

Kit SDS Cover SheetDoc. ID: 378045-75: Rev. AE
Revised (year/month/day) 2013/04/22

Product Information

Product Name	Vancomycin Calibrator
Part Number	378045
Series Name	SYNCHRON® Systems

Components

Description	Vancomycin Calibrator Level 1 Vancomycin Calibrator Level 2 Vancomycin Calibrator Level 3 Vancomycin Calibrator Level 4 Vancomycin Calibrator Level 5 Vancomycin Calibrator Level 6
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Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.



SAFETY DATA SHEET

Doc. ID: 378045-75 AE

Revised (year/month/day) 2013/04/22

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Vancomycin Calibrator
Level 1

Part Number Component of P/N 378045

Series Name SYNCHRON® Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of supplier of the safety data sheet

Manufacturer	EC REP Address
Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633	Beckman Coulter Ireland Inc. Mervue Business Park Mervue, Galway, Ireland Tel: 353 91 774068
e-mail address	
SDSNT@beckman.com	

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: [472050](#), for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture
Colorless; Clear; Liquid; Odorless

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

US OSHA Not applicable

WHMIS Exempt

2.2 Label Elements

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 2 Hazards Identification (Continued)

2.3 Other Hazard

Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

This product does not meet EU, OSHA or WHMIS criteria for hazardous materials. However, it does contain material of animal origin and should be considered potentially infectious.

Contains material of animal origin.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixture

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

Use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

None identified.

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (a dilute aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

None

Section 6 Accidental Release Measures

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions

This product contains a material of biological origin. Use universal precautions during clean up procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Keep away from incompatible material (see Section 10).

To maintain efficacy, store according to the instructions in the product labeling.

7.3 Specific end uses

No data available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

None established

DFG MAK

None established

Ireland

None established

NIOSH

None established

Japan

None established

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls

No special engineering controls are necessary for normal handling of this product.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (Water=1.0)	1.043 @20°C
Color	Colorless	Solubility	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	5.95 - 6.05	Coefficient of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not applicable
Evaporation Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor Threshold	Not applicable		

9.2 Other Information None

Section 10 Stability and Reactivity

- 10.1 Reactivity None
- 10.2 Chemical Stability Stable under normal temperatures and pressures.
- 10.3 Possibility of hazardous reactions None

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 10 Stability and Reactivity (Continued)

- 10.4 Conditions to Avoid** Avoid contact with incompatible materials.
- 10.5 Incompatible materials** Strong acids
Strong bases
Strong oxidizers
Metals and metallic compounds
Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
- 10.6 Hazardous Decomposition Products** No decomposition products posing significant hazards would be expected from this product (a dilute aqueous solution).

Section 11 Toxicological Information

- 11.1 Information on toxicological effects**
- Toxicity Data for Hazardous Ingredients** Not applicable
- Primary Routes of Exposure** Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
- Carcinogenicity** No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
- Potential Effects of Acute Exposure** This product contains materials of animal origin and should be considered potentially infectious. No other health hazards were identified from a review of available literature.
- Potential Effects of Chronic Exposure** Effects are similar to those for acute exposure.
- Symptoms of Overexposure** No specific symptoms identified.
- Conditions Aggravated by Exposure** None identified.
- Other Information** None identified.

Section 12 Ecological Information

- 12.1 Ecotoxicity**
- Fresh Water Species** No information available.
- Microtox** No information available.
- Water Flea** No information available.

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 12 Ecological Information (Continued)

Fresh Water Algae	No information available.
12.2 Persistence and degradability	No information available.
12.3 Bioaccumulation	No information available.
12.4 Mobility in soil	No information available.
12.5 Results of PBT and vPvB assessment	Not applicable
12.6 Other Adverse Effects	None

Section 13 Disposal Considerations

13.1 Waste treatment methods	
Product Waste Disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
13.2 Additional information	None

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	
<u>US Federal and State Regulations</u>	
SARA 313	Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration
CERCLA RG's, 40 CFR 302.4	Sodium Azide is listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	Sodium Azide is listed.
New Jersey Dept. of Health RTK List	Sodium Azide is listed.
Pennsylvania RTK	Sodium Azide is listed.
<u>EU Regulations</u>	
This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.	
REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.	No ingredients listed.
<u>Canada</u>	
This product is exempt from WHMIS label and SDS requirements.	

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 15 Regulatory Information (Continued)

PIN Not applicable
Ingredients on Ingredient Disclosure List
Sodium Azide
Ingredients with unknown toxicological properties
Product is exempt

15.2 Chemical Safety Assessment Not available

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	Flammability: 0 Health: 1 Reactivity with Water: 0 Contact: 1	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Revised per 453/2010 EC and ANSI Z400.1-2004 Standard.	

For further information, please contact your local Beckman Coulter representative.

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SAFETY DATA SHEET

Doc. ID: 378045-75 AE

Revised (year/month/day) 2013/04/22

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Vancomycin Calibrator
Level 2

Part Number Component of P/N 378045

Series Name SYNCHRON® Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Mervue Business Park
Mervue, Galway, Ireland
Tel: 353 91 774068

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: [472050](#), for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture
Colorless; Clear; Liquid; Odorless

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

US OSHA Not applicable

WHMIS Exempt

2.2 Label Elements

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 2 Hazards Identification (Continued)

2.3 Other Hazard

Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

This product does not meet EU, OSHA or WHMIS criteria for hazardous materials. However, it does contain material of animal origin and should be considered potentially infectious.

Contains material of animal origin.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixture

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

Use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

None identified.

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (a dilute aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

None

Section 6 Accidental Release Measures

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions

This product contains a material of biological origin. Use universal precautions during clean up procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Keep away from incompatible material (see Section 10).

To maintain efficacy, store according to the instructions in the product labeling.

7.3 Specific end uses

No data available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

None established

DFG MAK

None established

Ireland

None established

NIOSH

None established

Japan

None established

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls

No special engineering controls are necessary for normal handling of this product.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (Water=1.0)	1.043 @20°C
Color	Colorless	Solubility	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	5.95 - 6.05	Coefficient of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not applicable
Evaporation Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor Threshold	Not applicable		

9.2 Other Information

None

Section 10 Stability and Reactivity

10.1 Reactivity

None

10.2 Chemical Stability

Stable under normal temperatures and pressures.

10.3 Possibility of hazardous reactions

None

Section 10 Stability and Reactivity (Continued)

- 10.4 Conditions to Avoid** Avoid contact with incompatible materials.
- 10.5 Incompatible materials** Strong acids
Strong bases
Strong oxidizers
Metals and metallic compounds
Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
- 10.6 Hazardous Decomposition Products** No decomposition products posing significant hazards would be expected from this product (a dilute aqueous solution).

Section 11 Toxicological Information

- 11.1 Information on toxicological effects**
- Toxicity Data for Hazardous Ingredients** Not applicable
- Primary Routes of Exposure** Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
- Carcinogenicity** No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
- Potential Effects of Acute Exposure** This product contains materials of animal origin and should be considered potentially infectious. No other health hazards were identified from a review of available literature.
- Potential Effects of Chronic Exposure** Effects are similar to those for acute exposure.
- Symptoms of Overexposure** No specific symptoms identified.
- Conditions Aggravated by Exposure** None identified.
- Other Information** None identified.

Section 12 Ecological Information

- 12.1 Ecotoxicity**
- Fresh Water Species** No information available.
- Microtox** No information available.
- Water Flea** No information available.

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 12 Ecological Information (Continued)

Fresh Water Algae	No information available.
12.2 Persistence and degradability	No information available.
12.3 Bioaccumulation	No information available.
12.4 Mobility in soil	No information available.
12.5 Results of PBT and vPvB assessment	Not applicable
12.6 Other Adverse Effects	None

Section 13 Disposal Considerations

13.1 Waste treatment methods	
Product Waste Disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
13.2 Additional information	None

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	
<u>US Federal and State Regulations</u>	
SARA 313	Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration
CERCLA RG's, 40 CFR 302.4	Sodium Azide is listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	Sodium Azide is listed.
New Jersey Dept. of Health RTK List	Sodium Azide is listed.
Pennsylvania RTK	Sodium Azide is listed.
<u>EU Regulations</u>	
This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.	
REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.	No ingredients listed.
<u>Canada</u>	
This product is exempt from WHMIS label and SDS requirements.	

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 15 Regulatory Information (Continued)

PIN Not applicable
Ingredients on Ingredient Disclosure List
Sodium Azide
Ingredients with unknown toxicological properties
Product is exempt

15.2 Chemical Safety Assessment Not available

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	Flammability: 0 Health: 1 Reactivity with Water: 0 Contact: 1	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Revised per 453/2010 EC and ANSI Z400.1-2004 Standard.	

For further information, please contact your local Beckman Coulter representative.

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SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Vancomycin Calibrator
Level 3

Part Number Component of P/N 378045

Series Name SYNCHRON® Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of supplier of the safety data sheet

	Manufacturer	EC REP Address
	Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633	Beckman Coulter Ireland Inc. Mervue Business Park Mervue, Galway, Ireland Tel: 353 91 774068
e-mail address	SDSNT@beckman.com	

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: [472050](#), for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture
Colorless; Clear; Liquid; Odorless

Classification according to EC Directives 1999/45/EC and 67/548/EEC
Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

US OSHA Not applicable

WHMIS Exempt

2.2 Label Elements

According to EC Directives (1999/45/EC and 67/548 EEC)
Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 2 Hazards Identification (Continued)

2.3 Other Hazard

Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

This product does not meet EU, OSHA or WHMIS criteria for hazardous materials. However, it does contain material of animal origin and should be considered potentially infectious.

Contains material of animal origin.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixture

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

Use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

None identified.

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (a dilute aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

None

Section 6 Accidental Release Measures

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions

This product contains a material of biological origin. Use universal precautions during clean up procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Keep away from incompatible material (see Section 10).

To maintain efficacy, store according to the instructions in the product labeling.

7.3 Specific end uses

No data available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

None established

DFG MAK

None established

Ireland

None established

NIOSH

None established

Japan

None established

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls

No special engineering controls are necessary for normal handling of this product.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (Water=1.0)	1.043 @20°C
Color	Colorless	Solubility	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	5.95 - 6.05	Coefficient of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not applicable
Evaporation Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor Threshold	Not applicable		

9.2 Other Information None

Section 10 Stability and Reactivity

- 10.1 Reactivity None
- 10.2 Chemical Stability Stable under normal temperatures and pressures.
- 10.3 Possibility of hazardous reactions None

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 10 Stability and Reactivity (Continued)

- 10.4 Conditions to Avoid** Avoid contact with incompatible materials.
- 10.5 Incompatible materials** Strong acids
Strong bases
Strong oxidizers
Metals and metallic compounds
Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
- 10.6 Hazardous Decomposition Products** No decomposition products posing significant hazards would be expected from this product (a dilute aqueous solution).

Section 11 Toxicological Information

- 11.1 Information on toxicological effects**
- Toxicity Data for Hazardous Ingredients** Not applicable
- Primary Routes of Exposure** Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
- Carcinogenicity** No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
- Potential Effects of Acute Exposure** This product contains materials of animal origin and should be considered potentially infectious. No other health hazards were identified from a review of available literature.
- Potential Effects of Chronic Exposure** Effects are similar to those for acute exposure.
- Symptoms of Overexposure** No specific symptoms identified.
- Conditions Aggravated by Exposure** None identified.
- Other Information** None identified.

Section 12 Ecological Information

- 12.1 Ecotoxicity**
- Fresh Water Species** No information available.
- Microtox** No information available.
- Water Flea** No information available.

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 12 Ecological Information (Continued)

Fresh Water Algae	No information available.
12.2 Persistence and degradability	No information available.
12.3 Bioaccumulation	No information available.
12.4 Mobility in soil	No information available.
12.5 Results of PBT and vPvB assessment	Not applicable
12.6 Other Adverse Effects	None

Section 13 Disposal Considerations

13.1 Waste treatment methods	
Product Waste Disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
13.2 Additional information	None

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	
<u>US Federal and State Regulations</u>	
SARA 313	Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration
CERCLA RG's, 40 CFR 302.4	Sodium Azide is listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	Sodium Azide is listed.
New Jersey Dept. of Health RTK List	Sodium Azide is listed.
Pennsylvania RTK	Sodium Azide is listed.
<u>EU Regulations</u>	
This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.	
REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.	No ingredients listed.
<u>Canada</u>	
This product is exempt from WHMIS label and SDS requirements.	

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 15 Regulatory Information (Continued)

PIN Not applicable
Ingredients on Ingredient Disclosure List
Sodium Azide
Ingredients with unknown toxicological properties
Product is exempt

15.2 Chemical Safety Assessment Not available

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	Flammability: 0 Health: 1 Reactivity with Water: 0 Contact: 1	Code 0=None 1=Slight 2=Caution 3=Severe
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Revision Changes Revised per 453/2010 EC and ANSI Z400.1-2004 Standard.

For further information, please contact your local Beckman Coulter representative.

WHILE BECKMAN COULTER, INC. BELIEVES THE INFORMATION CONTAINED HEREIN IS VALID AND ACCURATE, BECKMAN COULTER MAKES NO WARRANTY OR REPRESENTATION AS TO ITS VALIDITY, ACCURACY, OR CURRENCY. BECKMAN COULTER SHALL NOT BE LIABLE OR OTHERWISE RESPONSIBLE IN ANY WAY FOR USE OF EITHER THIS INFORMATION OR MATERIALS TO WHICH IT APPLIES. DISPOSAL OF HAZARDOUS MATERIALS MAY BE SUBJECT TO LOCAL LAWS OR REGULATIONS.



SAFETY DATA SHEET

Doc. ID: 378045-75 AE

Revised (year/month/day) 2013/04/22

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Vancomycin Calibrator
Level 4

Part Number Component of P/N 378045

Series Name SYNCHRON® Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

EC REP Address

Beckman Coulter Ireland Inc.
Mervue Business Park
Mervue, Galway, Ireland
Tel: 353 91 774068

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: [472050](#), for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture
Colorless; Clear; Liquid; Odorless

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

US OSHA Not applicable

WHMIS Exempt

2.2 Label Elements

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 2 Hazards Identification (Continued)

2.3 Other Hazard

Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

This product does not meet EU, OSHA or WHMIS criteria for hazardous materials. However, it does contain material of animal origin and should be considered potentially infectious.

Contains material of animal origin.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixture

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

Use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

None identified.

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (a dilute aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

None

Section 6 Accidental Release Measures

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions

This product contains a material of biological origin. Use universal precautions during clean up procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Keep away from incompatible material (see Section 10).

To maintain efficacy, store according to the instructions in the product labeling.

7.3 Specific end uses

No data available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

None established

DFG MAK

None established

Ireland

None established

NIOSH

None established

Japan

None established

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls

No special engineering controls are necessary for normal handling of this product.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (Water=1.0)	1.043 @20°C
Color	Colorless	Solubility	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	5.95 - 6.05	Coefficient of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not applicable
Evaporation Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor Threshold	Not applicable		

9.2 Other Information None

Section 10 Stability and Reactivity

- 10.1 Reactivity None
- 10.2 Chemical Stability Stable under normal temperatures and pressures.
- 10.3 Possibility of hazardous reactions None

Section 10 Stability and Reactivity (Continued)

- 10.4 Conditions to Avoid** Avoid contact with incompatible materials.
- 10.5 Incompatible materials** Strong acids
Strong bases
Strong oxidizers
Metals and metallic compounds
Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
- 10.6 Hazardous Decomposition Products** No decomposition products posing significant hazards would be expected from this product (a dilute aqueous solution).

Section 11 Toxicological Information

- 11.1 Information on toxicological effects**
- Toxicity Data for Hazardous Ingredients** Not applicable
- Primary Routes of Exposure** Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
- Carcinogenicity** No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
- Potential Effects of Acute Exposure** This product contains materials of animal origin and should be considered potentially infectious. No other health hazards were identified from a review of available literature.
- Potential Effects of Chronic Exposure** Effects are similar to those for acute exposure.
- Symptoms of Overexposure** No specific symptoms identified.
- Conditions Aggravated by Exposure** None identified.
- Other Information** None identified.

Section 12 Ecological Information

- 12.1 Ecotoxicity**
- Fresh Water Species** No information available.
- Microtox** No information available.
- Water Flea** No information available.

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 12 Ecological Information (Continued)

Fresh Water Algae	No information available.
12.2 Persistence and degradability	No information available.
12.3 Bioaccumulation	No information available.
12.4 Mobility in soil	No information available.
12.5 Results of PBT and vPvB assessment	Not applicable
12.6 Other Adverse Effects	None

Section 13 Disposal Considerations

13.1 Waste treatment methods	
Product Waste Disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
13.2 Additional information	None

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	
<u>US Federal and State Regulations</u>	
SARA 313	Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration
CERCLA RG's, 40 CFR 302.4	Sodium Azide is listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	Sodium Azide is listed.
New Jersey Dept. of Health RTK List	Sodium Azide is listed.
Pennsylvania RTK	Sodium Azide is listed.
<u>EU Regulations</u>	
This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.	
REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.	No ingredients listed.
<u>Canada</u>	
This product is exempt from WHMIS label and SDS requirements.	

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 15 Regulatory Information (Continued)

PIN Not applicable
Ingredients on Ingredient Disclosure List
Sodium Azide
Ingredients with unknown toxicological properties
Product is exempt

15.2 Chemical Safety Assessment Not available

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	Flammability: 0 Health: 1 Reactivity with Water: 0 Contact: 1	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Revised per 453/2010 EC and ANSI Z400.1-2004 Standard.	

For further information, please contact your local Beckman Coulter representative.

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SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Vancomycin Calibrator
Level 5

Part Number Component of P/N 378045

Series Name SYNCHRON® Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of supplier of the safety data sheet

Manufacturer	EC REP Address
Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633	Beckman Coulter Ireland Inc. Mervue Business Park Mervue, Galway, Ireland Tel: 353 91 774068
e-mail address	
SDSNT@beckman.com	

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: [472050](#), for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Clear; Liquid; Odorless

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

US OSHA Not applicable

WHMIS Exempt

2.2 Label Elements

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 2 Hazards Identification (Continued)

2.3 Other Hazard

Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

This product does not meet EU, OSHA or WHMIS criteria for hazardous materials. However, it does contain material of animal origin and should be considered potentially infectious.

Contains material of animal origin.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixture

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

Use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

None identified.

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (a dilute aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

None

Section 6 Accidental Release Measures

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions

This product contains a material of biological origin. Use universal precautions during clean up procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Keep away from incompatible material (see Section 10).

To maintain efficacy, store according to the instructions in the product labeling.

7.3 Specific end uses

No data available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

None established

DFG MAK

None established

Ireland

None established

NIOSH

None established

Japan

None established

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls

No special engineering controls are necessary for normal handling of this product.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact.
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (Water=1.0)	1.043 @20°C
Color	Colorless	Solubility	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	5.95 - 6.05	Coefficient of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not applicable
Evaporation Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor Threshold	Not applicable		

9.2 Other Information None

Section 10 Stability and Reactivity

- 10.1 Reactivity None
- 10.2 Chemical Stability Stable under normal temperatures and pressures.
- 10.3 Possibility of hazardous reactions
None

Section 10 Stability and Reactivity (Continued)

- 10.4 Conditions to Avoid** Avoid contact with incompatible materials.
- 10.5 Incompatible materials** Strong acids
Strong bases
Strong oxidizers
Metals and metallic compounds
Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
- 10.6 Hazardous Decomposition Products** No decomposition products posing significant hazards would be expected from this product (a dilute aqueous solution).

Section 11 Toxicological Information

- 11.1 Information on toxicological effects**
- Toxicity Data for Hazardous Ingredients** Not applicable
- Primary Routes of Exposure** Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
- Carcinogenicity** No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
- Potential Effects of Acute Exposure** This product contains materials of animal origin and should be considered potentially infectious. No other health hazards were identified from a review of available literature.
- Potential Effects of Chronic Exposure** Effects are similar to those for acute exposure.
- Symptoms of Overexposure** No specific symptoms identified.
- Conditions Aggravated by Exposure** None identified.
- Other Information** None identified.

Section 12 Ecological Information

- 12.1 Ecotoxicity**
- Fresh Water Species** No information available.
- Microtox** No information available.
- Water Flea** No information available.

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 12 Ecological Information (Continued)

Fresh Water Algae	No information available.
12.2 Persistence and degradability	No information available.
12.3 Bioaccumulation	No information available.
12.4 Mobility in soil	No information available.
12.5 Results of PBT and vPvB assessment	Not applicable
12.6 Other Adverse Effects	None

Section 13 Disposal Considerations

13.1 Waste treatment methods	
Product Waste Disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
13.2 Additional information	None

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	
<u>US Federal and State Regulations</u>	
SARA 313	Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration
CERCLA RG's, 40 CFR 302.4	Sodium Azide is listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	Sodium Azide is listed.
New Jersey Dept. of Health RTK List	Sodium Azide is listed.
Pennsylvania RTK	Sodium Azide is listed.
<u>EU Regulations</u>	
This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.	
REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.	No ingredients listed.
<u>Canada</u>	
This product is exempt from WHMIS label and SDS requirements.	

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 15 Regulatory Information (Continued)

PIN Not applicable
Ingredients on Ingredient Disclosure List
Sodium Azide
Ingredients with unknown toxicological properties
Product is exempt

15.2 Chemical Safety Assessment Not available

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	Flammability: 0 Health: 1 Reactivity with Water: 0 Contact: 1	Code 0=None 1=Slight 2=Caution 3=Severe
Revision Changes	Revised per 453/2010 EC and ANSI Z400.1-2004 Standard.	

For further information, please contact your local Beckman Coulter representative.

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SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Vancomycin Calibrator
Level 6

Part Number Component of P/N 378045

Series Name SYNCHRON® Systems

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of supplier of the safety data sheet

	Manufacturer	EC REP Address
	Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633	Beckman Coulter Ireland Inc. Mervue Business Park Mervue, Galway, Ireland Tel: 353 91 774068
e-mail address	SDSNT@beckman.com	

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

Refer to attached list, Document ID: [472050](#), for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture
Colorless; Clear; Liquid; Odorless

Classification according to EC Directives 1999/45/EC and 67/548/EEC
Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

US OSHA Not applicable

WHMIS Exempt

2.2 Label Elements

According to EC Directives (1999/45/EC and 67/548 EEC)
Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 2 Hazards Identification (Continued)

2.3 Other Hazard

Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

This product does not meet EU, OSHA or WHMIS criteria for hazardous materials. However, it does contain material of animal origin and should be considered potentially infectious.

Contains material of animal origin.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixture

Hazardous Ingredients: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion

If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

Use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

None identified.

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product (a dilute aqueous solution).

5.3 Advice for fire fighters

Protective Equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information

None

Section 6 Accidental Release Measures

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions

This product contains a material of biological origin. Use universal precautions during clean up procedures.

6.2 Environmental Precautions

Contain spill to prevent migration.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Keep away from incompatible material (see Section 10).

To maintain efficacy, store according to the instructions in the product labeling.

7.3 Specific end uses

No data available.

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

US OSHA

None established

ACGIH

None established

DFG MAK

None established

Ireland

None established

NIOSH

None established

Japan

None established

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 8 Exposure Controls and Personal Protection (Continued)

8.2 Exposure controls

Engineering Controls

No special engineering controls are necessary for normal handling of this product.

Eye Protection

Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection

Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	Specific Gravity (Water=1.0)	1.043 @20°C
Color	Colorless	Solubility	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	5.95 - 6.05	Coefficient of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not applicable
Evaporation Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammable Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not determined
Odor Threshold	Not applicable		

9.2 Other Information None

Section 10 Stability and Reactivity

- 10.1 Reactivity None
- 10.2 Chemical Stability Stable under normal temperatures and pressures.
- 10.3 Possibility of hazardous reactions None

Section 10 Stability and Reactivity (Continued)

- 10.4 Conditions to Avoid** Avoid contact with incompatible materials.
- 10.5 Incompatible materials** Strong acids
Strong bases
Strong oxidizers
Metals and metallic compounds
Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
- 10.6 Hazardous Decomposition Products**
No decomposition products posing significant hazards would be expected from this product (a dilute aqueous solution).

Section 11 Toxicological Information

- 11.1 Information on toxicological effects**
- Toxicity Data for Hazardous Ingredients**
Not applicable
- Primary Routes of Exposure** Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
- Carcinogenicity** No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
- Potential Effects of Acute Exposure**
This product contains materials of animal origin and should be considered potentially infectious. No other health hazards were identified from a review of available literature.
- Potential Effects of Chronic Exposure**
Effects are similar to those for acute exposure.
- Symptoms of Overexposure** No specific symptoms identified.
- Conditions Aggravated by Exposure**
None identified.
- Other Information** None identified.

Section 12 Ecological Information

- 12.1 Ecotoxicity**
- Fresh Water Species** No information available.
- Microtox** No information available.
- Water Flea** No information available.

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 12 Ecological Information (Continued)

Fresh Water Algae	No information available.
12.2 Persistence and degradability	No information available.
12.3 Bioaccumulation	No information available.
12.4 Mobility in soil	No information available.
12.5 Results of PBT and vPvB assessment	Not applicable
12.6 Other Adverse Effects	None

Section 13 Disposal Considerations

13.1 Waste treatment methods	
Product Waste Disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
13.2 Additional information	None

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	
<u>US Federal and State Regulations</u>	
SARA 313	Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration
CERCLA RG's, 40 CFR 302.4	Sodium Azide is listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	Sodium Azide is listed.
New Jersey Dept. of Health RTK List	Sodium Azide is listed.
Pennsylvania RTK	Sodium Azide is listed.
<u>EU Regulations</u>	
This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.	
REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.	No ingredients listed.
<u>Canada</u>	
This product is exempt from WHMIS label and SDS requirements.	

SAFETY DATA SHEET

Doc. ID: 378045-75 AE
Revised (year/month/day) 2013/04/22

Section 15 Regulatory Information (Continued)

PIN Not applicable
Ingredients on Ingredient Disclosure List
Sodium Azide
Ingredients with unknown toxicological properties
Product is exempt

15.2 Chemical Safety Assessment Not available

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	Flammability: 0 Health: 1 Reactivity with Water: 0 Contact: 1	Code 0=None 1=Slight 2=Caution 3=Severe
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Revision Changes Revised per 453/2010 EC and ANSI Z400.1-2004 Standard.

For further information, please contact your local Beckman Coulter representative.

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