



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

1. SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier**
Trade name Alere TESTPACK + Plus hCG Urine with OBC, Test device
Reference No. 505798J (ROW), 505436J (Japan), 505436J40 (Japan), 506175J (Japan), 506175J40 (Japan)
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Identified use(s) In vitro diagnostic reagent. For professional use only.
- 1.3 Details of the supplier of the safety data sheet**
Company Identification Alere Medical Co., Ltd.
357 Matsuhidai, Matsudo-shi, Chiba
270-2214, Japan
Telephone +81 47 311 5750
E-Mail (competent person) Europe & Middle East: EMEproductsupport@alere.com
Asia Pacific: APproductsupport@alere.com
Africa, Russia & CIS: ARCISproductsupport@alere.com
Latin America: LAsproductsupport@alere.com
Canada: CANproductsupport@alere.com
- 1.4 Emergency telephone number**
Emergency Phone No. Europe & Middle East: +44 (0) 161 483 9032
Asia Pacific: + (61) 7 3363 7711
Africa, Russia & CIS: + (972) 8 9429 683
Latin America: + (57) 01800 094 9393
Canada: +1 800 818 8335

2. SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture**
Directive 67/548/EEC & Directive 1999/45/EC Not classified as dangerous for supply/use.
- 2.2 Label elements** No measures required.
- 2.3 Other hazards** None anticipated.

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: In vitro diagnostic reagent test device. Preparation.
Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.

Dangerous components:

Hazardous ingredient(s)	%W/W	EC No.	REACH Registration No.	EC Classification and Risk Phrases
Tris (hydroxymethyl) aminomethane	1 - 2	201-064-4	Not available	Xi; R36/37/38
Tris (hydroxymethyl) aminomethane hydrochloride	1 - 2	214-684-5	Not available	Xi; R36/37/38

- 3.3 Additional Information** For full text of R phrases see section 16.



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4. SECTION 4: FIRST AID MEASURES



4.1 Description of 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.

Inhalation
Skin Contact
Eye Contact

Supply fresh air; consult doctor in case of complaint.

Wash skin with soap and water.

Rinse cautiously with water for several minutes. Consult doctor in case of complaint.

Ingestion

Wash out mouth with water. Consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

None.

4.3 Indication of the immediate medical attention and special treatment needed

None.

5. SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released: Hazardous fumes and vapours.

5.3 Advice for fire-fighters

Use fire-extinguishing methods suitable to surrounding conditions.

Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Collect material and dispose of as waste according to Section 13

6.4 Reference to other sections

8, 13

7. SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with the eyes, skin and mucous membranes. Keep out of reach of children.

Specimens should be handled as potentially infectious materials. Refer to Directive 2000/54/EC for information on handling biohazardous materials.

Wash hands before breaks and after work.

Clean work areas with hypochlorite or other disinfecting agent.

7.2 Conditions for safe storage, including any incompatibilities

Store in original container at 2 to 30°C.

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7.3 **Specific end use(s)** Use as per instructions for use.

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits

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

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Not relevant for this material.

8.2.2 Personal protection equipment

Eye/face protection

Safety glasses recommended. (EN166)



Hand protection

Disposable gloves. (EN374).



Material of gloves:

Latex / natural rubber

Penetration time of glove material:

Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection

Laboratory coat.

Respiratory protection

Not normally required.

8.2.3 Environmental Exposure Controls

No special measures are required.

9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents. White.

Colour

No odour.

Odour

Odour Threshold (ppm)

Not applicable

pH (Value)

Not determined

Melting Point (°C) / Freezing Point (°C)

Not determined

Boiling point/boiling range (°C):

Not determined

Flash Point (°C)

Not applicable

Evaporation rate (BA = 1)

Not applicable

Flammability (solid, gas)

Not determined

Explosive limit ranges

Not applicable

Vapour Pressure (mm Hg)

Not applicable

Vapour Density (Air=1)

Not applicable

Density (g/ml)

Not determined

Solubility (Water)

Not determined

Solubility (Other)

Not determined

Partition Coefficient (n-Octanol/water)

Not determined

Auto Ignition Temperature (°C)

Not determined

Decomposition Temperature (°C)

Not determined

Viscosity (mPa.s)

Not determined

Explosive properties

Not explosive.

Oxidising properties

Not oxidising

9.2 Other information

Not available



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10. SECTION 10: STABILITY AND REACTIVITY

10.1	Reactivity	None known.
10.2	Chemical stability	The product is stable in accordance with the recommended storage conditions.
10.3	Possibility of hazardous reactions	None known. Hazardous polymerisation will not occur.
10.4	Conditions to avoid	None
10.5	Incompatible materials	None known.
10.6	Hazardous Decomposition Product(s)	None known.

11. SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Irritation	Based upon the available data, the classification criteria are not met.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitisation	Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	No data
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	No data
Toxicity for reproduction	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated
Eye Contact	No significant harmful effects anticipated
Ingestion	No significant harmful effects anticipated

11.2 Other information Not applicable

12. SECTION 12: ECOLOGICAL INFORMATION

12.1	Toxicity	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2	Persistence and degradability	The product is likely to persist in the environment.
12.3	Bioaccumulative potential	None anticipated.
12.4	Mobility in soil	The product is predicted to have low mobility in soil.
12.5	Results of PBT and vPvB assessment	Not applicable
12.6	Other adverse effects	Not applicable



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13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Used devices should be disposed of as potentially biohazardous material 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.

European waste catalogue: 18 01 03.

Packaging: Disposal should be in accordance with local, state or national legislation.
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. SECTION 14: TRANSPORT INFORMATION

14.1	UN number	Not applicable
14.2	Proper Shipping Name	Not applicable
14.3	Transport hazard class(es)	Not classified as dangerous for transport.
14.4	Packing Group	Not applicable
14.5	Environmental hazards	Not applicable
14.6	Special precautions for user	Not applicable
14.7	Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

15. SECTION 15: REGULATORY INFORMATION

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	In Vitro diagnostics medical devices directive 98/79/EC.
15.2	Chemical Safety Assessment	Not applicable.

16. SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

Classification code:

Xi IRRITANT

Risk Phrases

R36/37/38: Irritating to eyes, respiratory system and skin.

References:

Raw material safety data sheets.



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Additional Information

Reason for update: Update in accordance with Regulation (EU) No 453/2010.
Changes to all sections.

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