



Alere TESTPACK + Plus Strep A with OBC, Kit MSDS

Reference No.: 505715J (x20 ROW), 505796J (x40 ROW), 505435J (Japan),
506174J (Japan)

This document contains MSDS for the following kit components

Reagent 1

Reagent 2

Reagent 3

Test Device




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 Strep A with OBC, Reagent 1
Reference No. 505715J (x20 ROW), 505796J (x40 ROW), 505435J (Japan), 506174J (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 Toxic
Risk Phrases: R25: Toxic if swallowed.
- 2.2 Label elements**
Symbol and Nature of Danger. According to Directive 67/548/EEC & Directive 1999/45/EC
 TOXIC
- Risk Phrases: R25: Toxic if swallowed.
- Safety Phrases: S1/2: Keep locked up and out of the reach of children.
S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S60: This material and its container must be disposed of as hazardous waste.

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: *In vitro* diagnostic reagent. Aqueous preparation containing



SAFETY DATA SHEET

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

the hazardous components listed below.

Dangerous components:

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	%W/W	EC No.	REACH Registration No.	EC Classification and Risk Phrases
Sodium Nitrite	10 - 20	231-555-9	Not available	O, T, N; R 8-25-50

3.3 Additional Information

For full text of R phrases see section 16.

4. SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures

Inhalation
Skin Contact

Eye Contact

Ingestion

Supply fresh air; consult doctor in case of complaint.

Wash affected skin with plenty of water. Remove contaminated clothing and wash clothing before reuse.

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

Wash out mouth with water and give 200-300 ml (half a pint) of water to drink. OBTAIN IMMEDIATE MEDICAL ATTENTION.

4.2 Most important symptoms and effects, both acute and delayed

Cyanosis, Nausea, Narcosis, Unconsciousness.

4.3 Indication of the immediate medical attention and special treatment needed

Activated charcoal (10% Slurry). Treat symptomatically – sodium nitrite poisoning.

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: nitrogen oxides (NO_x).

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.

5.4 Additional Information

Non-combustible.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Isolate spillage and clean up immediately. Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions

Do not allow to enter drains, sewers or watercourses.

6.3 Methods and material for containment and cleaning up

Absorb spillages onto sand, earth or any suitable adsorbent material. Collect material and dispose of as waste according to Section 13. Rinse off area with water.

6.4 Reference to other sections

8, 13


SAFETY DATA SHEET

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

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.
Wash hands before breaks and after work. |
| 7.2 | Conditions for safe storage, including any incompatibilities | Store in original container at 2 to 30°C. |
| 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 | Not normally required. |
| | 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 | Liquid. |
| | Colour | Red. |
| | Odour | No odour. |
| | Odour Threshold (ppm) | Not applicable. |
| | pH (Value) | 6.9 |
| | Melting Point (°C) / Freezing Point (°C) | Similar to water, approximately 0°C. |
| | Boiling point/boiling range (°C): | Similar to water, approximately 100°C. |
| | Flash Point (°C) | Not applicable. |
| | Evaporation rate (BA = 1) | Not determined. |
| | Flammability (solid, gas) | Not applicable. |
| | Explosive limit ranges | Not applicable. |
| | Vapour Pressure (Pascal) | Similar to water, approximately 23 hPa. |
| | Vapour Density (Air=1) | Not determined. |
| | Density (g/ml) | 1.08 |
| | Solubility (Water) | Miscible. |
| | Solubility (Other) | Not determined. |
| | Partition Coefficient (n-Octanol/water) | Not determined. |
| | Auto Ignition Temperature (°C) | Not determined. |



SAFETY DATA SHEET

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

Decomposition Temperature (°C)	Not determined.
Viscosity (mPa.s)	Not determined.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.
9.2 Other information	Not available.

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	
11.1.1 Substances	
Acute toxicity	Sodium nitrite LD ₅₀ (oral, rat): 85 m/kg LD ₅₀ (Inhalation, rat): 5.5 mg/l/4hr LD ₀ (oral, Human): 1 – 2 g
11.1.2 Mixtures	
Acute toxicity	Toxic if swallowed. LD ₅₀ (oral, rat) calculated: 616 mg/kg
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	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	Based upon the available data, the classification criteria are not met.
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	Cyanosis, Nausea, Narcosis, Unconsciousness.
11.2 Other information	Not applicable



SAFETY DATA SHEET

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

12. SECTION 12: ECOLOGICAL INFORMATION

12.1	Toxicity	Sodium nitrite LC ₅₀ (96h, Fish): 0.19 mg/l EC ₅₀ (48h, Daphnia magna): 66 mg/l Based upon the available data, the classification criteria are not met. LC ₅₀ (96h, Fish) Mixture calculated: 1.38 mg/l
12.2	Persistence and degradability	No data.
12.3	Bioaccumulative potential	None anticipated.
12.4	Mobility in soil	No data.
12.5	Results of PBT and vPvB assessment	Not relevant for this material.
12.6	Other adverse effects	Not applicable

13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1	Waste treatment methods	
	Product:	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.
	European waste catalogue:	18 01 06.
	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. Water hazard class (Germany): 2, hazardous for water.
15.2	Chemical Safety Assessment	Not applicable.



SAFETY DATA SHEET

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

16. SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

Classification code:

T TOXIC
O OXIDIZING
N DANGEROUS FOR THE ENVIRONMENT

Risk Phrases

R8: Contact with combustible material may cause fire.
R25: Toxic if swallowed.
R50: Very toxic to aquatic organisms.

References:

Raw material safety data sheets.

Additional Information

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

Supersedes: Version: SDS 008.05

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.



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 Strep A with OBC, Reagent 2
Reference No. 505715J (x20 ROW), 505796J (x40 ROW), 505435J (Japan), 506174J (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**
Special labelling phrase: Safety data sheet available for professional user on request.

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: *In vitro* diagnostic reagent. Aqueous preparation containing the hazardous components listed below.
Dangerous components:

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	%W/W	EC No.	REACH Registration No.	EC Classification and Risk Phrases
Acetic Acid	5 - 10	200-580-7	Not available	C; R 10-35

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



SAFETY DATA SHEET

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

4. SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures

Inhalation
Skin Contact

Supply fresh air; consult doctor in case of complaint.
Wash affected skin with plenty of water. Remove contaminated clothing and wash clothing before reuse.

Eye Contact

Rinse cautiously with water for several minutes. If symptoms persist, obtain medical attention.

Ingestion

Wash out mouth with water and give 200-300 ml (half a pint) of water to drink. Consult doctor in case of complaint.

4.2 Most important symptoms and effects, both acute and delayed

Mild irritant.

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: Acetic acid 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.

5.4 Additional Information

Non-combustible.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Isolate spillage and clean up immediately.
Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Absorb spillages onto sand, earth or any suitable adsorbent material. Collect material and dispose of as waste according to Section 13. Rinse off area with water.

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.
Wash hands before breaks and after work.

7.2 Conditions for safe storage, including any incompatibilities

Store in original container at 2 to 30°C.



7.3 Specific end use(s)

Use as per instructions for use.

SAFETY DATA SHEET

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

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1	Control parameters	.
8.1.1	Occupational Exposure Limits	OELV (Irl): Acetic Acid Short Term Exposure Limit (15-min ref): 37mg/m ³ , 15 ppm Long Term Exposure Limit (8-hour TWA): 25 mg/m ³ , 10 ppm
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	Liquid.
	Colour	Colourless.
	Odour	Pungent.
	Odour Threshold (ppm)	Not available.
	pH (Value)	2.5
	Melting Point (°C) / Freezing Point (°C)	Similar to water, approximately 0°C.
	Boiling point/boiling range (°C):	Similar to water, approximately 100°C.
	Flash Point (°C)	Not applicable.
	Evaporation rate (BA = 1)	Not determined.
	Flammability (solid, gas)	Not applicable.
	Explosive limit ranges	Not applicable.
	Vapour Pressure (Pascal)	Similar to water, approximately 23 hPa.
	Vapour Density (Air=1)	Not determined.
	Density (g/ml)	1.0
	Solubility (Water)	Miscible.
	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.

10. SECTION 10: STABILITY AND REACTIVITY

10.1	Reactivity	None known.
-------------	-------------------	-------------



SAFETY DATA SHEET

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

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	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	Based upon the available data, the classification criteria are not met.
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	May cause transient irritation.
Eye Contact	May cause transient irritation.
Ingestion	No significant harmful effects anticipated.
Inhalation	May cause transient irritation.

11.2 Other information Not applicable

12. SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	May be harmful due to pH shift.
12.2 Persistence and degradability	The product is unlikely to persist in the environment.
12.3 Bioaccumulative potential	None anticipated.
12.4 Mobility in soil	No data.
12.5 Results of PBT and vPvB assessment	Not relevant for this material.
12.6 Other adverse effects	Not applicable



SAFETY DATA SHEET

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

13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: 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.

European waste catalogue: 18 01 07.

Packaging: Disposal should be in accordance with local, state or national legislation. 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. Water hazard class (Germany): 1, slightly hazardous for water.
15.2	Chemical Safety Assessment	Not applicable.

16. SECTION 16: OTHER INFORMATION

LEGEND

STOT	Specific Target Organ Toxicity
OELV	Occupational Exposure Limit Value
TWA	Time weighted average

Classification code:

C CORROSIVE

Risk Phrases

R10: Flammable.

R35: Causes severe burns.

References:

Raw material safety data sheets.

Additional Information



SAFETY DATA SHEET

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

Reason for update::

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

Supersedes:

Version: SDS 009.05

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.




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 Strep A with OBC, Reagent 3
Reference No. 505715J (x20 ROW), 505796J (x40 ROW), 505435J (Japan), 506174J (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 Harmful.
Risk Phrases: R22: Harmful if swallowed.
- 2.2 Label elements**
Symbol and Nature of Danger. According to Directive 67/548/EEC & Directive 1999/45/EC
 HARMFUL
- Risk Phrases: R22: Harmful if swallowed.
- Safety Phrases: S2: Keep out of the reach of children.
S35: This material and its container must be disposed of in a safe way.
S46: If swallowed, seek medical advice immediately and show this container or label.

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: *In vitro* diagnostic reagent. Aqueous preparation containing the hazardous components listed below.

SAFETY DATA SHEET

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

Dangerous components:

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	%W/W	EC No.	REACH Registration No.	EC Classification and Risk Phrases
Tris (hydroxymethyl) aminomethane	10 - 20	201-064-4	Not available	Xi; R36/37/38
Sodium azide	0.1 – 0.2	247-852-1	Not available	T+, N, R 28-32-50/53

3.3 Additional Information

For full text of R phrases see section 16.

4. SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures

Inhalation
Skin Contact

Supply fresh air; consult doctor in case of complaint.

Wash with plenty of soap and water. Remove contaminated clothing and wash clothing before reuse.

Eye Contact

Rinse cautiously with water for several minutes. If symptoms persist, obtain medical attention.

Ingestion

Wash out mouth with water. Consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

Headache, dizziness, nausea and vomiting.

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: Carbon oxides (CO_x), nitrogen oxides (NO_x).

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.

5.4 Additional Information

Non-combustible.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Isolate spillage and clean up immediately.

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

6.2 Environmental precautions

Do not allow to enter drains, sewers or watercourses.

6.3 Methods and material for containment and cleaning up

Adsorb spillages onto sand, earth or any suitable adsorbent material. Collect material and dispose of as waste according to Section 13. Rinse off area with water.

6.4 Reference to other sections

8, 13


SAFETY DATA SHEET

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

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.
Wash hands before breaks and after work. |
| 7.2 | Conditions for safe storage, including any incompatibilities | Store in original container at 2 to 30°C. |
| 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 | WEL (UK) / OELV (Irl): Sodium Azide
Short Term Exposure Limit (15-min ref): 0.3 mg/m ³
Long Term Exposure Limit (8-hour TWA): 0.1 mg/m ³
as NaN ₃ |
| 8.2 | Exposure controls | |
| 8.2.1 | Appropriate engineering controls | Not relevant for this material. |
| 8.2.2 | Personal protection equipment | |
| | Eye/face protection | Not normally required. |
| | 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 | Liquid. |
| | Colour | Colourless - Pale yellow. |
| | Odour | Odourless. |
| | Odour Threshold (ppm) | Not applicable. |
| | pH (Value) | 9.3 |
| | Melting Point (°C) / Freezing Point (°C) | Similar to water, approximately 0°C. |
| | Boiling point/boiling range (°C): | Similar to water, approximately 100°C. |
| | Flash Point (°C) | Not applicable. |
| | Evaporation rate (BA = 1) | Not determined. |
| | Flammability (solid, gas) | Not applicable. |
| | Explosive limit ranges | Not applicable. |
| | Vapour Pressure (Pascal) | Similar to water, approximately 23 hPa. |
| | Vapour Density (Air=1) | Not determined. |
| | Density (g/ml) | 1.05 |
| | Solubility (Water) | Miscible. |
| | Solubility (Other) | Not determined. |
| | Partition Coefficient (n-Octanol/water) | Not determined. |
| | Auto Ignition Temperature (°C) | Not determined. |



SAFETY DATA SHEET

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

	Decomposition Temperature (°C)	Not determined.
	Viscosity (mPa.s)	Not determined.
	Explosive properties	Not explosive.
	Oxidising properties	Not oxidising.
9.2	Other information	Not available.

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	Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerisation will not occur.
10.4	Conditions to avoid	None.
10.5	Incompatible materials	Strong Acids, heavy metals, metallic salts.
10.6	Hazardous Decomposition Product(s)	None known.

11. SECTION 11: TOXICOLOGICAL INFORMATION

11.1	Information on toxicological effects	
11.1.1	Substances	
	Acute toxicity	Sodium azide LD ₅₀ (oral, rat): 27 m/kg LD ₅₀ (Dermal, rabbit): 20 mg/kg LD ₀ (oral, Human): 0.71 mg/kg
11.1.2	Mixtures	
	Acute toxicity	Harmful if swallowed. LD ₅₀ (oral, rat) calculated: 27,000 mg/l
	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	Based upon the available data, the classification criteria are not met.
	Carcinogenicity	Based upon the available data, the classification criteria are not met.
	Mutagenicity	Based upon the available data, the classification criteria are not met.
	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 (substantial quantities)	Headache, dizziness, nausea and vomiting.
11.2	Other information	Not applicable



SAFETY DATA SHEET

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

12. SECTION 12: ECOLOGICAL INFORMATION

12.1	Toxicity	Sodium azide LC ₅₀ (96h, Fish) = 0.7 mg/l EC ₅₀ (48h, Daphnia magna) = 4.2 mg/l Based upon the available data, the classification criteria are not met.
12.2	Persistence and degradability	The product is substantially biodegradable.
12.3	Bioaccumulative potential	None anticipated.
12.4	Mobility in soil	No data.
12.5	Results of PBT and vPvB assessment	Not relevant for this material.
12.6	Other adverse effects	Not applicable

13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1	Waste treatment methods	
	Product:	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.
	European waste catalogue:	18 01 06.
	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. Water hazard class (Germany): 2, hazardous for water.
15.2	Chemical Safety Assessment	Not applicable.

16. SECTION 16: OTHER INFORMATION



SAFETY DATA SHEET

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

LEGEND

STOT	Specific Target Organ Toxicity
WEL	Workplace Exposure Limit
OELV	Occupational Exposure Limit Value
TWA	Time weighted average

Classification code:

T+	VERY TOXIC
Xi	IRRITANT
N	DANGEROUS FOR THE ENVIRONMENT

Risk Phrases

R28: Very toxic if swallowed.

R32: Contact with acids liberates very toxic gas.

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

R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

References:

Raw material safety data sheets.

Additional Information

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

Supersedes: Version: SDS 010.07

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.



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 Strep A with OBC, Test device
Reference No. 505715J (x20 ROW), 505796J (x40 ROW), 505435J (Japan), 506174J (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: LAproductsupport@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: The product does not contain reportable quantities of hazardous ingredients

4. SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures



SAFETY DATA SHEET

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

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	Supply fresh air; consult doctor in case of complaint.
Skin Contact	Wash skin with soap and water.
Eye Contact	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	CO ₂ , 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.
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

SAFETY DATA SHEET

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

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.

Colour

Light Grey.

Odour

No 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

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.



SAFETY DATA SHEET

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

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

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
------	-------------------------------------	--



SAFETY DATA SHEET

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

(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

References:

Raw material safety data sheets.

Additional Information

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

Supersedes: Version: SDS 011.05

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.