 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 21.03.2017
	Item Title: H. Pylori Antigen Rapid Test.	Item Code: 8.04.23.x.xxxx	Issue Level: 1.0

2. General Information.

Trade Names & Synonyms:	H. Pylori Antigen cassette, strip stool sample. All sizes.
Chemical Family:	In Vitro Diagnostic Test kit (Rapid Antigen tests- Infectious Diseases).
Formula:	not applicable.
Manufacturer:	Atlas Medical.
Manufacturer's address:	William James House Cowley Road Cambridge, CB4 0WX, UK.
Manufacturer's phone:	+44 (0) 1223 858 910
Manufacturer's Fax:	+44 (0) 1223 858 524
Email:	info@atlas-site.com.uk

3. Composition, Information on Active Ingredients.

Atlas H.Pylori test strip/cassette composed of different sheets: an absorbent with a complex of latex particles added to monoclonal antibodies against *H. pylori* antigens, a membrane where antibodies have been immobilized against the *H. pylori* antigen and an absorbent cellulose sheet.

Liquid reactive which contains: biological buffer, NaCl, proteins, surfactants and 0.1% of sodium azide preservative.

4. Hazard Information.


Hazard description:

The test strips, cassette contained in the kit are not classified as dangerous.

Information concerning particular hazards for human and environment:

Under the recommended conditions of use, there is no risk of exposure to any of the materials contained in the device.

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5. Health Hazard Data.

A) Biological hazards:

These products classified, according to directive 2001/58/EC, as **non hazardous**.

B) Chemical hazards:

Sodium Azide:

Spill: Not applicable.

Exposure Controls: Not applicable

Personal Protection: Not applicable

Physical Properties: Not applicable (contained within dry reagents in test dipstick)

Stability/Reactivity: Stable. Non-reactive in this test.

Toxicological Information: Exposure above acceptable limits may be harmful

6. Fire & Explosion Hazard Data.

Non-flammable

Using the reagents according to protocol should not incur a fire or explosion hazard.

In case of fire, use water, foam, carbon dioxide, or dry chemical, as suitable for the surrounding fire and materials.

7. Accidental release measures.

Health Hazards: Poison, Do Not Inhale or Swallow.

First Aid Measures: Inhale: Remove to fresh air.

Contact: Flush with water for 15 minutes.

Swallow: If conscious, wash mouth out with water
Call Physician.

8. Handling and Storage.

Information for safe handling:

Keep out of reach of children.


Storage:

Store in the original container at 2-30°C.

Requirements to be met by storerooms and receptacles:

No special requirements.

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9. Exposure control and personal gear.

Ingredients with limit values that require monitoring in the workplace:

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

Personal protective equipment:

General protective and hygienic measures: Adhere to good laboratory practices (GLP). Wash hands before breaks and at the end of work.

Respiratory protection: Not required

Protection of hands: Disposable gloves (for sample handling)

Material of gloves: Latex/natural rubber.

Penetration time of glove material: Glove resistance is not critical as the gloves are intended to provide protection against the sample material.

Eye protection: Not required

Body protection: Lab coat

10. Physical and chemical properties.

General Information

Atlas H.Pylori Antigen test strip, cassette is a rapid one step test for the detection of H.Pylori antigen in stool samples.

Color (outer casing): white.

Odor: Odorless.

Flash point: Not applicable.

Self-igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

11. Stability and Reactivity Data.

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

Materials to be avoided: None.

Hazardous reactions: No dangerous reactions known.

Hazardous decomposition products: No dangerous decomposition products known.


12. Toxicological information.

Acute toxicity: Quantitative data on the toxic effects of this product is not available.

Primary effects:

After skin contact: No irritating effects known.

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After eye contact: No irritating effects known.

Sensitization: No sensitizing effects known.

13. Ecological information.

Environmental Toxicity:

Quantitative data on the toxic effects of this product is not available.

Persistence and Degradability:

The device contains plastic and other components that are not readily degradable.

Incorrect sample and used kit disposable:

Bio-hazards may exert cumulative environmental effects due to chemicals and biological materials present in the test kit.

14. Waste disposal information.

Product:

Remains of samples, reagents and controls should be collected in a recipient for this purpose and autoclaved 1 hour at 121°C.

Proper disposal procedures should be followed, by wrapping the remains and placing them in a waste bin. Improper disposal of the test should be avoided. The overall quantities of the biological materials per unit test kit is small, and does not comprise a direct hazard. However, abuse and improper disposal should not be practiced.

Packaging:

Disposal must be made in accordance with local waste management regulations.

Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

15. Transport information.

The product is not subject to transport regulations.


16. Regulatory information.

Labeling according to directive 98/79/EC.

17. Other information.

The product is for in-vitro use only.

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18. Disclaimer.

The information above is believed to be accurate represents the best information currently available to us.

However we make no warranty of merchantability or any other warranty expressed or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purpose. In no way shall the company 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, howsoever arising, even if the company has been advised of the possibility of such damages.

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