Rat - > 2,000 mg/kg

##### Serious eye damage/irritation

ETHANOL

OECD Test Guideline 405 Eyes - Rabbit

Result: Moderate eye irritation

Sodium metabisulfite

- Rabbit

Result: Risk of serious damage to eyes.

##### Respiratory or skin sensitization

Acetic acid

LC50 Inhalation - Mouse - 5620 ppm - 1 h

Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste):Eye:Conjunctive irritation. Sense Organs and Special Senses (Nose, Eye, Ear, and Taste):Eye:Other. Blood:Other changes.

Acetic acid

LC50 Inhalation - Rat - 11.4 mg/l - 4 h

Sodium metabisulfite

Result: Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals

##### Germ cell mutagenicity

Based on available data, classification data are not met

##### Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

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### Reproductive toxicity

Based on available data, classification data are not met

### STOT-single exposure

No data available.

### STOT-repeated exposure

No data available.

### Aspiration hazard

Acetic acid

LC50 Inhalation - Mouse - 5620 ppm - 1 h

Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste):Eye:Conjunctive irritation. Sense Organs and Special Senses (Nose, Eye, Ear, and Taste):Eye:Other. Blood:Other changes.

Acetic acid

LC50 Inhalation - Rat - 11.4 mg/l - 4 h

ETHANOL

LD50 Inhalation - Rat - 30,000 mg/l - 4 h

## 11.2 Information on other hazards

### Endocrine disrupting properties

No data available.

### Other information

No data available.

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## SECTION 12: Ecological information

### 12.1 Toxicity

Acetic acid

LC50 - Oncorhynchus mykiss (rainbow trout) - >1,000 mg/l - 96 h

Citation: (OECD Test Guideline 203)

Acetic acid

EC50 - Daphnia magna (water flea) - >300.82 mg/l - 48 h

Citation: (OECD Test Guideline 202)

ETHANOL

EC50 - Chlorella vulgaris (Fresh water algae) - 275 mg/l - 72 h

ETHANOL

LC50 - Pimephales promelas (fathead minnow) - 14,200 mg/l - 96 h

ETHANOL

LC50 - Ceriodaphnia dubia (water flea) - 5,012 mg/l - 48 h

Sodium hydroxide solid or pellets

LC50 - Gambusia affinis (Mosquito fish) - 125 mg/l - 96 h

Citation: Sigma SDS

Sodium hydroxide solid or pellets

LC50 - Oncorhynchus mykiss (rainbow trout) - 45.4 mg/l - 96 h

Citation: Sigma SDS

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Sodium hydroxide solid or pellets  
EC50 - Daphnia magna (water flea) - 40.38 mg/l - 48 h  
Citation: Sigma SDS

Sodium hydroxide solid or pellets  
LC50 - Poecilia reticulata (guppy) - 196 mg/l - 96 h  
Citation: Ecotox, 63143 Adema,D.M.M., 1985

Sodium metabisulfite  
LC50 - Oncorhynchus mykiss (rainbow trout) - 150 - 220 mg/l - 96 h

Sodium metabisulfite  
EC50 - Daphnia magna (water flea) - 89 mg/l - 24 h

Sodium metabisulfite  
IC50 - Desmodemus subspicatus (chodat) - 48 mg/l - 72 h

### 12.2 Persistence and degradability

No data available.

### 12.3 Bioaccumulative potential

No data available.

### 12.4 Mobility in soil

No data available.

### 12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

### 12.6 Endocrine disrupting properties

No data available.

### 12.7 Other adverse effects

No data available.

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Product disposal

Offer surplus and non-recyclable solutions to a licensed disposal company.

#### Packaging disposal

Dispose of as unused product.

#### Waste treatment

No data available

#### Sewage disposal

Do not let product enter drains

#### Other disposal recommendations

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

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### SECTION 14: Transport information

14.1 UN Number	UN1760
14.2 UN Proper Shipping Name	Corrosive liquids, n.o.s.
14.3 Transport hazard class(es)	8
14.4 Packing group	I

#### 14.5 Environmental hazards

Marine pollutant

#### 14.6 Special precautions for user

For professional users only.  
Should not be released into the environment.

#### 14.7 Maritime transport in bulk according to IMO instruments

Not shipped in bulk

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### SECTION 15: Regulatory information

#### 15.2 Chemical Safety Assessment

The supplier of this product has not conducted any Chemical Safety Assessment

#### HMIS Rating

HELICO*STAT RAPID HELICOBACTER STAIN KIT EU	
HEALTH	2
FLAMMABILITY	1
PHYSICAL HAZARD	0
PERSONAL PROTECTION	C

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### SECTION 16: Other information

#### Full text of hazard statements referenced in Section 2

H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage

SDS-0127, Rev. A

#### Further information/disclaimer

DISCLAIMER: The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigation to determine the suitability of information for their particular purposes. In no event shall Diagnostic BioSystems be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, whatsoever arising, even if Diagnostic BioSystems has been advised of the possibility of such damages.