

Document Name	Material Safety Data Sheet Mononucleosis Test Device	Document No. NDC- MS- 0067
		Version: A Revision: 00
Effective Date:	2009 年 8 月 12 日	Page 1 of 22



MATERIAL SAFETY DATA SHEET
Mono Test Device Kit

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

This documentation contains MSDS for the following kit components

Test Device
Positive Control & Negative Control
Whole Blood Buffer

1. Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Trade name:	Reference No.	Part No.
Pro Advantage® Infectious Mononucleosis Test Device	IMO-402	P080016

Use of the substance/preparation: In vitro diagnostic medical device. For professional use only.

Company/undertaking identification:

Inverness Medical Innovations North America, Inc.
30 South Keller Road, Suite 100
Orlando, FL 32810 USA
Tel: + 1-877-441-7440
Fax: + 1-877-441-7441
Email: imi.customercare@invmed.com

Further information obtainable from: For further information, contact your local distributor/supplier.

Emergency telephone: ChemTel Inc. International access: + (0)1-813-248-0585
ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

2. Hazards identification

Hazard description:

Preparation not classified as dangerous according to Directive 1999/45/EC.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:

As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200.

3. Composition/information on ingredients

Chemical characterisation

Description:

In vitro diagnostic medical device. Test strip impregnated with dried chemical / biochemical reagents.

Dangerous components:

Component	CAS No.	EINECS No.	Classification	Concentration
Tris (hydroxymethyl) aminomethane	77-86-1	201-064-4	Xi, R 36/37/38	2 – 5 %

Additional information:

Each device is packaged in a foil pouch.
For the wording of the listed risk phrases refer to section 16.

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- Whole Blood Buffer

4. 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.

After ingestion:

If desiccant or other components are swallowed seek medical attention.

5. Fire-fighting measures

Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire-extinguishing methods suitable to surrounding conditions.

Special hazards caused by the substance, its products of combustion or resulting gases:

In case of fire, the following can be released: Hazardous fumes and vapours, Carbon oxides (CO_x), Nitrogen oxides (NO_x),

Protective equipment:

Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

Additional information:

The device contains combustible materials.

6. Accidental release measures

Person-related safety precautions:

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

Measures for environmental protection:

Avoid release to the environment.

Measures for cleaning/collecting:

Collect material and dispose of as waste according to Section 13.

7. 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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8. 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.

Additional information:

The lists valid during the creation of this MSDS were used as a basis for this assessment.

Personal protective equipment:

General protective and hygienic measures:

Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling bio hazardous materials.

Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

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

9. Physical and chemical properties

General Information

Form: The device is an article containing solid components

Appearance: Laminated test strip, which may be housed in a plastic holder.

Odour: Odourless

Flash point: Not applicable.

Self-igniting: Product is not self-igniting.

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

10. Stability and reactivity

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.

11. Toxicological information

Acute toxicity:

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

Primary effects:

After skin contact: No irritating effects anticipated.

After eye contact: No irritating effects anticipated.

Sensitisation: No sensitising effects known.

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12. 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.

13. Disposal considerations

Product:

Used devices and other contaminated materials should be disposed of as potentially bio hazardous waste. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

European waste catalogue:

18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.

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.

14. Transport information

Land transport ADR/RID (cross-border)

Not regulated for transport.

US DOT Transport Regulations:

Not regulated for transport.

Maritime transport IMDG:

Not regulated for transport.

Marine pollutant: No

Air transport ICAO-TI and IATA-DGR:

Not regulated for transport.

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15. Regulatory information

Labelling according to EU guidelines:

Safety data sheet available for professional user on request.

Note:

The preparation is exempt from the above labelling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:

Not required.

Chemical inventory listings relevant to US regulations:

Carcinogen listings

- IARC: None of the ingredients is listed.
- NTP: None of the ingredients is listed.
- ACGIH: None of the ingredients is listed.
- OSHA: None of the ingredients is listed.
- EPA None of the ingredients is listed.

Californian Proposition 65

- Chemicals known to cause cancer: None of the ingredients is listed.
- Chemicals known to cause reproductive toxicity: None of the ingredients is listed.

SARA

- Section 355 (extremely hazardous substances): None of the ingredients is listed.
- Section 313 (specific toxic chemical listings): None of the ingredients is listed.

16. Other information

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.

Relevant R-phrases

36/37/38 Irritating to eyes, respiratory system and skin.

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Whole Blood Buffer

1. Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Trade name: Mono, Negative Control

Trade name:	Reference No.	Part No.
Pro Advantage® Infectious Mononucleosis Test Device	IMO-402	P080016

Use of the substance/preparation: In vitro diagnostic medical device. For professional use only.

Company/undertaking identification:

Inverness Medical Innovations North America, Inc.
30 South Keller Road, Suite 100
Orlando, FL 32810 USA
Tel: + 1-877-441-7440
Fax: + 1-877-441-7441
Email: imi.customercare@invmed.com

Further information obtainable from: For further information, contact your local distributor/supplier.

Emergency telephone: ChemTel Inc. International access: + (0)1-813-248-0585
ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

2. Hazards identification

Hazard description:

Xn, Harmful

Information concerning particular hazards for human and environment:

R 22 Harmful if swallowed.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:

Not classified as hazardous.

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3. Composition/information on ingredients

Chemical characterisation

Description:

Aqueous preparation containing the hazardous components listed below. Also contains materials of human origin.

Dangerous components:

Component	CAS No.	EINECS No.	Classification	Concentration
Sodium Azide	26628-22-8	247-852-1	T+, N, R 28-32-50/53	0.09 %

Additional information:

Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1/2 on a single donor basis and found to be non-reactive.

For the wording of the listed risk phrases refer to section 16.

4. First-aid measures

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact:

Wash with soap and water and rinse thoroughly. Remove soiled clothing.

After eye contact:

Rinse opened eye for several minutes under running water. Consult a doctor in case of complaints.

After ingestion:

Wash out mouth with water. Consult a doctor.

5. Fire-fighting measures

Suitable extinguishing agents:

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

Use fire-extinguishing methods suitable to surrounding conditions.

Special hazards caused by the substance, its products of combustion or resulting gases:

In case of fire, the following can be released: Carbon oxides (CO_x), Nitrogen oxides (NO_x), Phosphorous oxides (P_xO_y)

Protective equipment:

Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

6. Accidental release measures

Person-related safety precautions:

Isolate spillage and clean up immediately.

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

Measures for environmental protection:

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

Measures for cleaning/collecting:

Absorb with liquid-binding material (sand, diatomite, acid binders, and universal binders)

Dispose of contaminated material as waste according to Section 13.

Swab down area with hypochlorite solution or other disinfecting agent.

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7. Handling and storage

Information for safe handling:

This product should be handled as a potentially infectious material, as no known test method can offer complete assurance that products derived from human blood will not transmit infectious agents.
Avoid contact with the eyes, skin and mucous membranes.
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.

8. Exposure controls/personal protection

Ingredients with limit values that require monitoring in the workplace:

Sodium azide CAS No.: 26628-22-8
UK WEL / IRL OELV 8-hour TWA: 0.1 mg/m³ Short-term value: 0.3 mg/m³ as NaN₃

Additional information:

The lists valid during the creation of this MSDS were used as a basis for this assessment.

Personal protective equipment:

General protective and hygienic measures:

Adhere to EU Directive 2000/54/EC / OSHA Regulation 29 CFR 1910.1030 for handling bio hazardous materials.
Clean work areas with hypochlorite solution or other disinfecting agent.
Wash hands before breaks and at the end of work.

Respiratory protection:

Face mask

Protection of hands:

Disposable gloves

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.

Eye protection:

Safety glasses

Body protection:

Lab coat

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This documentation contains MSDS for the following kit components

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- Whole Blood Buffer

9. Physical and chemical properties

General Information

- Form:** Liquid
- Colour:** Colourless
- Odour:** Odourless

Change in condition

- Melting point/Melting range:** Similar to water, approximately 0°C.
- Boiling point/Boiling range:** Similar to water, approximately 100°C.

Flash point: Not applicable.

Self-igniting: Product is not self-igniting.

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

Vapour pressure: Similar to water, approximately 23 hPa.

Density at 20°C: 1.01 g/cm³

Solubility in/Miscibility with:

Water: Fully miscible.

pH-value at 20°C: 7.4

10. Stability and reactivity

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

Materials to be avoided: concentrated acids, heavy metals, metallic salts

Hazardous reactions: Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic (azide) gas. Hazardous polymerisation will not occur.

Hazardous decomposition products: No dangerous decomposition products known.

11. Toxicological information

Acute toxicity:

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

LD₅₀/LC₅₀ values relevant for classification:

Sodium azide CAS No.: 26628-22-8

LD₅₀ (Oral, rat): 27 mg/kg

TDL₀ (Human): 0.71 mg/kg

LD₅₀ (Dermal, rabbit): 20 mg/kg

Primary effects:

After skin contact: No irritating effects anticipated.

After eye contact: No irritating effects anticipated.

After ingestion: Possible systemic effects following ingestion of substantial quantities: headache, dizziness, nausea, vomiting, CNS disorders, drop in blood pressure, cardiovascular failure, collapse.

Sensitization: No sensitizing effects known.

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This documentation contains MSDS for the following kit components

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- Whole Blood Buffer

12. Ecological information

Ecotoxic Effects:

Quantitative data on the toxic effects of this product are not available.
No ecological problems are to be expected when the product is handled and used with due care and attention.

Aquatic toxicity:

Sodium azide CAS No.: 26628-22-8
LC₅₀ (96 h, Fish): 0.7 mg/l
EC₅₀ (96 h, Daphnia): 4.2 mg/l

Persistence and Degradability:

The product is biodegradable.

Mobility and bioaccumulation potential:

Does not accumulate in organisms

13. Disposal considerations

Product:

Dispose of as potentially bio hazardous waste and 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 approved waste-disposal company for information.
To avoid the possible build-up of azide compounds, flush plumbing with water after the disposal of undiluted reagent.

European waste catalogue:

18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.

Packaging:

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

Land transport ADR/RID (cross-border)

Not regulated for transport.

US DOT Transport Regulations:

Not regulated for transport.

Maritime transport IMDG:

Not regulated for transport.

Marine pollutant: No

Air transport ICAO-TI and IATA-DGR:

Not regulated for transport.

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- Whole Blood Buffer

15. Regulatory information

Labelling according to EU guidelines:

Code letter and hazard designation of product:



Xn Harmful

Hazard-determining components of labelling:

Sodium Azide

Risk phrases:

22 Harmful if swallowed.

Safety phrases:

S2 Keep out of reach of children

35 This material and its container must be disposed of in a safe way.

46 If swallowed, seek medical advice immediately and show this container or label.

Water Hazard Class (Germany): WGK -, not hazardous for water.

US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:

Not required.

Chemical inventory listings relevant to US regulations:

Carcinogen listings

- IARC: None of the ingredients is listed.
- NTP: None of the ingredients is listed.
- ACGIH: None of the ingredients is listed.
- OSHA: None of the ingredients is listed.
- EPA None of the ingredients is listed.

Californian Proposition 65

Chemicals known to cause cancer: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity: None of the ingredients is listed.

SARA

Section 355 (extremely hazardous substances): Yes, Sodium azide CAS No. 26628-22-8.

Section 313 (specific toxic chemical listings): Yes, Sodium azide CAS No. 26628-22-8

16. Other information

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.

Relevant R-phrases

- 28 Very toxic if swallowed.
- 32 Contact with acids liberates very toxic gas.
- 50/53 Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

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This documentation contains MSDS for the following kit components

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- Whole Blood Buffer

1. Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Trade name: Mono Positive Control

Trade name:	Reference No.	Part No.
Pro Advantage® Infectious Mononucleosis Test Device	IMO-402	P080016

Use of the substance/preparation: In vitro diagnostic medical device. For professional use only.

Company/undertaking identification:

Inverness Medical Innovations North America, Inc.
30 South Keller Road, Suite 100
Orlando, FL 32810 USA
Tel: + 1-877-441-7440
Fax: + 1-877-441-7441
Email: imi.customercare@invmed.com

Further information obtainable from: For further information, contact your local distributor/supplier.

Emergency telephone: ChemTel Inc. International access: + (0)1-813-248-0585
ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

2. Hazards identification

Hazard description:

Xn, Harmful

Information concerning particular hazards for human and environment:

R 22 Harmful if swallowed.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:

Not classified as hazardous.

3. Composition/information on ingredients

Chemical characterisation

Description:

Aqueous preparation containing the hazardous components listed below.

Dangerous components:

Component	CAS No.	EINECS No.	Classification	Concentration
Sodium Azide	26628-22-8	247-852-1	T+, N, R 28-32-50/53	0.1 – 0.2 %

Additional information:

Also contains goat anti-mono antibody.
For the wording of the listed risk phrases refer to section 16.

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This documentation contains MSDS for the following kit components

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- Whole Blood Buffer

4. First-aid measures

- After inhalation:** Supply fresh air; consult doctor in case of complaints.
- After skin contact:**
Wash with soap and water and rinse thoroughly. Remove soiled clothing.
- After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After ingestion:**
Wash out mouth with water. Consult a doctor.

5. Fire-fighting measures

- Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire-extinguishing methods suitable to surrounding conditions.
- Special hazards caused by the substance, its products of combustion or resulting gases:**
In case of fire, the following can be released: Carbon oxides (CO_x), Nitrogen oxides (NO_x), Phosphorous oxides (P_xO_y)
- Protective equipment:**
Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

6. Accidental release measures

- Person-related safety precautions:**
Isolate spillage and clean up immediately.
Refer to Section 8 for protective measures when handling the spillage.
- Measures for environmental protection:**
Do not allow to enter sewers/surface or ground water.
- Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust)
Dispose of contaminated material as waste according to Section 13.
Rinse off area with water.

7. Handling and storage

- Information for safe handling:**
Observe the general safety regulations when handling chemicals.
Avoid contact with the eyes, skin and mucous membranes.
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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8. Exposure controls/personal protection

Ingredients with limit values that require monitoring in the workplace:

Sodium azide CAS No.: 26628-22-8
UK WEL / IRL OELV 8-hour TWA: 0.1 mg/m³ Short-term value: 0.3 mg/m³ as NaN₃
TLV (ACGIH) Short-term value: 0.29 mg/m³ as NaN₃, 0.11ppm as HN₃

Additional information:

The lists valid during the creation of this MSDS were used as a basis for this assessment.

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

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.

Eye protection:

Not required

Body protection:

Lab coat

9. Physical and chemical properties

General Information

Form: Liquid
Colour: Colourless
Odour: Odourless

Change in condition

Melting point/Melting range: Similar to water, approximately 0°C.
Boiling point/Boiling range: Similar to water, approximately 100°C.

Flash point: Not applicable.

Self-igniting: Product is not self-igniting.

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

Vapour pressure: Similar to water, approximately 23 hPa.

Density at 20°C: 1.01 g/cm³

Solubility in/Miscibility with:

Water: Fully miscible.

pH-value at 20°C: 7.4

10. Stability and reactivity

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

Materials to be avoided: concentrated acids, heavy metals, metallic salts

Hazardous reactions: Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic (azide) gas. Hazardous polymerisation will not occur.

Hazardous decomposition products: No dangerous decomposition products known.

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This documentation contains MSDS for the following kit components

- Test Device
- Positive Control & Negative Control
- Whole Blood Buffer

11. Toxicological information

Acute toxicity:

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

LD₅₀/LC₅₀ values relevant for classification:

- Sodium azide CAS No.: 26628-22-8
- LD₅₀ (Oral, rat): 27 mg/kg
- TDL₀ (Human): 0.71 mg/kg
- LD₅₀ (Dermal, rabbit): 20 mg/kg

Primary effects:

After skin contact: No irritating effects anticipated.

After eye contact: No irritating effects anticipated.

After ingestion: Possible systemic effects following ingestion of substantial quantities: headache, dizziness, nausea, vomiting, CNS disorders, drop in blood pressure, cardiovascular failure, collapse.

Sensitization: No sensitizing effects known.

12. Ecological information

Ecotoxic Effects:

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

No ecological problems are to be expected when the product is handled and used with due care and attention.

Aquatic toxicity:

- Sodium azide CAS No. 26628-22-8
- LC₅₀ (96 h, Fish): 0.7 mg/l
- EC₅₀ (96 h, Daphnia): 4.2 mg/l

Persistence and Degradability:

The product is biodegradable.

Mobility and bioaccumulation potential:

Does not accumulate in organisms

13. Disposal considerations

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.

To avoid the possible build-up of azide compounds, flush plumbing with water after the disposal of undiluted reagent.

European waste catalogue:

18 01 06 chemicals consisting of or containing dangerous substances

Packaging:

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.

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**MATERIAL SAFETY DATA SHEET
Mono Test Device Kit**

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

This documentation contains MSDS for the following kit components

- Test Device
- Positive Control & Negative Control
- Whole Blood Buffer

14. Transport information

Land transport ADR/RID (cross-border)

Not regulated for transport.

US DOT Transport Regulations:

Not regulated for transport.

Maritime transport IMDG:

Not regulated for transport.

Marine pollutant: No

Air transport ICAO-TI and IATA-DGR:

Not regulated for transport.

15. Regulatory information

Labelling according to EU guidelines:

Code letter and hazard designation of product:



Xn Harmful

Hazard-determining components of labelling:

Sodium Azide

Risk phrases:

22 Harmful if swallowed.

Safety phrases:

S2 Keep out of reach of children

35 This material and its container must be disposed of in a safe way.

46 If swallowed, seek medical advice immediately and show this container or label.

Water Hazard Class (Germany): WGK -, not hazardous for water.

US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:

Not required.

Chemical inventory listings relevant to US regulations:

Carcinogen listings

IARC: None of the ingredients is listed.

NTP: None of the ingredients is listed.

ACGIH: None of the ingredients is listed.

OSHA: None of the ingredients is listed.

EPA: None of the ingredients is listed.

Californian Proposition 65

Chemicals known to cause cancer: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity: None of the ingredients is listed.

SARA

Section 355 (extremely hazardous substances): Yes, Sodium azide CAS No. 26628-22-8.

Section 313 (specific toxic chemical listings): Yes, Sodium azide CAS No. 26628-22-8.

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Mono Test Device Kit

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This documentation contains MSDS for the following kit components

- Test Device
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16. Other information

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.

Relevant R-phrases

- 28 Very toxic if swallowed.
- 32 Contact with acids liberates very toxic gas.
- 50/53 Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

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1. Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Trade name: Whole blood buffer

Trade name:	Reference No.	Part No.
Pro Advantage® Infectious Mononucleosis Test Device	IMO-402	P080016

Use of the substance/preparation: In vitro diagnostic medical device. For professional use only.

Company/undertaking identification:

Inverness Medical Innovations North America, Inc.
30 South Keller Road, Suite 100
Orlando, FL 32810 USA
Tel: + 1-877-441-7440
Fax: + 1-877-441-7441
Email: imi.customercare@invmed.com

Further information obtainable from: For further information, contact your local distributor/supplier.

Emergency telephone: ChemTel Inc. International access: + (0)1-813-248-0585
ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

2. Hazards identification

Hazard description:

Preparation not classified as dangerous according to Directive 1999/45/EC.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:

Not classified as hazardous.

3. Composition/information on ingredients

Chemical characterisation

Description:

Aqueous preparation

Dangerous components:

The preparation does not contain reportable quantities of hazardous components.

4. First-aid measures

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact:

Wash with soap and water and rinse thoroughly. Remove soiled clothing.

After eye contact:

Rinse opened eye for several minutes under running water. Consult a doctor in case of complaints.

After ingestion:

Wash out mouth with water. Consult a doctor in case of complaint.

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5. Fire-fighting measures

Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire-extinguishing methods suitable to surrounding conditions.

Special hazards caused by the substance, its products of combustion or resulting gases:

In case of fire, the following can be released: Carbon oxides (CO_x), Nitrogen oxides (NO_x), Phosphorous oxides (P_xO_y)

Protective equipment:

Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

6. Accidental release measures

Person-related safety precautions:

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

Measures for environmental protection:

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

Measures for cleaning/collecting:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust)
Dispose of contaminated material as waste according to Section 13.
Rinse off area with water.

7. Handling and storage

Information for safe handling:

Observe the general safety regulations when handling chemicals.
Avoid contact with the eyes, skin and mucous membranes.
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.

8. 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.

Additional information:

The lists valid during the creation of this MSDS were used as a basis for this assessment.

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

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.

Eye protection:

Not required

Body protection:

Lab coat

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9. Physical and chemical properties

General Information

Form: Liquid
Colour: Colourless
Odour: Odourless

Change in condition

Melting point/Melting range: Similar to water, approximately 0°C.
Boiling point/Boiling range: Similar to water, approximately 100°C.

Flash point: Not applicable.

Self-igniting: Product is not self-igniting.

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

Vapour pressure: Similar to water, approximately 23 hPa.

Density at 20°C: 1.01 g/cm³

Solubility in/Miscibility with:

Water: Fully miscible.

pH-value at 20°C: 7.4

10. Stability and reactivity

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

Materials to be avoided: concentrated acids, heavy metals, metallic salts

Hazardous reactions: Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic (azide) gas. Hazardous polymerisation will not occur.

Hazardous decomposition products: No dangerous decomposition products known.

11. Toxicological information

Acute toxicity:

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

Primary effects:

After skin contact: No irritating effects anticipated.

After eye contact: No irritating effects anticipated.

After ingestion: No significant harmful effects anticipated

Sensitization: No sensitizing effects known.

Additional information:

The preparation contains trace amounts of Kanamycin sulphate, a chemical that may cause harm to the unborn child.

12. Ecological information

Ecotoxic Effects:

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

No ecological problems are to be expected when the product is handled and used with due care and attention.

Persistence and Degradability:

The product is biodegradable.

Mobility and bioaccumulation potential:

Does not accumulate in organisms

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Product:

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To avoid the possible build-up of azide compounds, flush plumbing with water after the disposal of undiluted reagent.

European waste catalogue:

18 01 07 chemicals other than those mentioned in 18 01 06.

Packaging:

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

Land transport ADR/RID (cross-border)

Not regulated for transport.

US DOT Transport Regulations:

Not regulated for transport.

Maritime transport IMDG:

Not regulated for transport.

Marine pollutant: No

Air transport ICAO-TI and IATA-DGR:

Not regulated for transport.

15. Regulatory information

Labelling according to EU guidelines:

No marking required.

Water Hazard Class (Germany): WGK -, not hazardous for water.

US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:

Not required.

Chemical inventory listings relevant to US regulations:

Carcinogen listings

- IARC: None of the ingredients is listed.
- NTP: None of the ingredients is listed.
- ACGIH: None of the ingredients is listed.
- OSHA: None of the ingredients is listed.
- EPA None of the ingredients is listed.

Californian Proposition 65

Chemicals known to cause cancer: None of the ingredients is listed.

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Section 355 (extremely hazardous substances): None of the ingredients is listed.

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