

Kit SDS Cover SheetDoc. ID: 469600-75: Rev. AF
Revised (year/month/day) 2013/04/22

Product Information

Product Name	Drug Calibrator 1
Part Number	469600
Series Name	SYNCHRON® Systems

Components

Description	Drug Calibrator 1 LEVEL 1 Drug Calibrator 1 LEVEL 2 Drug Calibrator 1 LEVEL 3 Drug Calibrator 1 LEVEL 4 Drug Calibrator 1 LEVEL 5 Drug Calibrator 1 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

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

1.1 Product Identifier

Product Name Drug Calibrator 1
LEVEL 1

Part Number Component of P/N 469600

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
Amber; Translucent; Liquid; Musty

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)

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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 human origin and should be considered potentially infectious.

Contains material of human 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 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.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

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 material of human origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed 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

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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)	1.02 @20°C
Color	Amber	Solubility	
Transparency	Translucent	Water	Miscible
Odor	Musty	Organic	Not determined
pH	6.5 - 7.5	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.

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 human 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.

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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.	

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

1.1 Product Identifier

Product Name Drug Calibrator 1
LEVEL 2

Part Number Component of P/N 469600

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
Amber; Translucent; Liquid; Musty

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)

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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 human origin and should be considered potentially infectious.

Contains material of human 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 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.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

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 material of human origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed 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

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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)	1.02 @20°C
Color	Amber	Solubility	
Transparency	Translucent	Water	Miscible
Odor	Musty	Organic	Not determined
pH	6.5 - 7.5	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.

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** This product does not contain a reportable concentration ($\geq 0.1\%$) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
- Potential Effects of Acute Exposure** This product contains materials of human 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.

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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	Phenytoin (PHY) is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration N,N-Dimethylformamide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration 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	N,N-Dimethylformamide is listed. Potassium Hydroxide is listed. Sodium Hydroxide is listed. Sodium Azide is listed.

Section 15 Regulatory Information (Continued)

California Proposition 65

Phenobarbital has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause cancer.

Phenytoin (PHY) has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Ethyl Alcohol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Valproic Acid has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Carbamazepine has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Phenobarbital is listed.

Phenytoin (PHY) is listed.

Ethyl Alcohol is listed.

N,N-Dimethylformamide is listed.

Valproic Acid is listed.

Potassium Hydroxide is listed.

Sodium Hydroxide is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Phenytoin (PHY) is listed.
Ethyl Alcohol is listed.
N,N-Dimethylformamide is listed.
Potassium Hydroxide is listed.
Sodium Hydroxide is listed.
Sodium Azide is listed.

Pennsylvania RTK

Phenytoin (PHY) is listed.
Ethyl Alcohol is listed.
N,N-Dimethylformamide is listed.
Potassium Hydroxide is listed.
Sodium Hydroxide is listed.
Sodium Azide is listed.

EU Regulations

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.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Ethyl Alcohol
N,N-Dimethylformamide
Potassium Hydroxide
Sodium Hydroxide
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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Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Drug Calibrator 1
LEVEL 3

Part Number Component of P/N 469600

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
Amber; Translucent; Liquid; Musty

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)

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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 human origin and should be considered potentially infectious.

Contains material of human 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 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.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

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 material of human origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed 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

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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)	1.02 @20°C
Color	Amber	Solubility	
Transparency	Translucent	Water	Miscible
Odor	Musty	Organic	Not determined
pH	6.5 - 7.5	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.

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** This product does not contain a reportable concentration ($\geq 0.1\%$) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
- Potential Effects of Acute Exposure** This product contains materials of human 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.

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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	Phenytoin (PHY) is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration N,N-Dimethylformamide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration 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	N,N-Dimethylformamide is listed. Potassium Hydroxide is listed. Sodium Hydroxide is listed. Sodium Azide is listed.

Section 15 Regulatory Information (Continued)

California Proposition 65

Phenobarbital has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause cancer.

Phenytoin (PHY) has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Ethyl Alcohol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Valproic Acid has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Carbamazepine has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Phenobarbital is listed.

Phenytoin (PHY) is listed.

Ethyl Alcohol is listed.

N,N-Dimethylformamide is listed.

Valproic Acid is listed.

Potassium Hydroxide is listed.

Sodium Hydroxide is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Phenytoin (PHY) is listed.
Ethyl Alcohol is listed.
N,N-Dimethylformamide is listed.
Potassium Hydroxide is listed.
Sodium Hydroxide is listed.
Sodium Azide is listed.

Pennsylvania RTK

Phenytoin (PHY) is listed.
Ethyl Alcohol is listed.
N,N-Dimethylformamide is listed.
Potassium Hydroxide is listed.
Sodium Hydroxide is listed.
Sodium Azide is listed.

EU Regulations

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.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Ethyl Alcohol
N,N-Dimethylformamide
Potassium Hydroxide
Sodium Hydroxide
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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SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name Drug Calibrator 1
LEVEL 4

Part Number Component of P/N 469600

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
Amber; Translucent; Liquid; Musty

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)

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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 human origin and should be considered potentially infectious.

Contains material of human 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 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.

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Section 5 Fire Fighting Measures (Continued)

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this product.

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 material of human origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed 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

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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)	1.02 @20°C
Color	Amber	Solubility	
Transparency	Translucent	Water	Miscible
Odor	Musty	Organic	Not determined
pH	6.5 - 7.5	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.

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** This product does not contain a reportable concentration ($\geq 0.1\%$) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
- Potential Effects of Acute Exposure** This product contains materials of human 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

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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	Phenytoin (PHY) is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration N,N-Dimethylformamide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration 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	N,N-Dimethylformamide is listed. Potassium Hydroxide is listed. Sodium Hydroxide is listed. Sodium Azide is listed.

Section 15 Regulatory Information (Continued)

California Proposition 65

Phenobarbital has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause cancer.

Phenytoin (PHY) has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Ethyl Alcohol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Valproic Acid has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Carbamazepine has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Phenobarbital is listed.

Phenytoin (PHY) is listed.

Ethyl Alcohol is listed.

N,N-Dimethylformamide is listed.

Valproic Acid is listed.

Potassium Hydroxide is listed.

Sodium Hydroxide is listed.

Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Phenytoin (PHY) is listed.
Ethyl Alcohol is listed.
N,N-Dimethylformamide is listed.
Potassium Hydroxide is listed.
Sodium Hydroxide is listed.
Sodium Azide is listed.

Pennsylvania RTK

Phenytoin (PHY) is listed.
Ethyl Alcohol is listed.
N,N-Dimethylformamide is listed.
Potassium Hydroxide is listed.
Sodium Hydroxide is listed.
Sodium Azide is listed.

EU Regulations

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.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Ethyl Alcohol
N,N-Dimethylformamide
Potassium Hydroxide
Sodium Hydroxide
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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SAFETY DATA SHEET

Doc. ID: 469600-75 AF

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 Drug Calibrator 1
LEVEL 5

Part Number Component of P/N 469600

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
Amber; Translucent; Liquid; Musty

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)

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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 human origin and should be considered potentially infectious.

Contains material of human origin.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixture

Hazardous Ingredients:		Hazard Classification of Pure Ingredients				
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	US OSHA	WHMIS	
N,N-Dimethylformamide CAS # 68-12-2 EINECS # 200-679-5 Index # 616-001-00-X	< 0.2	T;R61-20/21-36 Repr. Cat. 2	Acute Tox. Dermal 4 Acute Tox. Inhal. 4 Eye Irrit. 2 Flam. Liq. 3 Repr. 1B H226; H312; H319; H332; H360	Combustible Liquid Irritant	B2; D2A; D2B	8, SVHC

8 - Present at concentration below the cut-off limits.
SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

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.

SAFETY DATA SHEET

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Section 5 Fire Fighting Measures

Flammable Properties	Nonflammable 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.
Hazardous Combustion Products	
	No combustion products posing significant hazards are expected from this product.
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 material of human origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed 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

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Section 8 Exposure Controls and Personal Protection (Continued)

US OSHA

N,N-Dimethylformamide
CAS # 68-12-2 10 ppm TWA; 30 mg/m3 TWA; prevent or reduce skin absorption

ACGIH

N,N-Dimethylformamide
CAS # 68-12-2 10 ppm TWA; Skin - potential significant contribution to overall exposure by the cutaneous route

DFG MAK

N,N-Dimethylformamide
CAS # 68-12-2 10 ppm Peak; 30 mg/m3 Peak; skin notation; 5 ppm TWA MAK; 15 mg/m3 TWA MAK

Ireland

N,N-Dimethylformamide
CAS # 68-12-2 10 ppm TWA; 30 mg/m3 TWA; 20 ppm STEL; 60 mg/m3 STEL; Potential for cutaneous absorption

NIOSH

N,N-Dimethylformamide
CAS # 68-12-2 500 ppm IDLH; 10 ppm TWA; 30 mg/m3 TWA

Japan

N,N-Dimethylformamide
CAS # 68-12-2 10 ppm OEL; 30 mg/m3 OEL

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)	1.02 @20°C
Color	Amber	Solubility	
Transparency	Translucent	Water	Miscible
Odor	Musty	Organic	Not determined
pH	6.5 - 7.5	Coefficient of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

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	N,N-Dimethylformamide no geometric mean air odor threshold		
9.2 Other Information	None		

Section 10 Stability and Reactivity

10.1 Reactivity	No data available.
10.2 Chemical Stability	Stable under normal temperatures and pressures.
10.3 Possibility of hazardous reactions	No data available.
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.

Section 11 Toxicological Information

11.1 Information on toxicological effects	
Toxicity Data for Hazardous Ingredients	
N,N-Dimethylformamide CAS # 68-12-2	Oral LD50 Rat 2000 mg/kg; Dermal LD50 Rat >3.2 g/kg
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	This product does not contain a reportable concentration ($\geq 0.1\%$) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.

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Section 11 Toxicological Information (Continued)

Potential Effects of Acute Exposure

This product contains materials of human 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

N,N-Dimethylformamide
CAS # 68-12-2

96 h LC50 *Lepomis macrochirus*: 6300 mg/L; 96 h LC50 *Oncorhynchus mykiss*: 9800 mg/L [flow-through]; 96 h LC50 *Pimephales promelas*: 10410 mg/L [flow-through]

Microtox

No information available.

Water Flea

N,N-Dimethylformamide
CAS # 68-12-2

48 h EC50 *Daphnia magna*: 7500 mg/L; 48 h EC50 *Daphnia magna*: 8485 mg/L [semi-static]; 48 h EC50 *Daphnia magna*: 6800 - 13900 mg/L [Static]

Fresh Water Algae

N,N-Dimethylformamide
CAS # 68-12-2

96 h EC50 *Desmodesmus subspicatus*: >500 mg/L

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 No information available.

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

US Federal and State Regulations

SARA 313

Phenytoin (PHY) is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

N,N-Dimethylformamide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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

N,N-Dimethylformamide is listed.

Potassium Hydroxide is listed.

Sodium Hydroxide is listed.

Sodium Azide is listed.

California Proposition 65

Phenobarbital has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause cancer.

Phenytoin (PHY) has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Ethyl Alcohol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Valproic Acid has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Carbamazepine has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

Section 15 Regulatory Information (Continued)

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Phenobarbital is listed.
Phenytoin (PHY) is listed.
Ethyl Alcohol is listed.
N,N-Dimethylformamide is listed.
Valproic Acid is listed.
Potassium Hydroxide is listed.
Sodium Hydroxide is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Phenytoin (PHY) is listed.
Ethyl Alcohol is listed.
N,N-Dimethylformamide is listed.
Potassium Hydroxide is listed.
Sodium Hydroxide is listed.
Sodium Azide is listed.

Pennsylvania RTK

Phenytoin (PHY) is listed.
Ethyl Alcohol is listed.
N,N-Dimethylformamide is listed.
Potassium Hydroxide is listed.
Sodium Hydroxide is listed.
Sodium Azide is listed.

EU Regulations

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.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN

Not applicable

Ingredients on Ingredient Disclosure List

Ethyl Alcohol
N,N-Dimethylformamide
Potassium Hydroxide
Sodium Hydroxide
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 OSHA's and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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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.

Hazard Class, hazard statements and risk phrase description from section 3

T - Toxic

Repr. Cat. 2 - Toxic for Reproduction Category 2

R61 May cause harm to unborn child.

R20/21 Harmful by inhalation and in contact with skin.

R36 Irritating to eyes.

B2 - Flammable and Combustible Material: Flammable Liquid

D2A - Poisonous and Infections Material: Division 2 - Other Toxic Effects: Very Toxic (Teratogenicity and Embryotoxicity)

D2B - Poisonous and Infectious Material: Division 2 - Other Toxic Effects: Toxic (Chronic Toxic Effects)

Acute Tox. Dermal 4 - Acute Toxicity Dermal, Category 4

Acute Tox. Inhal. 4 - Acute Toxicity Inhalation, Category 4

Eye Irrit. 2 - Eye Irritation Category 2

Flam. Liq. 3 - Flammable Liquids, Category 3

Repr. 1B - Toxic to Reproductive Category 1B

H226 - Flammable liquid and vapour.

H312 - Harmful in contact with skin.

H319 - Causes serious eye irritation.

H332 - Harmful if inhaled.

H360 - May damage fertility or the unborn child.

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.



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

1.1 Product Identifier

Product Name Drug Calibrator 1
LEVEL 6

Part Number Component of P/N 469600

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
Amber; Translucent; Liquid; Musty

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)

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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 human origin and should be considered potentially infectious.

Contains material of human origin.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixture

Hazardous Ingredients:		Hazard Classification of Pure Ingredients				
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	US OSHA	WHMIS	
N,N-Dimethylformamide CAS # 68-12-2 EINECS # 200-679-5 Index # 616-001-00-X	< 0.2	T;R61-20/21-36 Repr. Cat. 2	Acute Tox. Dermal 4 Acute Tox. Inhal. 4 Eye Irrit. 2 Flam. Liq. 3 Repr. 1B H226; H312; H319; H332; H360	Combustible Liquid Irritant	B2; D2A; D2B	8, SVHC

8 - Present at concentration below the cut-off limits.
SVHC - Substance of very high concern

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for hazard class, hazard statements and risk phrase description

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.

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Section 5 Fire Fighting Measures

Flammable Properties	Nonflammable 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.
Hazardous Combustion Products	
	No combustion products posing significant hazards are expected from this product.
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 material of human origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed 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

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Section 8 Exposure Controls and Personal Protection (Continued)

US OSHA

N,N-Dimethylformamide
CAS # 68-12-2 10 ppm TWA; 30 mg/m3 TWA; prevent or reduce skin absorption

ACGIH

N,N-Dimethylformamide
CAS # 68-12-2 10 ppm TWA; Skin - potential significant contribution to overall exposure by the cutaneous route

DFG MAK

N,N-Dimethylformamide
CAS # 68-12-2 10 ppm Peak; 30 mg/m3 Peak; skin notation; 5 ppm TWA MAK; 15 mg/m3 TWA MAK

Ireland

N,N-Dimethylformamide
CAS # 68-12-2 10 ppm TWA; 30 mg/m3 TWA; 20 ppm STEL; 60 mg/m3 STEL; Potential for cutaneous absorption

NIOSH

N,N-Dimethylformamide
CAS # 68-12-2 500 ppm IDLH; 10 ppm TWA; 30 mg/m3 TWA

Japan

N,N-Dimethylformamide
CAS # 68-12-2 10 ppm OEL; 30 mg/m3 OEL

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)	1.02 @20°C
Color	Amber	Solubility	
Transparency	Translucent	Water	Miscible
Odor	Musty	Organic	Not determined
pH	6.5 - 7.5	Coefficient of Water/Oil Distribution	Not determined
Freezing Point	Not determined	Autoignition Temp.	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

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	N,N-Dimethylformamide no geometric mean air odor threshold		
9.2 Other Information	None		

Section 10 Stability and Reactivity

10.1 Reactivity	No data available.
10.2 Chemical Stability	Stable under normal temperatures and pressures.
10.3 Possibility of hazardous reactions	No data available.
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.

Section 11 Toxicological Information

11.1 Information on toxicological effects	
Toxicity Data for Hazardous Ingredients	
N,N-Dimethylformamide CAS # 68-12-2	Oral LD50 Rat 2000 mg/kg; Dermal LD50 Rat >3.2 g/kg
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	This product does not contain a reportable concentration ($\geq 0.1\%$) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.

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Section 11 Toxicological Information (Continued)

Potential Effects of Acute Exposure

This product contains materials of human 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

N,N-Dimethylformamide
CAS # 68-12-2

96 h LC50 *Lepomis macrochirus*: 6300 mg/L; 96 h LC50 *Oncorhynchus mykiss*: 9800 mg/L [flow-through]; 96 h LC50 *Pimephales promelas*: 10410 mg/L [flow-through]

Microtox

No information available.

Water Flea

N,N-Dimethylformamide
CAS # 68-12-2

48 h EC50 *Daphnia magna*: 7500 mg/L; 48 h EC50 *Daphnia magna*: 8485 mg/L [semi-static]; 48 h EC50 *Daphnia magna*: 6800 - 13900 mg/L [Static]

Fresh Water Algae

N,N-Dimethylformamide
CAS # 68-12-2

96 h EC50 *Desmodesmus subspicatus*: >500 mg/L

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 No information available.

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

US Federal and State Regulations

SARA 313

Phenytoin (PHY) is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

N,N-Dimethylformamide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

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

N,N-Dimethylformamide is listed.

Potassium Hydroxide is listed.

Sodium Hydroxide is listed.

Sodium Azide is listed.

California Proposition 65

Phenobarbital has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause cancer.

Phenytoin (PHY) has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Ethyl Alcohol has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Valproic Acid has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Carbamazepine has been identified by the State of California to cause reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:

Section 15 Regulatory Information (Continued)

WARNING: This product contains a chemical known to the State of California to cause reproductive harm.

Massachusetts MSL

Phenobarbital is listed.
Phenytoin (PHY) is listed.
Ethyl Alcohol is listed.
N,N-Dimethylformamide is listed.
Valproic Acid is listed.
Potassium Hydroxide is listed.
Sodium Hydroxide is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Phenytoin (PHY) is listed.
Ethyl Alcohol is listed.
N,N-Dimethylformamide is listed.
Potassium Hydroxide is listed.
Sodium Hydroxide is listed.
Sodium Azide is listed.

Pennsylvania RTK

Phenytoin (PHY) is listed.
Ethyl Alcohol is listed.
N,N-Dimethylformamide is listed.
Potassium Hydroxide is listed.
Sodium Hydroxide is listed.
Sodium Azide is listed.

EU Regulations

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.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN

Not applicable

Ingredients on Ingredient Disclosure List

Ethyl Alcohol
N,N-Dimethylformamide
Potassium Hydroxide
Sodium Hydroxide
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 OSHA's and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

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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.

Hazard Class, hazard statements and risk phrase description from section 3

T - Toxic

Repr. Cat. 2 - Toxic for Reproduction Category 2

R61 May cause harm to unborn child.

R20/21 Harmful by inhalation and in contact with skin.

R36 Irritating to eyes.

B2 - Flammable and Combustible Material: Flammable Liquid

D2A - Poisonous and Infections Material: Division 2 - Other Toxic Effects: Very Toxic (Teratogenicity and Embryotoxicity)

D2B - Poisonous and Infectious Material: Division 2 - Other Toxic Effects: Toxic (Chronic Toxic Effects)

Acute Tox. Dermal 4 - Acute Toxicity Dermal, Category 4

Acute Tox. Inhal. 4 - Acute Toxicity Inhalation, Category 4

Eye Irrit. 2 - Eye Irritation Category 2

Flam. Liq. 3 - Flammable Liquids, Category 3

Repr. 1B - Toxic to Reproductive Category 1B

H226 - Flammable liquid and vapour.

H312 - Harmful in contact with skin.

H319 - Causes serious eye irritation.

H332 - Harmful if inhaled.

H360 - May damage fertility or the unborn child.

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

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