



DIAGNOSTIC AUTOMATION, INC.

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MATERIAL SAFETY DATA SHEET

H.pylori Antigen RapiCard™ InstaTest

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY NAME.

Supplier: Diagnostic Automation Inc.
21250 Califa St. Suite 102 and 116
Woodland Hills, CA 91367 USA

Emergency Telephone number: Please contact the regional poison Control Center.

Product Name: H.pylori Antigen RapiCard™ InstaTest
Product classification: In-Vitro diagnostics
Catalog No: 18564-25-44

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable

Chemical Ingredient Chemical Data / Information

Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

2.2 Label elements

Labelling according to regulation (EC) No. 1272/2008

The product does not need to be labelled in accordance with EC directives or respective national laws.

Hazard pictograms and Signal word: No

Hazardous components for labeling: No

Hazard statements: No

Precautionary statements: No

2.3 Other hazards

At this concentration, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested (quantity es above those found in the kit). ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317].

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

This product is a mixture

3.2 Mixtures

Hazardous ingredients	CAS No.	EINECS No.	REACH Registration No.	Classification: Category Codes/ Hazard statement	W/W %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H - isothiazol-3-one (3:1)	55965-84-9	N/A	Not available	Acute Tox. 3: H301 H311-H331 Skin Corr. 1B: H314 Skin Sens. 1: H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	0.001%

Lowest generic cut-off value according to Table 1.1 Annex I: ≥ 0.1

Lowest specific concentration limits according to Table 3.1 Annex VI:

Skin Corr. 1B; H314 C ≥ 0.6 %

Skin Irrit. 2; H315: 0.06 % $\leq C < 0.6$ %

Eye Irrit. 2; H319: 0.06 % $\leq C < 0.6$ %

Skin Sens. 1; H317: C ≥ 0.015 %

4. FIRST-AID MEASURES

4.1 Description of first aid measures

After inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
After skin contact	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
After eye contact	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
After Ingestion	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

4.2 Most important symptoms and effects, both acute and delayed

Not applicable.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: The common fire extinguish media can be used

Unsuitable extinguishing media: Not investigate

5.2 Special hazards arising from the substance or mixture

Not find yet

5.3 Advice for fire-fighters

Dry-chemical fire extinguisher

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Clean up with broom.

6.4 Reference to other sections

Collect material and dispose of waste according to section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

General hygiene measures: Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must be removed before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Information about storage conditions: Note the storage conditions on product packaging.

Requirements for storage rooms and containers: Store in a cool dry place.

7.3 Specific end uses

Rapid chromatographic immunoassay for the qualitative detection of H.pylori antigen in human feces specimen.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.2.2 Personal protective equipment

<i>General protective and hygienic measures:</i>	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
<i>Respiratory protection</i>	Not required
<i>Protective gloves</i>	Disposable gloves
<i>Material of gloves</i>	Latex/natural rubber
<i>Penetration time of glove material</i>	Gloves resistance is not critical when the product is handled according to the instruction for use.
<i>Eye Protection</i>	Safety glasses
<i>Body protection</i>	Lab coat

8.2.3 Environmental exposure controls

There are no special precautions and measures. See section 6 and 7!

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

<i>Physical State:</i>	Solid
<i>Colour:</i>	White appearance and some content of the test strip is purple

<i>Odours:</i>	Tasteness
<i>Odours threshold</i>	Not established
<i>Flash point</i>	Not established
<i>Self-igniting:</i>	Product is not known to be self-igniting
<i>Danger of explosion:</i>	There is no substances in the kit could lead to the danger of explosion
<i>Melting point:</i>	Not established
<i>Boiling point:</i>	Not established
<i>Vapour pressure</i>	Not established
<i>Density (20°C):</i>	Not established
<i>pH-value at 20°C:</i>	Not established
<i>Solubility in water:</i>	The product almost could not solute in the water

9.2 Other safety information

No

10. STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable in accordance with the recommended storage conditions.

10.2 Chemical stability

All the chemicals in the test kits are stable.

10.3 Possibility of hazardous reactions

Almost impossible

10.4 Conditions to avoid

High humidity and the temperature out of 2-30°C

10.5 Incompatible materials

No

10.6 Hazardous decomposition products

No

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects (Mixture)

Acute toxicity:	Quantitative data on the toxic effects of this product is not available.
Irritation	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.
Corrosivity	Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed.
Sensitisation	Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly

	reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.
Repeated dose toxicity	Not yet investigate
Carcinogenicity:	Not yet investigate
Mutagenicity:	Not yet investigate
Toxicity for reproduction:	No reproductive toxic effect known.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

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 Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

<i>Product:</i>	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
<i>European waste catalogue:</i>	18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.
<i>Packaging:</i>	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further information.

14. TRANSPORT INFORMATION

14.1 UN proper shipping name

RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

14.2 Transport hazard class

ADR/RID: - IMDG: - IATA: -

14.3 Packing group

ADR/RID: - IMDG: - IATA: -

14.4 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No
Marine Pollutant: No

14.5 Special precautions for user

See sections 6-8

14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Delivery will only be taken in suitable and regulatory approved packaging

15. REGULATORY INFORMATION

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

EU regulations: This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

The mixture was not subjected to security assessment

16. OTHER INFORMATION

General information

The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501].

The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user's responsibility to determine the suitability of the information for their particular purposes.

Date Adopted	2017-09-05
REF 18564-25-44	H. pylori Antigen RapiCard™ InstaTest



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ISO 13485-2003



Revision Date: 2016-07-26



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MATERIAL SAFETY DATA SHEET

H.pylori Antigen RapiCard™ InstaTest Stool Collection buffer

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY NAME.

Supplier: Diagnostic Automation Inc.
21250 Califa St. Suite 102 and 116
Woodland Hills, CA 91367 USA

Emergency Telephone number: Please contact the regional poison Control Center.

Product Name: H.pylori Antigen RapiCard™ InstaTest Stool Collection buffer
Product classification: In-Vitro diagnostics
Catalog No: NA

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable

Chemical Ingredient Chemical Data / Information

Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

2.2 Label elements

Labelling according to regulation (EC) No. 1272/2008

The product does not need to be labelled in accordance with EC directives or respective national laws.

Hazard pictograms and Signal word: No

Hazardous components for labeling: No

Hazard statements: No

Precautionary statements: No

2.3 Other hazards

No

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

This product is a mixture

3.2 Mixtures

Hazardous ingredients	CAS No.	EINECS No.	REACH Registration No.	Classification: Category Codes/ Hazard statement	W/W %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H - isothiazol-3-one (3:1)	55965-84-9	N/A	Not available	Acute Tox. 3: H301 H311-H331 Skin Corr. 1B: H314 Skin Sens. 1: H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	0.001%

Lowest generic cut-off value according to Table 1.1 Annex I: ≥ 0.1

Lowest specific concentration limits according to Table 3.1 Annex VI:

Skin Corr. 1B; H314 C ≥ 0.6 %

Skin Irrit. 2; H315: 0.06 % $\leq C < 0.6$ %

Eye Irrit. 2; H319: 0.06 % $\leq C < 0.6$ %

Skin Sens. 1; H317: C ≥ 0.015 %

4. FIRST-AID MEASURES

4.1 Description of first aid measures

After inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat
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	symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
After skin contact	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
After eye contact	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
After Ingestion	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

4.2 Most important symptoms and effects, both acute and delayed

Not applicable.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: The common fire extinguish media can be used

Unsuitable extinguishing media: Not investigate

5.2 Special hazards arising from the substance or mixture

Not find yet

5.3 Advice for fire-fighters

Dry-chemical fire extinguisher

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Absorb in vermiculite, dry sand or earth and place into containers. Flush with plenty of water to clean spillage area.

6.4 Reference to other sections

Collect material and dispose of waste according to section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

General hygiene measures: Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must be removed before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Information about storage conditions: Note the storage conditions on product packaging.

Requirements for storage rooms and containers: Store in a cool dry place.

7.3 Specific end uses

Extract and dilute the feces specimens

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.2.2 Personal protective equipment

<i>General protective and hygienic measures:</i>	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
<i>Respiratory protection</i>	Not required
<i>Protective gloves</i>	Disposable gloves
<i>Material of gloves</i>	Latex/natural rubber
<i>Penetration time of glove material</i>	Gloves resistance is not critical when the product is handled according to the instruction for use.
<i>Eye Protection</i>	Safety glasses
<i>Body protection</i>	Lab coat

8.2.3 Environmental exposure controls

There are no special precautions and measures. See section 6 and 7!

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

<i>Physical State:</i>	Liquid
<i>Colour:</i>	Colorless
<i>Odours:</i>	Odourless

<i>Odours threshold</i>	Not established
<i>Flash point</i>	Not established
<i>Self-igniting:</i>	Product is not known to be self-igniting
<i>Danger of explosion:</i>	There is no substances in the kit could lead to the danger of explosion
<i>Melting point:</i>	Not established
<i>Boiling point:</i>	Not established
<i>Vapour pressure</i>	Not established
<i>Density (20°C):</i>	Not established
<i>pH-value at 20°C:</i>	Not established
<i>Solubility in water:</i>	The product could solute in the water

9.2 Other safety information

No

10. STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable in accordance with the recommended storage conditions.

10.2 Chemical stability

All the chemicals in the test kits are stable.

10.3 Possibility of hazardous reactions

Almost impossible

10.4 Conditions to avoid

Temperature out of 2-30°C

10.5 Incompatible materials

No

10.6 Hazardous decomposition products

No

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects (Mixture)

Acute toxicity:	Quantitative data on the toxic effects of this product is not available.
Irritation	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.
Corrosivity	Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed.
Sensitisation	Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle

	accordingly.
Repeated dose toxicity	Not yet investigate
Carcinogenicity:	Not yet investigate
Mutagenicity:	Not yet investigate
Toxicity for reproduction:	No reproductive toxic effect known.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

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 Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

<i>Product:</i>	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
<i>European waste catalogue:</i>	18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.
<i>Packaging:</i>	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further information.

14. TRANSPORT INFORMATION

14.1 UN proper shipping name

RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

14.2 Transport hazard class

ADR/RID: - IMDG: - IATA: -

14.3 Packing group

ADR/RID: - IMDG: - IATA: -

14.4 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No
Marine Pollutant: No

14.5 Special precautions for user

See sections 6-8

14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Delivery will only be taken in suitable and regulatory approved packaging

15. REGULATORY INFORMATION

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

EU regulations: This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment


The mixture was not subjected to security assessment

16. OTHER INFORMATION

General information

The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501].

The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user's responsibility to determine the suitability of the information for their particular purposes.

Date Adopted	2017-09-06
 NA	H. pylori Antigen RapiCard™ InstaTest Stool Collection buffer



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