03/02/2011	Kit Components	
Product code	Description	
255460	Directigen Group B Strep Test Kit	
Components:		
255460aa	Reagent 1, Group B Strep Antibody (w/ sodum azide)	
255460b	Positive Control	
255460c	Negative Control	
255460dd	Reagent A, Control Latex (w/ sodium azide)	

The preservative used for this product recently has changed. Two MSDSs are being provided, one for the discontinued formulation, containing thimerosal and the other is for the new formulation, containing sodium azide. You can identify the different products by the presence or absence on the outer package and package insert of a mercury warning associated with thimerosal.

0.2%



Material Safety Data Sheet acc. to ISO/DIS 11014

Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

1 Identification of the substance/mixture and of the company/undertaking

- · Product Identifier
- Product Name: Reagent 1, Group B Strep Antibody (w/ sodium azide) (Directigen Group B Strep Test Kit)
- · Catalog Number: 255460

· Details of the supplier of the safety data sheet

- *Manufacturer/Supplier:* BD Diagnostic Systems
- 7 Loveton Circle Sparks, MD 21152 Telephone.: (410) 771 - 0100 or (800) 638 – 8663
- Emergency telephone number:
- In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostic Systems (410) 771-0100 or (800)-638-8663, or ChemTrec at (800) 424-9300.

2 Composition/information on ingredients

· Chemical characterization: Mixture

- · Description: Mixture consisting of the following components.
- · Dangerous Components:
- 26628-22-8 *sodium azide*

3 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC

【 Xn; Harmful

R22: Harmful if swallowed.

· Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· Label elements

• Labelling according to EU guidelines:

The product has been classified and marked in accordance with regulations on hazardous materials.

- Code letter and hazard designation of product: Xn Harmful
- *Hazard-determining components of labelling:* sodium azide
- **Risk phrases:** 22 Harmful if swallowed.
- · Safety phrases:
- 23 Do not breathe gas/fumes/vapour/spray.36 Wear suitable protective clothing.
- · NFPA ratings (scale 0-4)



= 0

(Contd. on page 2)

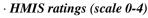


Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

Product Name: Reagent 1, Group B Strep Antibody (w/ sodium azide) (Directigen Group B Strep Test Kit)

(Contd. of page 1)





Health = 2Fire = 0

4 First aid measures

Symptoms of poisoning may even occur after several hours; therefore provide medical observation for at least 48 hours after the accident.

- · After inhalation Supply fresh air; consult doctor in case of complaints.
- After skin contact Immediately wash with water and soap and rinse thoroughly.
- After eye contact Rinse opened eye for 15 minutes under running water. Then consult a doctor.
- · After swallowing Immediately call a doctor.
- · Information for doctor Show this product label or this MSDS.

5 Firefighting measures

· Suitable extinguishing agents

CO2, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.

• Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Wipe up with damp sponge or mop.

· Methods and material for containment and cleaning up: Dispose contaminated material as waste according to item 13. Ensure adequate ventilation.

- · Reference to other sections
- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

7 Handling and storage

- · Handling
- · Precautions for safe handling Prevent formation of dust.
- · Information about protection against explosions and fires: No special measures required.
- \cdot Storage
- Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Store away from oxidizing agents.
- Further information about storage conditions: Store in cool, dry conditions in well sealed containers.

(Contd. on page 3)

[·] General information



Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

Product Name: Reagent 1, Group B Strep Antibody (w/ sodium azide) (Directigen Group B Strep Test Kit)

(Contd. of page 2)

8 Exposure controls/personal protection

• Additional information about design of technical systems: No further data; see Section 7.

· Components with limit values that require monitoring at the workplace:

26628-22-8 sodium azide

REL Short-term value: C 0.3** mg/m³, C 0.1* ppm *as HN3 vapor; **as NaN3; Skin

- *TLV* Short-term value: C 0.29** mg/m³, C 0.11* ppm *as HN3 vapor **as NaN3
- Additional information: The lists that were valid during the creation were used as basis.
- · Personal Protective Equipment
- General protective and hygienic measures Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work.

· Breathing equipment:

- In case of brief exposure, use a chemical fume hood or a NIOSH/MSHA-approved respirator.
- Protection of hands:



Chemical resistant gloves (i.e. nitrile, or equivalent).

• Eye protection: Safety glasses

• Body protection: Protective work clothing (lab coat).

9 Physical and chemical properties · General Information · Appearance: Form: Solid. Color: According to product specification · Odor: **Characteristic** · Change in condition Melting point/Melting range: Not determined Boiling point/Boiling range: Not determined · Flash point: Not applicable Product is not self igniting. • Auto igniting: · Danger of explosion: Product does not present an explosion hazard. Not determined · Density: · Solubility in / Miscibility with Water: Insoluble · Solvent content: 0.0 % **Organic** solvents: (Contd. on page 4)

(Contd. of page 3)



Material Safety Data Sheet acc. to ISO/DIS 11014

Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

Product Name: Reagent 1, Group B Strep Antibody (w/ sodium azide) (Directigen Group B Strep Test Kit)

Solids content:

100.0 %

10 Stability and reactivity

- *Thermal decomposition / conditions to be avoided:* No decomposition if used according to specifications. • *Incompatible materials:*
- Incompatible materials: acidic material and metals

Incompatible material: strong oxidizers.

- · Hazardous decomposition products: No dangerous decomposition products known.
- Additional information:

Sodium azide is present in this product. Contact with acidic solutions and metal compounds over time may form potentially explosive metal azides. Should any of this material be introduced into a sanitary sewer system, flush with copious amounts of water.

11 Toxicological information

• Acute toxicity:

· LD/LC50 values that are relevant for classification:

26628-22-8 sodium azide

Oral LD50 27 mg/kg (rat)

- · Primary irritant effect:
- on the skin: No irritating effect.
- on the eye: No irritating effect.
- Sensitization: No sensitizing effects known.
- Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations: Harmful

12 Ecological information

- · Acquatic toxicity: No further relevant information available.
- · Ecotoxical effects:
- Other information:
- The ecological effects have not been thoroughly investigated, but currently none have been identified.
- · Additional ecological information:
- · General notes: Water hazard class 1 (Self-assessment): slightly hazardous for water.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation
- Must not be disposed of with solid waste.

Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements.

(Contd. on page 5)

USA



Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

Product Name: Reagent 1, Group B Strep Antibody (w/ sodium azide) (Directigen Group B Strep Test Kit)

(Contd. of page 4)

- · Uncleaned packagings:
- Recommendation: Disposal must be made according to state and federal regulations.
- Recommended cleansing agent: Water, if necessary with cleansing agents.

14 Transport information

- · DOT regulations:
- · Hazard class:
- · Land transport ADR/RID (cross-border)
- · ADR/RID class:
- Maritime transport IMDG:
- · IMDG Class:
- Marine pollutant: No
- Air transport ICAO-TI and IATA-DGR:
- · ICAO/IATA Class: -
- · Transport/Additional information:

If a dashed line appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.

15 Regulatory information

· SARA Section 355 (extremely hazardous substances)

26628-22-8 sodium azide

· SARA Section 313 (specific toxic chemical listings)

26628-22-8 sodium azide

· TSCA (Toxic Substances Control Act)

26628-22-8 *sodium azide*

· California Proposition 65 - Chemicals known to cause cancer

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· NTP (National Toxicology Program)

None of the ingredients is listed.

(Contd. on page 6)



Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

Product Name: Reagent 1, Group B Strep Antibody (w/ sodium azide) (Directigen Group B Strep Test Kit)

(Contd. of page 5)

A4

· TLV (Threshold Limit Value established by ACGIH)

26628-22-8 sodium azide

16 Other information

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities 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 can not guarantee that these are the only hazards that exist.

· Department issuing MSDS:

Environmental, Health & Safety Created by Michael J. Spinazzola • Contact: Technical Service Representative

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Material Safety Data Sheet acc. to ISO/DIS 11014

Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

1 Identification of the substance/mixture and of the company/undertaking

- · Product Identifier
- Product Name: <u>Positive Control</u> (Directigen Group B Strep Test Kit)
 Catalog Number: 255460
- Details of the supplier of the safety data sheet
 Manufacturer/Supplier: BD Diagnostic Systems
 7 Loveton Circle
 Sparks, MD 21152
- Telephone.: (410) 771 0100 or (800) 638 8663
- Emergency telephone number:
- In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostic Systems (410) 771-0100 or (800)-638-8663, or ChemTrec at (800) 424-9300.

2 Composition/information on ingredients

· Chemical characterization: Mixture

- · Description: Mixture consisting of the following components.
- · Dangerous Components:
- 26628-22-8 *sodium azide*

3 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC

【 Xn; Harmful

R22: Harmful if swallowed.

· Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· Label elements

· Labelling according to EU guidelines:

The product has been classified and marked in accordance with regulations on hazardous materials.

- Code letter and hazard designation of product: Xn Harmful
- *Hazard-determining components of labelling:* sodium azide

• *Risk phrases:* 22 Harmful if swallowed.

- · Safety phrases:
- 23 Do not breathe gas/fumes/vapour/spray.36 Wear suitable protective clothing.
- · NFPA ratings (scale 0-4)



(Contd. on page 2)

USA

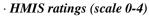


Date Prepared: 03/02/2011

Reviewed On: 02/11/2011



(Contd. of page 1)





Health = 2Fire = 0

4 First aid measures

· General information

Symptoms of poisoning may even occur after several hours; therefore provide medical observation for at least 48 hours after the accident.

Material Safety Data Sheet acc. to ISO/DIS 11014

- · After inhalation Supply fresh air; consult doctor in case of complaints.
- After skin contact Immediately wash with water and soap and rinse thoroughly.
- After eye contact Rinse opened eye for 15 minutes under running water. Then consult a doctor.
- · After swallowing Immediately call a doctor.
- · Information for doctor Show this product label or this MSDS.

5 Firefighting measures

· Suitable extinguishing agents

CO2, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · Special hazards arising from the substance or mixture During heating or in case of fire toxic gases may be produced.
- Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Wipe up with damp sponge or mop.
- Methods and material for containment and cleaning up: No special measures required.
- · Reference to other sections
- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

7 Handling and storage

- · Handling
- · Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
- Information about protection against explosions and fires: No special measures required.
- \cdot Storage
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility:

Do not store together with oxidizing and acidic materials as well as heavy-metal compounds.

(Contd. on page 3)



Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

Product Name: Positive Control (Directigen Group B Strep Test Kit)

(Contd. of page 2)

· Further information about storage conditions: None.

8 Exposure controls/personal protection

• Additional information about design of technical systems: No further data; see Section 7.

· Components with limit values that require monitoring at the workplace:

26628-22-8 sodium azide

- REL Short-term value: C 0.3** mg/m³, C 0.1* ppm *as HN3 vapor; **as NaN3
- *TLV Short-term value: C 0.29** mg/m³, C 0.11* ppm *as HN3 vapor; **as NaN3*
- · Additional information: The lists that were valid during the creation were used as basis.
- · Personal Protective Equipment
- General protective and hygienic measures Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work.
- Breathing equipment:
- In case of brief exposure, use a chemical fume hood or a NIOSH/MSHA-approved respirator.
- · Protection of hands:



Chemical resistant gloves (i.e. nitrile, or equivalent).

- Eye protection: Safety glasses
- · Body protection: Protective work clothing (lab coat).

• General Information		
Appearance:		
Form:	Liquid	
Color:	Clear	
· Odor:	Characteristic	
· Change in condition		
Melting point/Melting range:	Not determined	
Boiling point/Boiling range:	Not determined	
· Flash point:	Not applicable	
• Danger of explosion:	Forms very sensitive explosive metallic compounds.	
· Density:	Not determined	
· Solubility in / Miscibility with		
Water:	Soluble	



Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

Product Name: Positive Control (Directigen Group B Strep Test Kit)

(Contd. of page 3)

· Solvent content:

Organic solvents:

10 Stability and reactivity

• *Thermal decomposition / conditions to be avoided:* No decomposition if used according to specifications. • *Incompatible materials:*

Incompatible material: strong oxidizers.

Incompatible materials: acidic material and metals

· Hazardous decomposition products: Nitrogen oxides (NOx)

0.0 %

• Additional information:

Sodium azide is present in this product. Contact with acidic solutions and metal compounds over time may form potentially explosive metal azides. Should any of this material be introduced into a sanitary sewer system, flush with copious amounts of water.

11 Toxicological information

• Acute toxicity:

· LD/LC50 values that are relevant for classification:

26628-22-8 sodium azide

Oral LD50 27 mg/kg (rat)

- · Primary irritant effect:
- on the skin: No irritating effect.
- on the eye: No irritating effect.
- Sensitization: No sensitizing effects known.
- Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations: Harmful

12 Ecological information

- · Acquatic toxicity: No further relevant information available.
- · Ecotoxical effects:
- Other information:

The ecological effects have not been thoroughly investigated, but currently none have been identified.

- · Additional ecological information:
- · General notes: Water hazard class 1 (Self-assessment): slightly hazardous for water.

13 Disposal considerations

- Waste treatment methods
- · Recommendation
- Smaller quantities can be disposed of with solid waste.
- This product is not considered a RCRA hazardous waste.

Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements.

(Contd. on page 5)



Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

Product Name: Positive Control (Directigen Group B Strep Test Kit)

(Contd. of page 4)

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to state and federal regulations.
- Recommended cleansing agent: Water, if necessary with cleansing agents.

14 Transport information

- · DOT regulations:
- · Hazard class:
- · Land transport ADR/RID (cross-border)
- · ADR/RID class:
- Maritime transport IMDG:
- · IMDG Class:
- Marine pollutant: No
- Air transport ICAO-TI and IATA-DGR:
- · ICAO/IATA Class: -
- Transport/Additional information:

If a dashed line appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.

15 Regulatory information

· SARA Section 355 (extremely hazardous substances)

26628-22-8 sodium azide

· SARA Section 313 (specific toxic chemical listings)

26628-22-8 sodium azide

· TSCA (Toxic Substances Control Act)

26628-22-8 *sodium azide*

· California Proposition 65 - Chemicals known to cause cancer

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· NTP (National Toxicology Program)

None of the ingredients is listed.

(Contd. on page 6)



Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

Product Name: Positive Control (Directigen Group B Strep Test Kit)

(Contd. of page 5)

A4

· TLV (Threshold Limit Value established by ACGIH)

26628-22-8 sodium azide

16 Other information

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities 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 can not guarantee that these are the only hazards that exist.

• Department issuing MSDS:

Environmental, Health & Safety Created by Michael J. Spinazzola • Contact: Technical Service Representative

0.2%



Material Safety Data Sheet acc. to ISO/DIS 11014

Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

1 Identification of the substance/mixture and of the company/undertaking

- · Product Identifier
- Product Name: <u>Negative Control</u> (Directigen Group B Strep Test Kit)
 Catalog Number: 255460
- Details of the sumplion of the safety day
- Details of the supplier of the safety data sheet
 Manufacturer/Supplier: BD Diagnostic Systems
 7 Loveton Circle
 Sparks, MD 21152
 Telephone.: (410) 771 - 0100 or (800) 638 – 8663
- Emergency telephone number:
- In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostic Systems (410) 771-0100 or (800)-638-8663, or ChemTrec at (800) 424-9300.

2 Composition/information on ingredients

· Chemical characterization: Mixture

- · Description: Mixture consisting of the following components.
- · Dangerous Components:
- 26628-22-8 *sodium azide*

3 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC

【 Xn; Harmful

R22: Harmful if swallowed.

· Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· Label elements

• Labelling according to EU guidelines:

The product has been classified and marked in accordance with regulations on hazardous materials.

- Code letter and hazard designation of product: Xn Harmful
- *Hazard-determining components of labelling:* sodium azide

• **Risk phrases:** 22 Harmful if swallowed.

- · Safety phrases:
- 23 Do not breathe gas/fumes/vapour/spray.36 Wear suitable protective clothing.
- · NFPA ratings (scale 0-4)



(Contd. on page 2)



Date Prepared: 03/02/2011

Reviewed On: 02/11/2011



(Contd. of page 1)





Health = 2Fire = 0

4 First aid measures

· General information

Symptoms of poisoning may even occur after several hours; therefore provide medical observation for at least 48 hours after the accident.

Material Safety Data Sheet acc. to ISO/DIS 11014

- After inhalation Supply fresh air; consult doctor in case of complaints.
- After skin contact Immediately wash with water and soap and rinse thoroughly.
- After eye contact Rinse opened eye for 15 minutes under running water. Then consult a doctor.
- · After swallowing Immediately call a doctor.
- · Information for doctor Show this product label or this MSDS.

5 Firefighting measures

· Suitable extinguishing agents

CO2, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · Special hazards arising from the substance or mixture During heating or in case of fire toxic gases may be produced.
- Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Wipe up with damp sponge or mop.
- Methods and material for containment and cleaning up: No special measures required.
- · Reference to other sections
- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

7 Handling and storage

- · Handling
- · Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
- Information about protection against explosions and fires: No special measures required.
- \cdot Storage
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility:

Do not store together with oxidizing and acidic materials as well as heavy-metal compounds.

(Contd. on page 3)



Date Prepared: 03/02/2011

Product Name: Negative Control (Directigen Group B Strep Test Kit)

(Contd. of page 2)

• Further information about storage conditions: Store in cool, dry conditions in well sealed containers.

8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see Section 7.

 \cdot Components with limit values that require monitoring at the workplace:

26628-22-8 sodium azide

REL Short-term value: C 0.3** mg/m³, C 0.1* ppm *as HN3 vapor; **as NaN3

- *TLV Short-term value: C 0.29** mg/m³, C 0.11* ppm *as HN3 vapor; **as NaN3*
- Additional information: The lists that were valid during the creation were used as basis.
- · Personal Protective Equipment
- General protective and hygienic measures Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work.
- · Breathing equipment: Not required.
- Protection of hands:



Chemical resistant gloves (i.e. nitrile, or equivalent).

- · Eye protection: Safety glasses
- · Body protection: Protective work clothing (lab coat).

9 Physical and chemical properties

· General Information		
· Appearance:		
Form:	Liquid	
Color:	Clear	
· Odor:	Characteristic	
• Change in condition Melting point/Melting range:	Not determined	
Boiling point/Boiling range:		
· Flash point:	Not applicable	
• Auto igniting:	Product is not self igniting.	
• Danger of explosion:	Forms very sensitive explosive metallic compounds.	
· Density:	Not determined	
· Solubility in / Miscibility with		
Water:	Soluble	
		(Contd. on page 4)

JSA –



Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

Product Name: Negative Control (Directigen Group B Strep Test Kit)

(Contd. of page 3)

· Solvent content:

Organic solvents:

10 Stability and reactivity

• *Thermal decomposition / conditions to be avoided:* No decomposition if used according to specifications. • *Incompatible materials:*

Incompatible material: strong oxidizers.

Incompatible materials: acidic material and metals

· Hazardous decomposition products: Nitrogen oxides (NOx)

0.0 %

• Additional information:

Sodium azide is present in this product. Contact with acidic solutions and metal compounds over time may form potentially explosive metal azides. Should any of this material be introduced into a sanitary sewer system, flush with copious amounts of water.

11 Toxicological information

• Acute toxicity:

· LD/LC50 values that are relevant for classification:

26628-22-8 sodium azide

Oral LD50 27 mg/kg (rat)

- · Primary irritant effect:
- on the skin: No irritating effect.
- on the eye: No irritating effect.
- Sensitization: No sensitizing effects known.
- Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations: Harmful

12 Ecological information

- · Acquatic toxicity: No further relevant information available.
- · Ecotoxical effects:
- Other information:

The ecological effects have not been thoroughly investigated, but currently none have been identified.

- · Additional ecological information:
- · General notes: Water hazard class 1 (Self-assessment): slightly hazardous for water.

13 Disposal considerations

- Waste treatment methods
- · Recommendation

Smaller quantities can be disposed of with solid waste.

This product is not considered a RCRA hazardous waste.

Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements.

(Contd. on page 5)

USA



Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

Product Name: Negative Control (Directigen Group B Strep Test Kit)

(Contd. of page 4)

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to state and federal regulations.
- Recommended cleansing agent: Water, if necessary with cleansing agents.

14 Transport information

- · DOT regulations:
- · Hazard class:
- · Land transport ADR/RID (cross-border)
- · ADR/RID class:
- Maritime transport IMDG:
- · IMDG Class:
- Marine pollutant: No
- Air transport ICAO-TI and IATA-DGR:
- · ICAO/IATA Class: -
- · Transport/Additional information:

If a dashed line appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.

15 Regulatory information

· SARA Section 355 (extremely hazardous substances)

26628-22-8 sodium azide

· SARA Section 313 (specific toxic chemical listings)

26628-22-8 sodium azide

· TSCA (Toxic Substances Control Act)

26628-22-8 *sodium azide*

· California Proposition 65 - Chemicals known to cause cancer

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· NTP (National Toxicology Program)

None of the ingredients is listed.

(Contd. on page 6)



Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

Product Name: Negative Control (Directigen Group B Strep Test Kit)

(Contd. of page 5)

A4

· TLV (Threshold Limit Value established by ACGIH)

26628-22-8 sodium azide

16 Other information

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities 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 can not guarantee that these are the only hazards that exist.

• Department issuing MSDS:

Environmental, Health & Safety Created by Michael J. Spinazzola • Contact: Technical Service Representative

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Material Safety Data Sheet acc. to ISO/DIS 11014

Date Prepared: 03/02/2011

Reviewed On: 02/11/2011

1 Identification of the substance/mixture and of the company/undertaking

- · Product Identifier
- Product Name: <u>Reagent A, Control Latex</u> (Directigen Group B Strep Test Kit)
- Catalog Number: 255460

· Details of the supplier of the safety data sheet

- *Manufacturer/Supplier:* BD Diagnostic Systems 7 Loveton Circle Sparks, MD 21152 Telephone.: (410) 771 - 0100 or (800) 638 – 8663
- Emergency telephone number:
- In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostic Systems (410) 771-0100 or (800)-638-8663, or ChemTrec at (800) 424-9300.

2 Composition/information on ingredients

· Chemical characterization: Mixture

- · Description: Mixture consisting of the following components.
- · Dangerous Components:
- 26628-22-8 *sodium azide*

3 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC

【 Xn; Harmful

R22: Harmful if swallowed.

· Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· Label elements

· Labelling according to EU guidelines:

The product has been classified and marked in accordance with regulations on hazardous materials.

- Code letter and hazard designation of product: Xn Harmful
- *Hazard-determining components of labelling:* sodium azide
- **Risk phrases:** 22 Harmful if swallowed.
- Safety phrases: 23 Do not breathe gas/fumes/vapour/spray.
- 36 Wear suitable protective clothing.
- · NFPA ratings (scale 0-4)



(Contd. on page 2)

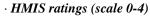


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HEALTH2Health = 2FIRE0Fire = 0REACTIVITY0Reactivity = 0

4 First aid measures

Symptoms of poisoning may even occur after several hours; therefore provide medical observation for at least 48 hours after the accident.

Material Safety Data Sheet acc. to ISO/DIS 11014

- · After inhalation Supply fresh air; consult doctor in case of complaints.
- · After skin contact Immediately wash with water and soap and rinse thoroughly.
- After eye contact Rinse opened eye for 15 minutes under running water. Then consult a doctor.
- · After swallowing Immediately call a doctor.
- Information for doctor Show this product label or this MSDS.

5 Firefighting measures

· Suitable extinguishing agents

CO2, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.

• Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Wipe up with damp sponge or mop.

• *Methods and material for containment and cleaning up:* Dispose contaminated material as waste according to item 13. Ensure adequate ventilation.

- · Reference to other sections
- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

7 Handling and storage

· Handling

· Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

- Prevent formation of dust.
- · Information about protection against explosions and fires: No special measures required.

· Storage

- · Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Store away from oxidizing agents.

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[·] General information

USA



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• Further information about storage conditions: Store in cool, dry conditions in well sealed containers.

8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see Section 7.

• Components with limit values that require monitoring at the workplace:

26628-22-8 sodium azide

- REL
 Short-term value: C 0.3** mg/m³, C 0.1* ppm

 *as HN3 vapor; **as NaN3; Skin
- *TLV Short-term value: C 0.29** mg/m³, C 0.11* ppm *as HN3 vapor **as NaN3*

· Additional information: The lists that were valid during the creation were used as basis.

· Personal Protective Equipment

- General protective and hygienic measures Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work.
- Breathing equipment:
- In case of brief exposure, use a chemical fume hood or a NIOSH/MSHA-approved respirator.
- · Protection of hands:



Chemical resistant gloves (i.e. nitrile, or equivalent).

• Eye protection: Safety glasses

· Body protection: Protective work clothing (lab coat).

General Information	
Appearance:	
Form:	Solid.
Color:	According to product specification
Odor:	Characteristic
Change in condition Melting point/Melting range: Boiling point/Boiling range:	
Flash point:	Not applicable
Auto igniting:	Product is not self igniting.
Danger of explosion:	Product does not present an explosion hazard.
Density:	Not determined

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10 Stability and reactivity

- *Thermal decomposition / conditions to be avoided:* No decomposition if used according to specifications. • *Incompatible materials:*
- Incompatible materials: acidic material and metals
- Incompatible material: strong oxidizers.
- · Hazardous decomposition products: No dangerous decomposition products known.
- Additional information:

Sodium azide is present in this product. Contact with acidic solutions and metal compounds over time may form potentially explosive metal azides. Should any of this material be introduced into a sanitary sewer system, flush with copious amounts of water.

11 Toxicological information

• Acute toxicity:

· LD/LC50 values that are relevant for classification:

26628-22-8 sodium azide

Oral LD50 27 mg/kg (rat)

- · Primary irritant effect:
- on the skin: No irritating effect.
- on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations: Harmful

12 Ecological information

- · Acquatic toxicity: No further relevant information available.
- · Ecotoxical effects:
- Other information:

The ecological effects have not been thoroughly investigated, but currently none have been identified.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Smaller quantities can be disposed of with solid waste. This product is not considered a RCRA hazardous waste. Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements.

- · Uncleaned packagings:
- *Recommendation:* Disposal must be made according to state and federal regulations.
- Recommended cleansing agent: Water, if necessary with cleansing agents.

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14 Transport information

· DOT regulations:

- · Hazard class:
- · Land transport ADR/RID (cross-border)
- · ADR/RID class:
- Maritime transport IMDG:
- · IMDG Class:
- Marine pollutant: No
- Air transport ICAO-TI and IATA-DGR:
- · ICAO/IATA Class: -

· Transport/Additional information:

If a dashed line appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.

15 Regulatory information

· SARA Section 355 (extremely hazardous substances)

- 26628-22-8 sodium azide
- · SARA Section 313 (specific toxic chemical listings)

26628-22-8 sodium azide

· TSCA (Toxic Substances Control Act)

26628-22-8 sodium azide

· California Proposition 65 - Chemicals known to cause cancer

None of the ingredients is listed.

 \cdot California Proposition 65 - Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· NTP (National Toxicology Program)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

26628-22-8 sodium azide

16 Other information

(Contd. on page 6)

A4

USA



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 Department issuing MSDS: Environmental, Health & Safety Created by Michael J. Spinazzola
 Contact: Technical Service Representative