

#### **SECTION 1: Identification**

#### 1.1 GHS Product identifier

Product name HELICO\*STAT RAPID HELICOBACTER STAIN KIT

Product number KT019

Brand HELICO\*STAT RAPID HELICOBACTER STAIN KIT

### 1.2 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

### 1.3 Recommended use of the chemical and restrictions on use

In Vitro Diagnostic Use

# 1.4 Supplier's details

Name Diagnostic Biosystems Address 6616 Owens Drive Pleasanton CA 94588

USA

Telephone (888) 896-3350

email customersupport@dbiosys.com

#### 1.5 Emergency phone number

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

# **SECTION 2: Hazard identification**

#### 2.1 Classification of the substance or mixture

GHS classification in accordance with: OSHA (29 CFR 1910.1200)

- Eye damage/irritation (C.4.5), Cat. 1
- Skin corrosion/irritation (C.4.4), Cat. 1A

### 2.2 GHS label elements, including precautionary statements

### **Pictogram**



1. Exclamation mark; 2. Corrosion

Signal word Danger

Hazard statement(s)

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 statement(s)

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 must 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 (or hair): Take off immediately all contaminated clothing. Rinse

skin with water/shower.

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.

Take off contaminated clothing and wash it before reuse.

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

P501 Dispose of contents/container to a licensed disposal company.

# **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)

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. 4Eye 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:  $25 \% \le C < 90 \%$ Skin Irrit. 2; H315:  $10 \% \le C < 25 \%$ Eye Irrit. 2; H319:  $10 \% \le C < 25 \%$ 

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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:  $2 \% \le C < 5 \%$ Skin Irrit. 2; H315:  $0,5 \% \le C < 2 \%$ Eye Irrit. 2; H319:  $0,5 \% \le C < 2 \%$ 

## **SECTION 4: First-aid measures**

# 4.1 Description of necessary first-aid measures

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

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.

In case of skin contact Rinse with plenty of water. Get medical attention if irritation develops and

persists.

In case of eye contact Rinse thoroughly with plenty of water for at least 15 minutes. Get medical

attention if symptoms occur.

If swallowed 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.

Personal protective equipment for first-aid responders

Ensure adequate ventilation. Use personal protective equipment. For

personal protection see section 8.

# 4.2 Most important symptoms/effects, 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 immediate medical attention and special treatment needed, if necessary

No data available

# **SECTION 5: Fire-fighting measures**

#### 5.1 Suitable extinguishing media

Use extinguishing media appropriate for surrounding fire.

#### 5.2 Specific hazards arising from the chemical

Ethanol: Carbon oxides

# 5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

## **Further information**

No data available.

## **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 materials 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).

#### Reference to other sections

For disposal see section 13.

# **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.

#### Specific end use(s)

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

# **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### CAS: 1310-73-2

Sodium hydroxide

ACGIH (USA): (C) 2 mg/m3 TLV® inhalation; Cal/OSHA (USA): (C) 2 mg/m3 PEL inhalation; NIOSH (USA): (C) 2 mg/m3 REL inhalation; OSHA (USA): 2 mg/m3 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/m3 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/m3 PEL inhalation; 15 ppm, 37 mg/m3 STEL inhalation; NIOSH (USA): 10 ppm, (ST) 15 ppm REL inhalation; 15 ppm, 37 mg/m3 ST inhalation; 10 ppm, 25 mg/m3 TWA inhalation; OSHA (USA): 25 mg/m3 PEL inhalation; 10 ppm PEL inhalation; 10 ppm, 25 mg/m3 TWA inhalation

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

Sodium metabisulfite

ACGIH: 5 mg/m3 (STEL) STEL inhalation; NIOSH: 5 mg/m3 REL-TWA inhalation

#### 8.2 Appropriate engineering controls

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

#### 8.3 Individual protection measures, such as personal protective equipment (PPE)

#### **Pictograms**







## Eye/face protection

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.

# SECTION 9: Physical and chemical properties and safety characteristics

Physical state
Appearance
Color
Various dyes
Various dyes
Various dyes
Odor
Alcohol, Acetic Acid
Odor threshold
PH
Various
Various
Various

Melting point/freezing point

Boiling point or initial boiling point and boiling range
Flash point

Evaporation rate

No data available.

No data available.

No data available.

No data available.

Evaporation rate

Flammability

Lower and upper explosion limit/flammability limit

Vapor pressure

No data available.

No data available.

No data available.

No data available.

Vapor pressure No data available. Relative vapor density No data available. Density and/or relative density No data available.

Solubility

Partition coefficient n-octanol/water (log value)

Auto-ignition temperature

No data available.

No data available.

No data available.

No data available.

Kinematic viscosity

Explosive properties

Oxidizing properties

No data available.

No data available.

No data available.

## **Particle characteristics**

No data available.

#### Supplemental information regarding physical hazard classes

No data available.

### Further safety characteristics (supplemental)

No data available.

# **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 AlO2(-), ZnO2(-2), SNO2(-2), and H2 (or H2O 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

# **SECTION 11: Toxicological information**

# Information on toxicological effects

### **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.

#### Reproductive toxicity

Based on available data, classification data are not met

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### 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

#### Additional information

No data available.

# **SECTION 12: Ecological information**

## **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

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

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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 - Desmodesmus subspicatus (chodat) - 48 mg/l - 72 h

#### Persistence and degradability

No data available.

#### Bioaccumulative potential

No data available.

### Mobility in soil

No data available.

#### Results of PBT and vPvB assessment

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

# **Endocrine disrupting properties**

No data available.

#### Other adverse effects

No data available.

# **SECTION 13: Disposal considerations**

#### Disposal 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.

# **SECTION 14: Transport information**

DOT (US)

UN Number: UN1760

Class: 8

Packing Group: I

Proper Shipping Name: Corrosive liquids, n.o.s.

Reportable quantity (RQ):

Marine pollutant:

Poison inhalation hazard:

**IMDG** 

UN Number: UN1760

Class: 8

Packing Group: I EMS Number:

Proper Shipping Name: Corrosive liquids, n.o.s.

**IATA** 

UN Number: UN1760

Class: 8

Packing Group: I

Proper Shipping Name: Corrosive liquids, n.o.s.

# **SECTION 15: Regulatory information**

## 15.1 Safety, health and environmental regulations specific for the product in question

# California Prop. 65 Components

WARNING! This product contains a chemical known to the State of California to cause cancer.

CAS-No. 64-17-5: Ethanol

WARNING: This product contains a chemical known to the State of California to cause birth defects or other

reproductive harm.

CAS-No. 64-17-5: Ethanol

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

## **Canadian Domestic Substances List (DSL)**

Chemical name: Periodic acid (H5IO6)

CAS: 10450-60-9

Chemical name: Ethanol

CAS: 64-17-5

Chemical name: Acetic acid

CAS: 64-19-7

Chemical name: Phenothiazin-5-ium, 3-amino-7-(dimethylamino)-2-methyl-, chloride

CAS: 92-31-9

Chemical name: Sodium hydroxide (Na(OH))

CAS: 1310-73-2

## **Massachusetts Right To Know Components**

Sodium metabisulfite CAS number: 7681-57-4

Chemical name: Ethanol CAS number: 64-17-5

Acetic acid

CAS number: 64-19-7

Chemical name: Sodium hydroxide

CAS number: 1310-73-2

## **New Jersey Right To Know Components**

Sodium metabisulfite CAS number: 7681-57-4

Common name: ETHYL ALCOHOL

CAS number: 64-17-5

Acetic acid

CAS number: 64-19-7

Common name: SODIUM HYDROXIDE

CAS number: 1310-73-2

# Pennsylvania Right To Know Components

Sodium metabisulfite CAS number: 7681-57-4

Chemical name: Ethanol CAS number: 64-17-5

Acetic acid

CAS number: 64-19-7

Chemical name: Sodium hydroxide

CAS number: 1310-73-2

#### **SARA 302 Components**

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

## SARA 311/312 Hazards

Acute Health Hazard

Fire Hazard, Acute Health Hazard, Chronic Health Hazard

# **SARA 313 Components**

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### 15.2 Chemical Safety Assessment

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

**HMIS Rating** 



# **SECTION 16: Other information**

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## 16.1 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.