

Kit SDS Cover SheetDoc. ID: B36452: Rev. AB
Revised (year/month/day) 2014/08/06

Product Information

Product Name	HbA1c3 DxC
Part Number	B36415
Series Name	SYNCHRON® Systems

Components

Description	A1c CAL L1, L2, L3, L4, L5 Hemoglobin Reagent (Compartment A) Anti-HbA1c (Sheep) (Compartment A) HbA1c-Polyhapten (Compartment B)
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Transport Information

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



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

1.1 Product Identifier

Product Name A1c CAL L1, L2, L3, L4, L5
Part Number Component of P/N B36415
Series Name SYNCHRON® Systems

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

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

1.3 Details of supplier of the safety data sheet

Manufacturer

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

EC REP Address

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

e-mail address

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
Yellow; Translucent; Lyophilized Powder - Liquid after reconstitution.; Odorless

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

Xi;R36/38

Potential Health Effects Summary

US-OSHA Hazards: May cause irritation of skin and eyes.
This product is exempt from WHMIS label and SDS requirements.

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

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

Irritant

Xi



Risk and Safety Phrases

R36/38 Irritating to eyes and skin.

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

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S45 In case of accident or if you feel unwell, seek medical advice immediately.

2.3 Other Hazard

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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	GHS	
Ethylenediaminetetraacetic Acid, Disodium Salt, Dihydrate CAS # 6381-92-6 EINECS # 205-358-3 Index # Not available	5 - 10	No	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 H315; H319; H335	
Tetradecyltrimethylammonium bromide CAS # 1119-97-7 EINECS # 214-291-9 Index # Not available	5 - 10	C;R34	Aquatic Acute 1 Eye Dam. 1 Skin Corr. 1C H314; H318; H400	Aquatic Acute 1 Eye Dam. 1 Skin Corr. 1C H314; H318; H400	
2-Methyl-4-isothiazolin-3-one CAS # 2682-20-4 EINECS # 220-239-6 Index # Not available	< 1	T;R24/25-34-43	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Eye Dam. 1 STOT SE 3 Skin Corr. 1B Skin Sens. 1 H301; H311; H317; H318; H331; H335; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Eye Dam. 1 STOT SE 3 Skin Corr. 1B Skin Sens. 1 H301; H311; H317; H318; H331; H335; H400; H410	1, 15, 8

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Section 3 Composition and Information on Ingredients (Continued)

1 - Health or Environmental Hazard by Regulation EC 1272/2008
15 - May produce an allergic reaction.
8 - Present at concentration below the cut-off limits.

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

May cause irritation of the eyes, skin, and respiratory system.
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.
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5.1 Extinguishing Media	Use extinguishing media suitable for surrounding fire.
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5.2 Special hazards arising from the substance or mixture

Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

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

5.3 Advice for fire fighters

Protective Equipment	Wear full protective suit and self-contained respiratory protective device.
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5.4 Additional information	No additional information available
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Section 6 Accidental Release Measures

6.1 Personal precaution, protective equipment and emergency procedures

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Section 6 Accidental Release Measures (Continued)

- | | |
|---|---|
| Personal Precautions | This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.
Avoid contact with skin and eyes. |
| 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.
If the product is solid or lyophilized form, use vacuum or carefully sweep up spilled material and place in container for suitable disposal. Avoid generating dust. |
| 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.
Avoid contact with eyes and skin. |
| 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 | |
| 2-Methyl-4-isothiazolin-3-one
CAS # 2682-20-4 | 0.4 mg/m ³ Peak (mixture in ratio 1:3 with CAS #26172-55-4) (inhalable fraction);
0.2 mg/m ³ TWA MAK (mixture in ratio 1:3 with CAS #26172-55-4) (inhalable fraction) |
| Ireland | None established |
| IOELVs | None established |
| NIOSH | None established |
| Japan | None established |
| 8.2 Exposure controls | |
| Engineering Controls | No special engineering controls are required. Use with good general ventilation. |

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Section 8 Exposure Controls and Personal Protection (Continued)

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. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Lyophilized Powder - Liquid after reconstitution.	Specific Gravity (Water=1.0)	≈ 1.0
Color	Yellow	Solubility	
Transparency	Translucent	Water	Soluble
Odor	Odorless	Organic	Not determined
pH	7.3	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 applicable	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not applicable
Odor Threshold	Not applicable		

9.2 Other Information Data given is for reconstituted solution.

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 further relevant information available.

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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.
- 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

Tetradecyltrimethylammonium
bromide
CAS # 1119-97-7 Oral LD50 Rat 3900 mg/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.

Skin Corrosion/Irritation Causes skin irritation.

Serious eye damage/eye irritation Causes eye irritation

Skin/Respiratory sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.

Mutagenicity None identified

Reproductive Toxicity None identified

Specific target organ toxicity – single exposure

None identified

Specific target organ toxicity – repeated exposure

None identified

Aspiration hazard None identified

Potential Effects of Acute Exposure

Contact with the skin or eyes may cause irritation.

Potential Effects of Chronic Exposure

Frequent or long-term exposure may result in conjunctivitis and dermatitis.

Symptoms of Overexposure Symptoms of overexposure may include: dry, red, cracked skin; red irritated eyes; nausea and vomiting.

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Section 11 Toxicological Information (Continued)

Conditions Aggravated by Exposure

Individuals with central nervous system, cardiovascular, or kidney disorders may find these conditions aggravated by exposure to this product.

Other Information

This product contains materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

- | | |
|--|---|
| 12.1 Ecotoxicity | |
| Fresh Water Species | No information available. |
| Microtox | No information available. |
| Water Flea | No information available. |
| 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 | May cause long lasting harmful effects to aquatic life. |

Section 13 Disposal Considerations

- | | |
|-------------------------------------|---|
| 13.1 Waste treatment methods | |
| Product Waste Disposal | Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or approved waste-disposal company for information. |
| Package 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. |
| 13.2 Additional information | European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. |

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

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| 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture | |
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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313	No ingredients listed.
CERCLA RG's, 40 CFR 302.4	Sodium Phosphate, Dibasic is listed.
Toxic Substance Control Act (TSCA)	Tetradecyltrimethylammonium bromide is listed. 2-Methyl-4-isothiazolin-3-one is listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	Sucrose is listed. Sodium Phosphate, Dibasic is listed.

New Jersey Dept. of Health RTK List

Sodium Phosphate, Dibasic is listed.

Pennsylvania RTK

Sucrose is listed.
Sodium Phosphate, Dibasic is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 3, severely water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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

Irritant
Xi



Risk and Safety Phrases

R36/38 Irritating to eyes and skin.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S45 In case of accident or if you feel unwell, seek medical advice immediately.

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

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.

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Section 16 Other Information

Beckman Coulter Safety Rating	Flammability: 0 Health: 3 Reactivity with Water: 0 Contact: 3	Code 0=None 1=Slight 2=Caution 3=Severe
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Revision Changes

Updated Section 11.
Updated Section 16.

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

C - Corrosive
T - Toxic
R24/25 Toxic in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1
Eye Irrit. 2 - Eye Irritation Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Irrit. 2 - Skin Irritation Category 2
Skin Sens. 1 - Skin Sensitization Category 1
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H319 - Causes serious eye irritation.
H331 - Toxic if inhaled.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
OSHA - Occupational Safety and Health Administration
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
ACGIH - American Conference of Governmental Industrial Hygienists
NTP - National Toxicology Program
IARC - Internal Agency for Research on Cancer
LD50 - Lethal Dose, 50%

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 Hemoglobin Reagent (Compartment A)
Part Number Component of P/N B36415
Series Name SYNCHRON® Systems

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

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

1.3 Details of supplier of the safety data sheet

Manufacturer

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

EC REP Address

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

e-mail address

1.4 Emergency telephone number

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

Distributor and Emergency Phone No.

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

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture
Colorless; Clear; Liquid; Odorless

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

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

Potential Health Effects Summary

US-OSHA : Not hazardous
This product is exempt from WHMIS label and SDS requirements.

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

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

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	GHS	
2-Methyl-4-isothiazolin-3-one CAS # 2682-20-4 EINECS # 220-239-6 Index # Not available	< 0.1	T;R24/25-34-43	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Eye Dam. 1 STOT SE 3 Skin Corr. 1B Skin Sens. 1 H301; H311; H317; H318; H331; H335; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Eye Dam. 1 STOT SE 3 Skin Corr. 1B Skin Sens. 1 H301; H311; H317; H318; H331; H335; H400; H410	15, 8

15 - May produce an allergic reaction.

8 - Present at concentration below the cut-off limits.

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. 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 aqueous solution.
5.1 Extinguishing Media	Use extinguishing media suitable for surrounding fire.
5.2 Special hazards arising from the substance or mixture	
Special Fire and Explosion Hazards	
	No special hazards determined.
Hazardous Combustion Products	
	No combustion products posing significant hazards are expected from this product (an aqueous solution).
5.3 Advice for fire fighters	
Protective Equipment	Wear full protective suit and self-contained respiratory protective device.
5.4 Additional information	No additional information available

Section 6 Accidental Release Measures

6.1 Personal precaution, protective equipment and emergency procedures	
Personal Precautions	Wear protective gloves, protective clothing and eye/face protection. Avoid contact with skin and eyes.
6.2 Environmental Precautions	Contain spill to prevent migration.
6.3 Methods and material for containment and cleaning up	
Spill and Leak Procedures	Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.
6.4 Reference to other sections	Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling	No special precautions are necessary; use good laboratory procedures. Avoid contact with eyes and skin.
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

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Section 8 Exposure Controls and Personal Protection (Continued)

DFG MAK

2-Methyl-4-isothiazolin-3-one
CAS # 2682-20-4

0.4 mg/m³ Peak (mixture in ratio 1:3 with CAS #26172-55-4) (inhalable fraction);
0.2 mg/m³ TWA MAK (mixture in ratio 1:3 with CAS #26172-55-4) (inhalable fraction)

Ireland

None established

IOELVs

None established

NIOSH

None established

Japan

None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

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)	≈ 1.0 @20°C
Color	Colorless	Solubility	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	7.4	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 applicable	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

Odor Threshold Not applicable

9.2 Other Information No further relevant information available.

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 further relevant information available.

10.4 Conditions to Avoid Avoid contact with incompatible materials.

10.5 Incompatible materials Strong acids, strong bases, strong oxidizers.

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Not applicable

Primary Routes of Exposure Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation None identified

Serious eye damage/eye irritation None identified

Skin/Respiratory sensitization May cause sensitization by skin contact.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.

Mutagenicity None identified

Reproductive Toxicity None identified

Specific target organ toxicity – single exposure

None identified

Specific target organ toxicity – repeated exposure

None identified

Aspiration hazard None identified

Other Information No further relevant information available.

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Section 12 Ecological Information

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

Section 13 Disposal Considerations

13.1 Waste treatment methods	
Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Package 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.
13.2 Additional information	European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06.

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	No ingredients listed.
Toxic Substance Control Act (TSCA)	2-Methyl-4-isothiazolin-3-one is listed.
California Proposition 65	No ingredients listed.
Massachusetts MSL	No ingredients listed.
New Jersey Dept. of Health RTK List	No ingredients listed.

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Section 15 Regulatory Information (Continued)

Pennsylvania RTK

No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN

Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

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

Updated Section 11.

Updated Section 16.

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

T - Toxic

R24/25 Toxic in contact with skin and if swallowed.

R34 Causes burns.

R43 May cause sensitization by skin contact.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3

Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3

Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3

Eye Dam. 1 - Eye Damage Category 1

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Skin Corr. 1B - Skin Corrosion Category 1B

Skin Sens. 1 - Skin Sensitization Category 1

STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3

H301 - Toxic if swallowed.

H311 - Toxic in contact with skin.

Section 16 Other Information (Continued)

Abbreviations and Acronyms

H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
OSHA - Occupational Safety and Health Administration
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
ACGIH - American Conference of Governmental Industrial Hygienists
NTP - National Toxicology Program
IARC - Internal Agency for Research on Cancer

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

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SAFETY DATA SHEET

Doc. ID: B36452 Rev. AB
Revised (year/month/day) 2014/08/06

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

1.1 Product Identifier

Product Name Anti-HbA1c (Sheep) (Compartment A)
Part Number Component of P/N B36415
Series Name SYNCHRON® Systems

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

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

1.3 Details of supplier of the safety data sheet

Manufacturer

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

EC REP Address

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

e-mail address

1.4 Emergency telephone number

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

Distributor and Emergency Phone No.

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

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture
Colorless; Clear; Liquid; Odorless

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

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

Potential Health Effects Summary

US-OSHA : Not hazardous
This product is exempt from WHMIS label and SDS requirements.

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

This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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	GHS	
2-Methyl-4-isothiazolin-3-one CAS # 2682-20-4 EINECS # 220-239-6 Index # Not available	< 0.1	T;R24/25-34-43	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Eye Dam. 1 STOT SE 3 Skin Corr. 1B Skin Sens. 1 H301; H311; H317; H318; H331; H335; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Eye Dam. 1 STOT SE 3 Skin Corr. 1B Skin Sens. 1 H301; H311; H317; H318; H331; H335; H400; H410	15, 8

15 - May produce an allergic reaction.

8 - Present at concentration below the cut-off limits.

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, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. 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.

SAFETY DATA SHEET

Doc. ID: B36452 Rev. AB
Revised (year/month/day) 2014/08/06

Section 4 First Aid Measures (Continued)

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

No special hazards determined.

Hazardous Combustion Products

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

5.3 Advice for fire fighters

Protective Equipment

Wear full protective suit and self-contained respiratory protective device.

5.4 Additional information

No additional information available

Section 6 Accidental Release Measures

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions

This product contains material of animal origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

Avoid contact with skin and eyes.

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.

Avoid contact with eyes and skin.

SAFETY DATA SHEET

Doc. ID: B36452 Rev. AB
Revised (year/month/day) 2014/08/06

Section 7 Handling and Storage (Continued)

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

2-Methyl-4-isothiazolin-3-one
CAS # 2682-20-4 0.4 mg/m³ Peak (mixture in ratio 1:3 with CAS #26172-55-4) (inhalable fraction);
0.2 mg/m³ TWA MAK (mixture in ratio 1:3 with CAS #26172-55-4) (inhalable fraction)

Ireland None established

IOELVs None established

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls No special engineering controls are required. Use with good general ventilation.

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)	≈ 1.00 @20°C
Color	Colorless	Solubility	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined

SAFETY DATA SHEET

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Revised (year/month/day) 2014/08/06

Section 9 Physical and Chemical Properties (Continued)

pH	6.05 - 6.35	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 applicable	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not applicable
Odor Threshold	Not applicable		
9.2 Other Information	No further relevant information available.		

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 further relevant information available.
10.4 Conditions to Avoid	Avoid contact with incompatible materials.
10.5 Incompatible materials	Strong acids, strong bases, strong oxidizers.
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.
Skin Corrosion/Irritation	None identified
Serious eye damage/eye irritation	None identified
Skin/Respiratory sensitization	May cause sensitization by skin contact.

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Section 11 Toxicological Information (Continued)

Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
Mutagenicity	None identified
Reproductive Toxicity	None identified
Specific target organ toxicity – single exposure	None identified
Specific target organ toxicity – repeated exposure	None identified
Aspiration hazard	None identified
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

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

Section 13 Disposal Considerations

13.1 Waste treatment methods	
Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

SAFETY DATA SHEET

Doc. ID: B36452 Rev. AB
Revised (year/month/day) 2014/08/06

Package 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.

13.2 Additional information

European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection.

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 No ingredients listed.

Toxic Substance Control Act (TSCA) 2-Methyl-4-isothiazolin-3-one is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

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.

SAFETY DATA SHEET

Doc. ID: B36452 Rev. AB
Revised (year/month/day) 2014/08/06

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

Updated Section 11.
Updated Section 16.

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

T - Toxic
R24/25 Toxic in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
OSHA - Occupational Safety and Health Administration
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.

Section 16 Other Information (Continued)

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

ACGIH - American Conference of Governmental Industrial Hygienists

NTP - National Toxicology Program

IARC - Internal Agency for Research on Cancer

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

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SAFETY DATA SHEET

Doc. ID: B36452 Rev. AB
Revised (year/month/day) 2014/08/06

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

1.1 Product Identifier

Product Name HbA1c-Polyhapten (Compartment B)
Part Number Component of P/N B36415
Series Name SYNCHRON® Systems

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

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

1.3 Details of supplier of the safety data sheet

Manufacturer

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

EC REP Address

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

e-mail address

1.4 Emergency telephone number

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

Distributor and Emergency Phone No.

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

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture
Colorless; Clear; Liquid; Odorless

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

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

Potential Health Effects Summary

US-OSHA : Not hazardous
This product is exempt from WHMIS label and SDS requirements.

2.2 Label Elements

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

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

SAFETY DATA SHEET

Doc. ID: B36452 Rev. AB
Revised (year/month/day) 2014/08/06

Section 2 Hazards Identification (Continued)

2.3 Other Hazard

This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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	GHS	
2-Methyl-4-isothiazolin-3-one CAS # 2682-20-4 EINECS # 220-239-6 Index # Not available	< 0.1	T;R24/25-34-43	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Eye Dam. 1 STOT SE 3 Skin Corr. 1B Skin Sens. 1 H301; H311; H317; H318; H331; H335; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Eye Dam. 1 STOT SE 3 Skin Corr. 1B Skin Sens. 1 H301; H311; H317; H318; H331; H335; H400; H410	15, 8

15 - May produce an allergic reaction.

8 - Present at concentration below the cut-off limits.

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, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. 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.

SAFETY DATA SHEET

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Section 4 First Aid Measures (Continued)

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

No special hazards determined.

Hazardous Combustion Products

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

5.3 Advice for fire fighters

Protective Equipment

Wear full protective suit and self-contained respiratory protective device.

5.4 Additional information

No additional information available

Section 6 Accidental Release Measures

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions

This product contains material of animal origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

Avoid contact with skin and eyes.

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.

Avoid contact with eyes and skin.

SAFETY DATA SHEET

Doc. ID: B36452 Rev. AB
Revised (year/month/day) 2014/08/06

Section 7 Handling and Storage (Continued)

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

2-Methyl-4-isothiazolin-3-one
CAS # 2682-20-4 0.4 mg/m³ Peak (mixture in ratio 1:3 with CAS #26172-55-4) (inhalable fraction);
0.2 mg/m³ TWA MAK (mixture in ratio 1:3 with CAS #26172-55-4) (inhalable fraction)

Ireland None established

IOELVs None established

NIOSH None established

Japan None established

8.2 Exposure controls

Engineering Controls

No special engineering controls are required. Use with good general ventilation.

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)	≈ 1.00 @20°C
Color	Colorless	Solubility	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined

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Doc. ID: B36452 Rev. AB
Revised (year/month/day) 2014/08/06

Section 9 Physical and Chemical Properties (Continued)

pH	6.05 - 6.35	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 applicable	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not applicable
Odor Threshold	Not applicable		
9.2 Other Information	No further relevant information available.		

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 further relevant information available.
10.4 Conditions to Avoid	Avoid contact with incompatible materials.
10.5 Incompatible materials	Strong acids, strong bases, strong oxidizers.
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.
Skin Corrosion/Irritation	None identified
Serious eye damage/eye irritation	None identified
Skin/Respiratory sensitization	May cause sensitization by skin contact.

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Section 11 Toxicological Information (Continued)

Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
Mutagenicity	None identified
Reproductive Toxicity	None identified
Specific target organ toxicity – single exposure	None identified
Specific target organ toxicity – repeated exposure	None identified
Aspiration hazard	None identified
Other Information	This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

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

Section 13 Disposal Considerations

13.1 Waste treatment methods	
Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

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Package 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.

13.2 Additional information

European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection.

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 No ingredients listed.

Toxic Substance Control Act (TSCA) 2-Methyl-4-isothiazolin-3-one is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL No ingredients listed.

New Jersey Dept. of Health RTK List

No ingredients listed.

Pennsylvania RTK No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

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)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

None

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

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.

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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

Updated Section 11.
Updated Section 16.

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

T - Toxic
R24/25 Toxic in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
OSHA - Occupational Safety and Health Administration
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.

Section 16 Other Information (Continued)

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

ACGIH - American Conference of Governmental Industrial Hygienists

NTP - National Toxicology Program

IARC - Internal Agency for Research on Cancer

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

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