



inverness medical
professional diagnostics

Safety Data Sheet

Material Name: Wampole ColorCard Streptozyme
Product Number: 46050, 46150

*** Section 1 - Identification of the Substance/Preparation and the Company/Undertaking ***

Manufacturer Information

Inverness Medical Professional Diagnostics
2 Research Way
Princeton, NJ 08540

Phone: 609-627-8000
Main: 800-257-9525

*** Section 2 - Composition / Information on Ingredients ***

| EC # | Component | Percent | Symbols | Risks |
|-----------|---------------------------------|---------|---------|---------------|
| - | Human Source Material nonhaz | 99.9 | | |
| 247-852-1 | Sodium azide 26628-22-8 | 0.1 | T+ N | R:28-32-50-53 |

*** Section 3 - Hazards Identification ***

Human and Environmental Hazards

Occupational exposure is not expected to produce adverse human health effects following prudent workplace practices. Each donor unit used in the preparation of the positive control and the negative control was tested by a FDA approved method for the presence of the antibody to HIV, HCV, as well as for hepatitis B surface antigen and found to be negative. Because no test method can offer complete assurance that HIV, HCV, hepatitis B virus or other infectious agents are absent, this product should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories".

*** Section 4 - First Aid Measures ***

First Aid: Eyes

Immediately flush eyes with plenty of water for at least 15 minutes.

First Aid: Skin

For skin contact, wash immediately with soap and water.

First Aid: Ingestion

If the material is swallowed, get immediate medical attention or advice.

First Aid: Inhalation

If the affected person is not breathing, apply artificial respiration.

*** Section 5 - Fire Fighting Measures ***

General Fire Hazards

If involved in a fire, the packaging materials may produce poisonous gas.

Hazardous Combustion Products

None

Extinguishing Media

Use standard fire fighting procedures depending on the source of the surrounding fire.

Fire Fighting Equipment/Instructions

Firefighters should wear full protective gear.

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*** Section 6 - Accidental Release Measures ***

Containment Procedures

Contain the discharged material.

Clean-Up Procedures

Decontaminate spill with a bleach solution or appropriate germicide prior to pick up. If material is spilled down drain, flush with a large volume of water to prevent azide buildup in copper or lead plumbing. Decontamination procedures are available on request. Wear appropriate protective equipment and clothing during clean-up.

Evacuation Procedures

Isolate area. Keep unnecessary personnel away.

Special Procedures

Place material in a sealed container and dispose of as medical/infectious waste in accordance with applicable environmental regulations.

*** Section 7 - Handling and Storage ***

Handling Procedures

Always follow good laboratory practices when using this product. Handle all controls in this kit as if capable of transmitting disease.

Storage Procedures

No special measures required

Specific Use

Diagnostic test

*** Section 8 - Exposure Controls / Personal Protection ***

Substance Exposure Limits

Sodium azide (247-852-1)

| | |
|--------------|--|
| ACGIH: | 0.29 mg/m ³ Ceiling (as NaN ₃); 0.11 ppm Ceiling (vapor, as hydrazoic acid) |
| Austria: | 0.3 mg/m ³ STEL 0.1 mg/m ³ MAK skin notation |
| Belgium: | Skin |
| Denmark: | 0.1 mg/m ³ TWA Potential for cutaneous absorption |
| Finland: | 0.3 mg/m ³ STEL 0.1 mg/m ³ TWA Potential for cutaneous absorption |
| France: | 0.3 mg/m ³ VLCT 0.1 mg/m ³ VME |
| Germany: | 0.2 mg/m ³ TWA (exposure factor 2) 0.2 mg/m ³ MAK (inhalable fraction) 0.4 mg/m ³ Peak (inhalable fraction) |
| Greece: | 0.1 ppm STEL; 0.3 mg/m ³ STEL 0.1 ppm TWA; 0.3 mg/m ³ TWA |
| Ireland: | 0.3 mg/m ³ STEL (as NaN ₃) 0.1 mg/m ³ TWA (as NaN ₃) Potential for cutaneous absorption |
| Italy: | 0.1 mg/m ³ TWA |
| Netherlands: | 0.3 mg/m ³ STEL 0.1 mg/m ³ MAC skin notation |
| Spain: | 0.3 mg/m ³ VLA-EC; 0.1 ppm VLA-EC (as hydrazoic acid vapor); 0.18 mg/m ³ VLA-EC (as hydrazoic acid vapor) 0.1 mg/m ³ VLA-ED skin - potential for cutaneous exposure |
| Sweden: | 0.1 mg/m ³ LLV 0.3 mg/m ³ STV |

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Engineering Controls

A biosafety cabinet, as recommended in the CDC/NIH manual, may be necessary if there is a possibility of aerosolization during handling of the controls or test specimens.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

Wear safety glasses; chemical goggles (if splashing is possible).

Personal Protective Equipment: Skin

Use appropriate hand protection.

Personal Protective Equipment: Respiratory

Not normally needed.

Personal Protective Equipment: General

Eye wash fountain and emergency showers are recommended. Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

*** Section 9 - Physical & Chemical Properties ***

Appearance: Test kit consisting of three reagents with natural rubber bulb droppers, pipette/stirrers and disposable cards.

Odor: N/A

Physical State: Solid and Liquid

pH: ND

Vapor Pressure: ND

Vapor Density: N/A

Boiling Point: N/A

Melting Point: ND

Solubility (H₂O): Fully Miscible

Specific Gravity: ND

Evaporation Rate: ND

VOC: ND

Octanol/H₂O Coeff.: N/A

Flash Point: ND

Flash Point Method: ND

Upper Flammability Limit (UFL): ND

Lower Flammability Limit (LFL): ND

Burning Rate: ND

Auto Ignition: Not Self Igniting

*** Section 10 - Chemical Stability & Reactivity Information ***

Chemical Stability

This is a stable material.

Chemical Stability: Conditions to Avoid

None

Incompatibility

If disposed down a drain, the sodium azide in this kit may react with lead and copper plumbing to form highly explosive metal azides.

Hazardous Decomposition

No dangerous decomposition products known. If involved in a fire, the packaging materials may produce poisonous gas.

Hazardous Polymerisation

Will not occur.

*** Section 11 - Toxicological Information ***

Potential Health Effects

A: General Product Information

Occupational exposure is not expected to produce adverse human health effects following prudent workplace practices.

B: Substance Analysis - LD₅₀/LC₅₀

Sodium azide (247-852-1)

Oral LD₅₀ Rat: 27 mg/kg; Dermal LD₅₀ Rabbit: 20 mg/kg

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Carcinogenicity

A: General Product Information

No information available for the product.

B: Substance Carcinogenicity

None of the substances in this preparation are listed by IARC, Austria, Belgium, Denmark, France, Germany, Ireland, Luxembourg, Netherlands, Spain, or United Kingdom.

*** Section 12 - Ecological Information ***

Ecotoxicity

A: General Product Information

No information available for the product.

B: Substance Analysis - Ecotoxicity - Aquatic Toxicity

Sodium azide (247-852-1)

Test & Species

| | Conditions |
|--------------------------------------|--------------------------|
| 96 Hr LC50 Oncorhynchus mykiss | 0.8 mg/L |
| 96 Hr LC50 Lepomis macrochirus | 0.7 mg/L |
| 96 Hr LC50 Pimephales promelas | 5.46 mg/L [flow-through] |

Mobility

No information available for the product.

Persistence & Degradation

No information available for the product.

Bioaccumulation

No information available for the product.

Other Adverse Effects

No information available for the product.

*** Section 13 - Disposal Considerations ***

Waste Disposal Instructions

Must not be disposed together with household garbage. Do not allow product to reach sewage system. Disposal must be made according to official regulations.

*** Section 14 - Transportation Information ***

IATA Information

Shipping Name: Not Regulated

ICAO Information

Shipping Name: Not Regulated

IMDG Information

Shipping Name: Not Regulated

ADR Information

Shipping Name: Not Regulated

*** Section 15 - Regulatory Information ***

EU MARKING AND LABELLING:

Symbol(s):

Xn

Risk Phrases:

R22 Harmful if swallowed.

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R32 Contact with acids liberates very toxic gas.

Safety Phrases:

A: General Product Information

S25 Avoid contact with eyes.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

B: Substance Analysis - Inventory

| Component/CAS | EC # | EEC | CAN | TSCA |
|----------------------------|-----------|--------|-----|------|
| Sodium azide 26628-22-8 | 247-852-1 | EINECS | DSL | Yes |

*** Section 16 - Other Information ***

Key/Legend

NA - Not Applicable

ND - Not Determined

ACGIH - American Conference of Governmental Industrial Hygienists

OSHA - Occupational Safety and Health Administration

TLV - Threshold Limit Value

PEL - Permissible Exposure Limit

TWA - Time Weighted Average

STEL - Short Term Exposure Limit

NTP - National Toxicology Program

IARC - International Agency for Research on Cancer