 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 17.11.2019
	Item Title: Pregnancy Rapid Test.	Item Code: 8.04.01.0.0xxxx	Issue Level: 1.5


Contents

1. Amendment Record.
2. General Information.
3. Composition, Information on Active Ingredients.
4. Hazard Information.
5. First-aid measures.
6. Fire -fighting measures.
7. Accidental release measures.
8. Handling and Storage.
9. Exposure controls/personal protection.
10. Physical and chemical properties.
11. Stability and Reactivity Data.
12. Toxicological information.
13. Ecological information.
14. Waste disposal information.
15. Transport information.
16. Regulatory information.
17. Other information.
18. Disclaimer.

1. Amendment Record

Issue Level	Date Issued	Summary of Amendment	Reviewed by
1.1	16.01.2010	Update the Item Code	Noor
1.2	24.02.2016	General Review	Saba'a Shtaiwi
1.3	13.03.2018	General Review	Amani AL-Habahbeh
1.4	27.06.2019	General Review	Amani AL-Habahbeh
1.5	17.11.2019	Amend the Manufacturer's address from UK to German.	Amani AL-Habahbeh

PMX8.04.01.0.xxx D.15	Issued for Date:	Prepared by. QA Date: 17.11.2019	Reviewed by. QA Date: 17.11.2019	Approved by. QA Date: 17.11.2019	Page 1 of 5
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 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 17.11.2019
	Item Title: Pregnancy Rapid Test.	Item Code: 8.04.01.0.0xxxx	Issue Level: 1.5

2. General Information.

Trade Names & Synonyms:	Pregnancy (hCG) Rapid Test (Cassette, Strip and Midstream (Urine and/or Serum)), All sizes.
Chemical Family:	In Vitro Diagnostic Test kit (Rapid tests- Pregnancy tests).
Manufacturer:	Atlas Medical.
Manufacturer's address:	Ludwig-Erhaed-Ring 3 15827 Blankenefelde-Mahlow Germany
Manufacturer's phone:	+49(0)33708355030
Email:	info@atlas-medical.com

3. Composition, Information on Active Ingredients.

Chemical characterization:

Description: In vitro diagnostics medical device.

Dangerous components:

Chemical substances	CAS number	Concentration
Sodium Azide	26628-22-8	0.1%

4. Hazard Information.

Hazard description:

The test strip contained in the device is 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.

5. First-aid measures.

General Information:

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.


After skin contact:

Wash with soap and water and rinse thoroughly.

After eye contact:

Rinse opened eye for several minutes under running water.

PMX8.04.01.0.xxx D.15	Issued for	Prepared by.	Reviewed by.	Approved by.	Page
	Date:	QA	QA	QA	2 of 5
		Date: 17.11.2019	Date: 17.11.2019	Date: 17.11.2019	

 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 17.11.2019
	Item Title: Pregnancy Rapid Test.	Item Code: 8.04.01.0.0xxxx	Issue Level: 1.5

After ingestion:

If desiccant or other components are swallowed seek medical attention.

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.

9. Exposure controls/personal protection.

- **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

PMX8.04.01.0.xxx D.15	Issued for	Prepared by. QA	Reviewed by. QA	Approved by. QA	Page 3 of 5
	Date:	Date: 17.11.2019	Date: 17.11.2019	Date: 17.11.2019	

 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 17.11.2019
	Item Title: Pregnancy Rapid Test.	Item Code: 8.04.01.0.0xxxx	Issue Level: 1.5

10. Physical and chemical properties.

General Information

hCG test is a one-step immuno-chromatographic screening test designed for the detection of human Chorionic Gonadotropin (hCG) in urine for early detection of pregnancy. The method employs a unique combination of a monoclonal-dye conjugate and polyclonal-solid phase antibodies to selectively identify hCG in the test samples with an extremely high degree of sensitivity. In less than 5 minutes, levels of hCG as low as 25mIU/ml can be detected.

Colour (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.

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.

PMX8.04.01.0.xxx D.15	Issued for Date:	Prepared by. QA Date: 17.11.2019	Reviewed by. QA Date: 17.11.2019	Approved by. QA Date: 17.11.2019	Page 4 of 5
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	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 17.11.2019
	Item Title: Pregnancy Rapid Test.	Item Code: 8.04.01.0.0xxxx	Issue Level: 1.5

14. Waste disposal information.

Product:

Proper disposal procedures should be followed, by wrapping the remains and placing them in a waste bin. This is clearly outlined in the package insert. 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.

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.

PMX8.04.01.0.xxx D.15	Issued for Date:	Prepared by. QA Date: 17.11.2019	Reviewed by. QA Date: 17.11.2019	Approved by. QA Date: 17.11.2019	Page 5 of 5
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