

## Kit SDS Cover Sheet

Document ID: B00389-75: Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

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### Product Information

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<b>Product Name</b>	HbA1c
<b>Part Number</b>	B00389

### Components

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<b>Description</b>	HbA1c R1 HbA1c R2 HbA1c THb R1 HbA1c Calibrator (Levels 2 - 6)
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### Transport Information

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



## SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
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### Section 1 Identification of the Substance/mixture and of the Company/undertaking

#### 1.1 Product Identifier

**Product Name** HbA1c R1  
**Part Number** Component of P/N B00389

#### 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 the supplier of the safety data sheet

##### Manufacturer

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

##### EC REP Address

Beckman Coulter Ireland Inc.  
 Lismeehan  
 O'Callaghan's Mills  
 Co. Clare  
 Ireland  
 Tel: 353 (0)65 6831100

##### e-mail address

SDSNT@beckman.com  
 Further information Contact:  
 Customer support Unit, Beckman Coulter Ireland Inc.  
 Technical Service Department Tel. +001-800-854-3633 (PST)  
 E-mail: Techsupportuk@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  
 Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri  
 (GMT) Tel +001-800-223-0130 (PST)

##### 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** In vitro diagnostic reagent.  
 Colorless; Clear; Liquid; Odorless

##### Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

##### Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

## Section 2 Hazards Identification (Continued)

### 2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS  
Hazardous Ingredients

2-Methyl-4-isothiazolin-3-one

#### Pictogram



#### Signal Word

WARNING

#### Hazard Statements

H317 May cause an allergic skin reaction.

H402 Harmful to aquatic life.

#### Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements. 1.5% of product contains ingredients of unknown hazards to aquatic environment.

### 2.3 Other hazards

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

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 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	Note

## Section 3 Composition and Information on Ingredients (Continued)

<p>2-Methyl-4-isothiazolin-3-one</p> <p>CAS # 2682-20-4 EINECS # 220-239-6 Index # Not available</p>	<p>&lt; 0.06</p>	<p>Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=10 M-factor Chronic=1 Skin Corr. 1B, H314 Skin Sens. 1A, H317</p>	<p>Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1B, H314 Skin Sens. 1A, H317</p>	
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See section 8 for available Occupational exposure limits  
See Section 15 for additional regulatory information  
See Section 16 for description of hazard class and hazard statements

## 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 by trained personnel and obtain medical attention immediately.

#### Eye Contact

If product enters eyes, rinse eyes gently with water as a precaution.

#### Skin Contact

In case of skin contact, rinse with water as a precaution.

#### Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

### 4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.

See Section 11 Toxicological Information for more detailed health information.

### 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

## Section 5 Fire Fighting Measures

### 5.1 Extinguishing Media

In case of fire use carbon dioxide (CO<sub>2</sub>), dry chemical, water spray or foam.  
For large fires 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).

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## Section 5 Fire Fighting Measures (Continued)

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### 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

No further relevant information available.

## Section 6 Accidental Release Measures

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### 6.1 Personal precautions, protective equipment and emergency procedures

#### Personal Precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

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

### 6.2 Environmental Precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

### 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

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### 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

Store at 2 to 8°C, as directed on the product label.

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

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

### 7.3 Specific end uses

No further relevant information available.

## Section 8 Exposure Controls and Personal Protection

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### 8.1 Control parameters

#### Exposure Limits

##### US OSHA

None established

##### ACGIH

None established

## Section 8 Exposure Controls and Personal Protection (Continued)

### DFG MAK

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

### Sweden (AFS 2015:7 and amendments)

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

Wear impervious gloves such as Nitrile or equivalent and protective clothing.

Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 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

<b>Physical State</b>	Liquid	<b>Specific Gravity (Water=1.0)</b>	Not determined
<b>Color</b>	Colorless	<b>Solubility</b>	
<b>Transparency</b>	Clear	<b>Water</b>	Fully miscible
<b>Odor</b>	Odorless	<b>Organic</b>	Not determined
<b>pH</b>	6.2	<b>Partition coefficient: n-octanol/water</b>	Not determined
<b>Freezing Point</b>	Similar to water, approximately 0°C	<b>Auto-ignition Temp.</b>	Product is not selfigniting
<b>Boiling Point</b>	Similar to water, approximately 100°C	<b>Decomposition Temperature</b>	Not determined
<b>Flash Point</b>	Not applicable	<b>Percent Volatiles</b>	Not applicable

## Section 9 Physical and Chemical Properties (Continued)

<b>Evaporation Rate</b>	Not determined	<b>Vapor Pressure</b>	Similar to water, approximately 23 hPa
<b>Flammability (Solid, Gas)</b>	Not applicable	<b>Viscosity</b>	Not determined
<b>Flammability Limits</b>	Not applicable	<b>Explosive Properties</b>	Not applicable
<b>Vapor Density</b>	Not determined	<b>Oxidizing Properties</b>	Not applicable
<b>Odor Threshold</b>	Not applicable		
<b>9.2 Other Information</b>	No further relevant information available.		

## Section 10 Stability and Reactivity

<b>10.1 Reactivity</b>	No further relevant information available.
<b>10.2 Chemical Stability</b>	The product is stable in accordance with recommended storage conditions.
<b>10.3 Possibility of hazardous reactions</b>	No further relevant information available.
<b>10.4 Conditions to Avoid</b>	Avoid exposure to heat and direct sunlight. To maintain product performance keep away from strong acids, strong bases, strong oxidizers.
<b>10.5 Incompatible materials</b>	No further relevant information available.
<b>10.6 Hazardous Decomposition Products</b>	No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

## Section 11 Toxicological Information

<b>11.1 Information on toxicological effects</b>	
<b>Toxicity Data for Hazardous Ingredients</b>	
2-Methyl-4-isothiazolin-3-one CAS # 2682-20-4	Dermal LD50 Rabbit 200 mg/kg; Inhalation LC50 Rat 0.11 mg/L 4 h; Oral LD50 Rat 232 - 249 mg/kg (50% MIT in water); Oral LD50 Rat 120 mg/kg (50% MIT in water)
<b>Primary Routes of Exposure</b>	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.
<b>Acute Toxicity</b>	Not classified based on available data.
<b>Skin Corrosion/Irritation</b>	Not classified based on available data.
<b>Serious eye damage/eye irritation</b>	Not classified based on available data.
<b>Respiratory/skin sensitization</b>	May cause an allergic skin reaction.

## SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

### Section 11 Toxicological Information (Continued)

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<b>Carcinogenicity</b>	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
<b>Germ cell mutagenicity</b>	Not classified based on available data.
<b>Reproductive Toxicity</b>	Not classified based on available data.
<b>Specific target organ toxicity – single exposure</b>	Not classified based on available data.
<b>Specific target organ toxicity – repeated exposure</b>	Not classified based on available data.
<b>Aspiration hazard</b>	Not classified based on available data.
<b>Other Information</b>	This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

### Section 12 Ecological Information

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<b>12.1 Ecotoxicity</b>	
<b>Fresh Water Species</b>	No information available.
<b>Microtox</b>	No information available.
<b>Water Flea</b>	No information available.
<b>Fresh Water Algae</b>	No information available.
<b>12.2 Persistence and degradability</b>	Not determined for the product.
<b>12.3 Bioaccumulation</b>	Not determined for the product.
<b>12.4 Mobility in soil</b>	Not determined for the product.
<b>12.5 Results of PBT and vPvB assessment</b>	Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
<b>12.6 Other Adverse Effects</b>	This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

### Section 13 Disposal Considerations

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<b>13.1 Waste treatment methods</b>	
<b>Product Waste Disposal</b>	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



## SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

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

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

## Section 14 Transport Information

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

**14.1 UN/ID Number:** Not regulated for transportation

**14.2 Shipping Name:** Not regulated for transportation

**14.3 Hazard Class:** Not regulated for transportation

**14.4 Packing Group:** Not regulated for transportation

**14.5 Environmental Hazards:** Not regulated for transportation

**14.6 Special Precautions for user:** None

**14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code:** Not applicable

## 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 (Section 313, Title III reporting requirements)

No ingredients listed.

#### CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

No ingredients listed.

#### California Proposition 65

##### Chemical which is known to the State of California to cause cancer

No ingredients listed.

##### Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

##### Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

## Section 15 Regulatory Information (Continued)

### Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

### Massachusetts Right To Know (RTK) List

No ingredients listed.

### New Jersey Dept. of Health Right To Know (RTK) List

No ingredients listed.

### Pennsylvania Right To Know (RTK) List

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.

### Canada

This product is exempt from WHMIS label and SDS requirements.

## 15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

*Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.*

## Section 16 Other Information

<b>Beckman Coulter Safety Rating</b>	<b>Flammability: 0</b> <b>Health: 2</b> <b>Reactivity with Water: 0</b> <b>Physical Contact: 2</b>	Code 0=None 1=Slight 2=Caution 3=Severe
<b>Revision Changes</b>	Updated E-mail address in Sec. 1.3. Update of product hazard classifications and label elements in Sec. 2. Updated hazardous ingredients in Section 3. Revised Beckman Coulter safety rating. Updated Section 4, 6, 8, 11, 12, 16.	
<b>Document version and issue/revision date</b>	Revision Date (year/month/day) 2020/05/26 Last Revision Date (year/month/day) 2019/03/12 Document ID: B00389-75	

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## Section 16 Other Information (Continued)

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Version: 07

### Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1  
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3  
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2  
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. 1A - Skin Sensitization Category 1A  
H301 - Toxic if swallowed.  
H311 - Toxic in contact with skin.  
H314 - Causes severe skin burns and eye damage.  
H317 - May cause an allergic skin reaction.  
H318 - Causes serious eye damage.  
H330 - Fatal if inhaled.  
H400 - Very toxic to aquatic life.  
H410 - Very toxic to aquatic life with long lasting effects.

### Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists  
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail  
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  
IARC - International Agency for Research on Cancer  
IATA DGR - International Air Transport Association Dangerous Goods Regulation  
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  
NTP - National Toxicology Program  
OSHA - Occupational Safety and Health Administration  
PBT - Persistent bioaccumulative and toxic substances  
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  
WHMIS - Workplace Hazardous Material Information System  
vPvB - Very persistent and very bioaccumulative substances  
LD50 - Lethal Dose, 50%

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## Section 16 Other Information (Continued)

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### LC50 - Lethal Concentration, 50%

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

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## SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
 Revision Date (year/month/day) 2020/05/26  
 Last Revision Date (year/month/day) 2019/03/12

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

#### 1.1 Product Identifier

**Product Name** HbA1c R2  
**Part Number** Component of P/N B00389

#### 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 the supplier of the safety data sheet

##### Manufacturer

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

##### EC REP Address

Beckman Coulter Ireland Inc.  
 Lismeehan  
 O'Callaghan's Mills  
 Co. Clare  
 Ireland  
 Tel: 353 (0)65 6831100

##### e-mail address

SDSNT@beckman.com  
 Further information Contact:  
 Customer support Unit, Beckman Coulter Ireland Inc.  
 Technical Service Department Tel. +001-800-854-3633 (PST)  
 E-mail: Techsupportuk@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  
 Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

##### 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** In vitro diagnostic reagent.  
 Colorless; Clear; Liquid; Characteristic odor

##### Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

##### Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

## Section 2 Hazards Identification (Continued)

### 2.2 Label Elements

**According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS Hazardous Ingredients**

2-Methyl-4-isothiazolin-3-one

**Pictogram**



**Signal Word**

WARNING

**Hazard Statements**

H317 May cause an allergic skin reaction.

H402 Harmful to aquatic life.

**Precautionary Statements**

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements. 1.5% of product contains ingredients of unknown hazards to aquatic environment.

### 2.3 Other hazards

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 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	Note

# SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

## Section 3 Composition and Information on Ingredients (Continued)

<p>2-Methyl-4-isothiazolin-3-one</p> <p>CAS # 2682-20-4 EINECS # 220-239-6 Index # Not available</p>	<p>&lt; 0.06</p>	<p>Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=10 M-factor Chronic=1 Skin Corr. 1B, H314 Skin Sens. 1A, H317</p>	<p>Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1B, H314 Skin Sens. 1A, H317</p>	
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See section 8 for available Occupational exposure limits  
See Section 15 for additional regulatory information  
See Section 16 for description of hazard class and hazard statements

## Section 4 First Aid Measures

### 4.1 Description of first aid measures

<b>Inhalation</b>	If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.
<b>Eye Contact</b>	If product enters eyes, rinse eyes gently with water as a precaution.
<b>Skin Contact</b>	In case of skin contact, rinse with water as a precaution.
<b>Ingestion</b>	If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

### 4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.  
See Section 11 Toxicological Information for more detailed health information.

### 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

## Section 5 Fire Fighting Measures

**5.1 Extinguishing Media** In case of fire use carbon dioxide (CO<sub>2</sub>), dry chemical, water spray or foam.  
For large fires 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).

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## Section 5 Fire Fighting Measures (Continued)

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### 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** No further relevant information available.

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## Section 6 Accidental Release Measures

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### 6.1 Personal precautions, protective equipment and emergency procedures

**Personal Precautions** Observe general safety guidelines for protection; avoid eye and skin contact. Wear protective gloves, protective clothing and eye/face protection.

6.2 **Environmental Precautions** Contain spill to prevent migration.  
Do not allow the undiluted product to enter sewers/surface or ground water.  
Dispose of contents/container in accordance with local regulations

### 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.

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## Section 7 Handling and Storage

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7.1 **Precautions for safe handling** Use good laboratory procedures; avoid eye and skin contact.

### 7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.  
To maintain product quality, store according to the instructions in the product labeling.  
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 **Specific end uses** No further relevant information available.

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## Section 8 Exposure Controls and Personal Protection

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

**Ireland** None established



## Section 8 Exposure Controls and Personal Protection (Continued)

<b>IOELVs</b>	None established
<b>NIOSH</b>	None established
<b>Japan</b>	None established
<b>Sweden (AFS 2015:7 and amendments)</b>	None established
<b>8.2 Exposure controls</b>	
<b>Engineering Controls</b>	No special engineering controls are required. Use with good general ventilation.
<b>Eye Protection</b>	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.
<b>Skin Protection</b>	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
<b>Respiratory Protection</b>	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

<b>Physical State</b>	Liquid	<b>Specific Gravity (Water=1.0)</b>	Not determined
<b>Color</b>	Colorless	<b>Solubility</b>	
<b>Transparency</b>	Clear	<b>Water</b>	Fully miscible
<b>Odor</b>	Characteristic odor	<b>Organic</b>	Not determined
<b>pH</b>	6.2	<b>Partition coefficient: n-octanol/water</b>	Not determined
<b>Freezing Point</b>	Similar to water, approximately 0°C	<b>Auto-ignition Temp.</b>	Product is not selfigniting
<b>Boiling Point</b>	Similar to water, approximately 100°C	<b>Decomposition Temperature</b>	Not determined
<b>Flash Point</b>	Not applicable	<b>Percent Volatiles</b>	Not applicable
<b>Evaporation Rate</b>	Not determined	<b>Vapor Pressure</b>	Similar to water, approximately 23 hPa
<b>Flammability (Solid, Gas)</b>	Not applicable	<b>Viscosity</b>	Not determined
<b>Flammability Limits</b>	Not applicable	<b>Explosive Properties</b>	Not applicable
<b>Vapor Density</b>	Not determined	<b>Oxidizing Properties</b>	Not applicable

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## Section 9 Physical and Chemical Properties (Continued)

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<b>Odor Threshold</b>	Not applicable
<b>9.2 Other Information</b>	No further relevant information available.

## Section 10 Stability and Reactivity

---

<b>10.1 Reactivity</b>	No further relevant information available.
<b>10.2 Chemical Stability</b>	The product is stable in accordance with recommended storage conditions.
<b>10.3 Possibility of hazardous reactions</b>	No further relevant information available.
<b>10.4 Conditions to Avoid</b>	Avoid exposure to heat and direct sunlight. To maintain product performance keep away from strong acids, strong bases, strong oxidizers.
<b>10.5 Incompatible materials</b>	No further relevant information available.
<b>10.6 Hazardous Decomposition Products</b>	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

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

Dermal LD50 Rabbit 200 mg/kg; Inhalation LC50 Rat 0.11 mg/L 4 h; Oral LD50 Rat 232 - 249 mg/kg (50% MIT in water); Oral LD50 Rat 120 mg/kg (50% MIT in water)

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

**Acute Toxicity** Not classified based on available data.

**Skin Corrosion/Irritation** Not classified based on available data.

**Serious eye damage/eye irritation** Not classified based on available data.

**Respiratory/skin sensitization** May cause an allergic skin reaction.

**Carcinogenicity** No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

**Germ cell mutagenicity** Not classified based on available data.

**Reproductive Toxicity** Not classified based on available data.

**Specific target organ toxicity – single exposure**

Not classified based on available data.

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## Section 11 Toxicological Information (Continued)

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### Specific target organ toxicity – repeated exposure

Not classified based on available data.

### Aspiration hazard

Not classified based on available data.

### Other Information

No further relevant information available.

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## Section 12 Ecological Information

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### 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** Not determined for the product.

**12.3 Bioaccumulation** Not determined for the product.

**12.4 Mobility in soil** Not determined for the product.

### 12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

### 12.6 Other Adverse Effects

This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

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## 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

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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## Section 14 Transport Information

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

**14.1 UN/ID Number:** Not regulated for transportation

**14.2 Shipping Name:** Not regulated for transportation

**14.3 Hazard Class:** Not regulated for transportation

**14.4 Packing Group:** Not regulated for transportation

**14.5 Environmental Hazards:** Not regulated for transportation

**14.6 Special Precautions for user:** None

**14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code:** Not applicable

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## Section 15 Regulatory Information

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**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

**US Federal and State Regulations**

**SARA 313 (Section 313, Title III reporting requirements)**

No ingredients listed.

**CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4**

No ingredients listed.

**California Proposition 65**

**Chemical which is known to the State of California to cause cancer**

No ingredients listed.

**Chemical which is known to the State of California to cause development toxicity**

No ingredients listed.

**Chemical which is known to the State of California to cause male reproductive toxicity**

No ingredients listed.

**Chemical which is known to the State of California to cause female reproductive toxicity**

No ingredients listed.

**Massachusetts Right To Know (RTK) List**

No ingredients listed.

**New Jersey Dept. of Health Right To Know (RTK) List**

No ingredients listed.

# SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

## Section 15 Regulatory Information (Continued)

### Pennsylvania Right To Know (RTK) List

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.

### Canada

This product is exempt from WHMIS label and SDS requirements.

### 15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

*Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.*

## Section 16 Other Information

<b>Beckman Coulter Safety Rating</b>	<b>Flammability: 0</b> <b>Health: 2</b> <b>Reactivity with Water: 0</b> <b>Physical Contact: 2</b>	<b>Code</b> 0=None 1=Slight 2=Caution 3=Severe
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### Revision Changes

Updated E-mail address in Sec. 1.3.  
Update of product hazard classifications and label elements in Sec. 2.  
Updated hazardous ingredients in Section 3.  
Revised Beckman Coulter safety rating.  
Updated Section 4, 6, 7, 8, 11, 16  
Updated Section 12.

### Document version and issue/revision date

Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12  
Document ID: B00389-75  
Version: 07

### Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1  
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3  
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2  
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

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## Section 16 Other Information (Continued)

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Skin Sens. 1A - Skin Sensitization Category 1A  
H301 - Toxic if swallowed.  
H311 - Toxic in contact with skin.  
H314 - Causes severe skin burns and eye damage.  
H317 - May cause an allergic skin reaction.  
H318 - Causes serious eye damage.  
H330 - Fatal if inhaled.  
H400 - Very toxic to aquatic life.  
H410 - Very toxic to aquatic life with long lasting effects.

### Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists  
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail  
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  
IARC - International Agency for Research on Cancer  
IATA DGR - International Air Transport Association Dangerous Goods Regulation  
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  
NTP - National Toxicology Program  
OSHA - Occupational Safety and Health Administration  
PBT - Persistent bioaccumulative and toxic substances  
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  
WHMIS - Workplace Hazardous Material Information System  
vPvB - Very persistent and very bioaccumulative substances  
LD50 - Lethal Dose, 50%  
LC50 - Lethal Concentration, 50%

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

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



## SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
 Revision Date (year/month/day) 2020/05/26  
 Last Revision Date (year/month/day) 2019/03/12

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

#### 1.1 Product Identifier

**Product Name** HbA1c THb R1  
**Part Number** Component of P/N B00389

#### 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 the supplier of the safety data sheet

##### Manufacturer

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

##### EC REP Address

Beckman Coulter Ireland Inc.  
 Lismeehan  
 O'Callaghan's Mills  
 Co. Clare  
 Ireland  
 Tel: 353 (0)65 6831100

##### e-mail address

SDSNT@beckman.com  
 Further information Contact:  
 Customer support Unit, Beckman Coulter Ireland Inc.  
 Technical Service Department Tel. +001-800-854-3633 (PST)  
 E-mail: Techsupportuk@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  
 Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

##### 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** In vitro diagnostic reagent.  
 Colorless; Clear; Liquid; Characteristic odor

##### Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1

##### Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

## Section 2 Hazards Identification (Continued)

### 2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS  
**Hazardous Ingredients**

2-Methyl-4-isothiazolin-3-one

**Pictogram**



**Signal Word**

WARNING

**Hazard Statements**

H317 May cause an allergic skin reaction.

H402 Harmful to aquatic life.

**Precautionary Statements**

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

### 2.3 Other hazards

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 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	Note



# SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

## Section 3 Composition and Information on Ingredients (Continued)

<p>2-Methyl-4-isothiazolin-3-one</p> <p>CAS # 2682-20-4 EINECS # 220-239-6 Index # Not available</p>	<p>&lt; 0.06</p>	<p>Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=10 M-factor Chronic=1 Skin Corr. 1B, H314 Skin Sens. 1A, H317</p>	<p>Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1B, H314 Skin Sens. 1A, H317</p>	
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See section 8 for available Occupational exposure limits  
See Section 15 for additional regulatory information  
See Section 16 for description of hazard class and hazard statements

## Section 4 First Aid Measures

### 4.1 Description of first aid measures

<b>Inhalation</b>	If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.
<b>Eye Contact</b>	If product enters eyes, rinse eyes gently with water as a precaution.
<b>Skin Contact</b>	In case of skin contact, rinse with water as a precaution.
<b>Ingestion</b>	If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

### 4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.  
See Section 11 Toxicological Information for more detailed health information.

### 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

## Section 5 Fire Fighting Measures

**5.1 Extinguishing Media** In case of fire use carbon dioxide (CO<sub>2</sub>), dry chemical, water spray or foam.  
For large fires 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).

## SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

### Section 5 Fire Fighting Measures (Continued)

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#### 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

No further relevant information available.

### Section 6 Accidental Release Measures

---

#### 6.1 Personal precautions, protective equipment and emergency procedures

##### Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact. Wear protective gloves, protective clothing and eye/face protection.

#### 6.2 Environmental Precautions

Contain spill to prevent migration.  
Do not allow the undiluted product to enter sewers/surface or ground water.  
Dispose of contents/container in accordance with local regulations

#### 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** Use good laboratory procedures; avoid eye and skin contact.

#### 7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.  
To maintain product quality, store according to the instructions in the product labeling.  
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

#### 7.3 Specific end uses

No further relevant information 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<sup>3</sup> Peak (mixture in ratio 1:3 with CAS 26172-55-4) (inhalable fraction); 0.2 mg/m<sup>3</sup> TWA MAK (mixture in ratio 1:3 with CAS 26172-55-4) (inhalable fraction)

##### Ireland

None established

## Section 8 Exposure Controls and Personal Protection (Continued)

<b>IOELVs</b>	None established
<b>NIOSH</b>	None established
<b>Japan</b>	None established
<b>Sweden (AFS 2015:7 and amendments)</b>	None established
<b>8.2 Exposure controls</b>	
<b>Engineering Controls</b>	No special engineering controls are required. Use with good general ventilation.
<b>Eye Protection</b>	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.
<b>Skin Protection</b>	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
<b>Respiratory Protection</b>	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

<b>Physical State</b>	Liquid	<b>Specific Gravity (Water=1.0)</b>	Not determined
<b>Color</b>	Colorless	<b>Solubility</b>	
<b>Transparency</b>	Clear	<b>Water</b>	Miscible
<b>Odor</b>	Characteristic odor	<b>Organic</b>	Not determined
<b>pH</b>	7.4	<b>Partition coefficient: n-octanol/water</b>	Not determined
<b>Freezing Point</b>	Similar to water, approximately 0°C	<b>Auto-ignition Temp.</b>	Not applicable
<b>Boiling Point</b>	Similar to water, approximately 100°C	<b>Decomposition Temperature</b>	Not determined
<b>Flash Point</b>	Not applicable	<b>Percent Volatiles</b>	Not applicable
<b>Evaporation Rate</b>	Not determined	<b>Vapor Pressure</b>	Not determined
<b>Flammability (Solid, Gas)</b>	Not applicable	<b>Viscosity</b>	Not determined
<b>Flammability Limits</b>	Not applicable	<b>Explosive Properties</b>	Not applicable
<b>Vapor Density</b>	Not determined	<b>Oxidizing Properties</b>	Not applicable

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## Section 9 Physical and Chemical Properties (Continued)

---

<b>Odor Threshold</b>	Not applicable
<b>9.2 Other Information</b>	No further relevant information available.

## Section 10 Stability and Reactivity

---

<b>10.1 Reactivity</b>	No further relevant information available.
<b>10.2 Chemical Stability</b>	The product is stable in accordance with recommended storage conditions.
<b>10.3 Possibility of hazardous reactions</b>	No further relevant information available.
<b>10.4 Conditions to Avoid</b>	Avoid exposure to heat and direct sunlight. To maintain product performance keep away from strong acids, strong bases, strong oxidizers.
<b>10.5 Incompatible materials</b>	No further relevant information available.
<b>10.6 Hazardous Decomposition Products</b>	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

2-Methyl-4-isothiazolin-3-one CAS # 2682-20-4	Dermal LD50 Rabbit 200 mg/kg; Inhalation LC50 Rat 0.11 mg/L 4 h; Oral LD50 Rat 232 - 249 mg/kg (50% MIT in water); Oral LD50 Rat 120 mg/kg (50% MIT in water)
--	---

<b>Primary Routes of Exposure</b>	Eye contact, ingestion, inhalation, and skin contact.
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<b>Acute Toxicity</b>	Not classified based on available data.
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<b>Skin Corrosion/Irritation</b>	Not classified based on available data.
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<b>Serious eye damage/eye irritation</b>	Not classified based on available data.
--	---

<b>Respiratory/skin sensitization</b>	May cause an allergic skin reaction.
---------------------------------------	--------------------------------------

<b>Carcinogenicity</b>	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
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<b>Germ cell mutagenicity</b>	Not classified based on available data.
-------------------------------	---

<b>Reproductive Toxicity</b>	Not classified based on available data.
------------------------------	---

<b>Specific target organ toxicity – single exposure</b>	Not classified based on available data.
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## Section 11 Toxicological Information (Continued)

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### Specific target organ toxicity – repeated exposure

Not classified based on available data.

### Aspiration hazard

Not classified based on available data.

### Other Information

No further relevant information available.

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## Section 12 Ecological Information

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### 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** Not determined for the product.

**12.3 Bioaccumulation** Not determined for the product.

**12.4 Mobility in soil** Not determined for the product.

### 12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

### 12.6 Other Adverse Effects

This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

---

## 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

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

---

## Section 14 Transport Information

---

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

**14.1 UN/ID Number:** Not regulated for transportation

**14.2 Shipping Name:** Not regulated for transportation

**14.3 Hazard Class:** Not regulated for transportation

**14.4 Packing Group:** Not regulated for transportation

**14.5 Environmental Hazards:** Not regulated for transportation

**14.6 Special Precautions for user:** None

**14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code:** Not applicable

---

## 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 (Section 313, Title III reporting requirements)**

No ingredients listed.

**CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4**

No ingredients listed.

**California Proposition 65**

**Chemical which is known to the State of California to cause cancer**

No ingredients listed.

**Chemical which is known to the State of California to cause development toxicity**

No ingredients listed.

**Chemical which is known to the State of California to cause male reproductive toxicity**

No ingredients listed.

**Chemical which is known to the State of California to cause female reproductive toxicity**

No ingredients listed.

**Massachusetts Right To Know (RTK) List**

No ingredients listed.

**New Jersey Dept. of Health Right To Know (RTK) List**

No ingredients listed.

## Section 15 Regulatory Information (Continued)

### Pennsylvania Right To Know (RTK) List

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.

### Canada

This product is exempt from WHMIS label and SDS requirements.

### 15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

*Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.*

## Section 16 Other Information

<b>Beckman Coulter Safety Rating</b>	<b>Flammability: 0</b> <b>Health: 2</b> <b>Reactivity with Water: 0</b> <b>Physical Contact: 2</b>	Code 0=None 1=Slight 2=Caution 3=Severe
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### Revision Changes

Updated E-mail address in Sec. 1.3.  
 Update of product hazard classifications and label elements in Sec. 2.  
 Updated hazardous ingredients in Section 3.  
 Revised Beckman Coulter safety rating.  
 Updated Section 4, 6, 7, 8, 11, 16  
 Updated Section 12.

### Document version and issue/revision date

Revision Date (year/month/day) 2020/05/26  
 Last Revision Date (year/month/day) 2019/03/12  
 Document ID: B00389-75  
 Version: 07

### Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1  
 Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3  
 Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2  
 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

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## Section 16 Other Information (Continued)

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Skin Sens. 1A - Skin Sensitization Category 1A  
H301 - Toxic if swallowed.  
H311 - Toxic in contact with skin.  
H314 - Causes severe skin burns and eye damage.  
H317 - May cause an allergic skin reaction.  
H318 - Causes serious eye damage.  
H330 - Fatal if inhaled.  
H400 - Very toxic to aquatic life.  
H410 - Very toxic to aquatic life with long lasting effects.

### Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists  
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail  
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  
IARC - International Agency for Research on Cancer  
IATA DGR - International Air Transport Association Dangerous Goods Regulation  
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  
NTP - National Toxicology Program  
OSHA - Occupational Safety and Health Administration  
PBT - Persistent bioaccumulative and toxic substances  
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  
WHMIS - Workplace Hazardous Material Information System  
vPvB - Very persistent and very bioaccumulative substances  
LD50 - Lethal Dose, 50%  
LC50 - Lethal Concentration, 50%

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## SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
 Revision Date (year/month/day) 2020/05/26  
 Last Revision Date (year/month/day) 2019/03/12

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

#### 1.1 Product Identifier

**Product Name** HbA1c Calibrator (Levels 2 - 6)

**Part Number** Component of P/N B00389

#### 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 the supplier of the safety data sheet

##### Manufacturer

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

##### EC REP Address

Beckman Coulter Ireland Inc.  
 Lismeehan  
 O'Callaghan's Mills  
 Co. Clare  
 Ireland  
 Tel: 353 (0)65 6831100

##### e-mail address

SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-854-3633 (PST)

E-mail: Techsupportuk@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

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri  
 (GMT) Tel +001-800-223-0130 (PST)

##### 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** In vitro diagnostic reagent.

Reddish-brown; Opaque; Lyophilized; Odorless

##### Classification according to EC 1272/2008 (CLP/GHS)

Skin Irritation Category 2

Skin Sensitization Category 1

Eye Irritation Category 2

## Section 2 Hazards Identification (Continued)

### Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 2  
Aquatic Hazard Acute, Category 3  
Eye Irritation Category 2

#### 2.2 Label Elements

#### According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

##### Hazardous Ingredients

Tetradecyltrimethylammonium bromide  
2-Methyl-4-isothiazolin-3-one

##### Pictogram



##### Signal Word

WARNING

##### Hazard Statements

H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H402 Harmful to aquatic life.

##### Precautionary Statements

P261 Avoid breathing vapours.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P273 Avoid release to the environment.  
P280 Wear protective gloves, protective clothing and eye/face protection.  
P302+P352 IF ON SKIN: Wash with plenty of soap and water.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P332+P313 If skin irritation occurs: Get medical advice/attention.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P337+P313 If eye irritation persists: Get medical advice/attention.  
P362+P364 Take off contaminated clothing and wash it before use.  
P501 Dispose of contents/container in accordance with local/national regulations  
Product label will display most significant precautionary statements. 1% of product contains ingredients of unknown hazards to the aquatic environment.

#### 2.3 Other hazards

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.

# SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

## Section 3 Composition and Information on Ingredients

### 3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients		
Chemical Name	% by wt.	EU 1272/2008 CLP/GHS	GHS	Note
Ethylenediaminetetraacetic Acid, Disodium Salt, Dihydrate  CAS # 6381-92-6 EINECS # 205-358-3 Index # Not available	1 - 2	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315	3, 8
Tetradecyltrimethylammonium bromide  CAS # 1119-97-7 EINECS # 214-291-9 Index # Not available	1 - 2	Aquatic Acute 1, H400 Eye Dam. 1, H318 Skin Corr. 1C, H314	Aquatic Acute 1, H400 Eye Dam. 1, H318 Skin Corr. 1C, H314	
2-Methyl-4-isothiazolin-3-one  CAS # 2682-20-4 EINECS # 220-239-6 Index # Not available	< 0.05	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=10 M-factor Chronic=1 Skin Corr. 1B, H314 Skin Sens. 1A, H317	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1B, H314 Skin Sens. 1A, H317	

3 - Health hazard

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 description of hazard class and hazard statements

## 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 by trained personnel and obtain medical attention immediately.

#### Eye Contact

If product enters eyes, rinse eyes gently with water for 15 minutes or longer, making sure that the eyelid is held open. If pain or irritation occurs, obtain medical advice/attention.

#### Skin Contact

In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

#### Ingestion

If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

## SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

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### Section 4 First Aid Measures (Continued)

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**4.2 Most important symptoms and effects, both acute and delayed**

Exposure may result in irritation of skin and eyes.  
May cause an allergic skin reaction.  
See Section 11 Toxicological Information for more detailed health information.

**4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available. Refer to Section 4.1.

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### Section 5 Fire Fighting Measures

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**5.1 Extinguishing Media**

In case of fire use carbon dioxide (CO<sub>2</sub>), dry chemical, water spray or foam.  
For large fires 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**

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

**5.4 Additional information**

No further relevant information available.

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### Section 6 Accidental Release Measures

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**6.1 Personal precautions, protective equipment and emergency procedures**

**Personal Precautions**

This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.  
Wear protective gloves, protective clothing and eye/face protection.

**6.2 Environmental Precautions**

Contain spill to prevent migration.  
Do not allow the undiluted product to enter sewers/surface or ground water.  
Dispose of contents/container in accordance with local regulations

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## Section 6 Accidental Release Measures (Continued)

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### 6.3 Methods and material for containment and cleaning up

#### Spill and Leak Procedures

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.

If the product is liquid form, 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.

Dispose of all waste material in accordance with local guidelines.

### 6.4 Reference to other sections

Refer sections 8 and 13.

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## Section 7 Handling and Storage

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**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

Store at 2 to 8°C, as directed on the product label.

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

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

### 7.3 Specific end uses

No further relevant information available.

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## Section 8 Exposure Controls and Personal Protection

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### 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<sup>3</sup> Peak (mixture in ratio 1:3 with CAS 26172-55-4) (inhalable fraction); 0.2 mg/m<sup>3</sup> 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

#### Sweden (AFS 2015:7 and amendments)

None established

### 8.2 Exposure controls

#### Engineering Controls

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

## SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

### Section 8 Exposure Controls and Personal Protection (Continued)

<b>Eye Protection</b>	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.
<b>Skin Protection</b>	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
<b>Respiratory Protection</b>	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

<b>Physical State</b>	Lyophilized	<b>Specific Gravity (Water=1.0)</b>	Not applicable
<b>Color</b>	Reddish-brown	<b>Solubility</b>	
<b>Transparency</b>	Opaque	<b>Water</b>	Fully miscible
<b>Odor</b>	Odorless	<b>Organic</b>	Not determined
<b>pH</b>	7.3	<b>Partition coefficient: n-octanol/water</b>	Not applicable
<b>Melting Point</b>	Not determined	<b>Auto-ignition Temp.</b>	Product is not selfigniting
<b>Boiling Point</b>	Not applicable	<b>Decomposition Temperature</b>	Not determined
<b>Flash Point</b>	Not applicable	<b>Percent Volatiles</b>	Not applicable
<b>Evaporation Rate</b>	Not applicable	<b>Vapor Pressure</b>	Not applicable
<b>Flammability (Solid, Gas)</b>	Not determined	<b>Viscosity</b>	Not applicable
<b>Flammability Limits</b>	Not determined	<b>Explosive Properties</b>	Not applicable
<b>Vapor Density</b>	Not applicable	<b>Oxidizing Properties</b>	Not applicable
<b>Odor Threshold</b>	Not applicable		

**9.2 Other Information** No further relevant information available.

### Section 10 Stability and Reactivity

<b>10.1 Reactivity</b>	No further relevant information available.
<b>10.2 Chemical Stability</b>	The product is stable in accordance with recommended storage conditions.

## SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

### Section 10 Stability and Reactivity (Continued)

#### 10.3 Possibility of hazardous reactions

No further relevant information available.

#### 10.4 Conditions to Avoid

Avoid exposure to heat and direct sunlight.

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

#### 10.5 Incompatible materials

No further relevant information available.

#### 10.6 Hazardous Decomposition Products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

### Section 11 Toxicological Information

#### 11.1 Information on toxicological effects

##### Toxicity Data for Hazardous Ingredients

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

Dermal LD50 Rabbit 200 mg/kg; Inhalation LC50 Rat 0.11 mg/L 4 h; Oral LD50 Rat 232 - 249 mg/kg (50% MIT in water); Oral LD50 Rat 120 mg/kg (50% MIT in water)

Tetradecyltrimethylammonium  
bromide  
CAS # 1119-97-7

Oral LD50 Rat 1000 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.

##### Acute Toxicity

Not classified based on available data.

##### Skin Corrosion/Irritation

May cause skin irritation.

##### Serious eye damage/eye irritation

May cause eye irritation.

##### Respiratory/skin sensitization

May cause an allergic skin reaction.

##### Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

##### Germ cell mutagenicity

Not classified based on available data.

##### Reproductive Toxicity

Not classified based on available data.

##### Specific target organ toxicity – single exposure

Not classified based on available data.

##### Specific target organ toxicity – repeated exposure

Not classified based on available data.

## SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

### Section 11 Toxicological Information (Continued)

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<b>Aspiration hazard</b>	Not classified based on available data.
<b>Other Information</b>	This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

### Section 12 Ecological Information

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<b>12.1 Ecotoxicity</b>	
<b>Fresh Water Species</b>	No information available.
<b>Microtox</b>	No information available.
<b>Water Flea</b>	No information available.
<b>Fresh Water Algae</b>	No information available.
<b>12.2 Persistence and degradability</b>	Not determined for the product.
<b>12.3 Bioaccumulation</b>	Not determined for the product.
<b>12.4 Mobility in soil</b>	Not determined for the product.
<b>12.5 Results of PBT and vPvB assessment</b>	
	Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
<b>12.6 Other Adverse Effects</b>	This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

### Section 13 Disposal Considerations

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<b>13.1 Waste treatment methods</b>	
<b>Product Waste Disposal</b>	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.
<b>Package disposal</b>	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.
<b>13.2 Additional information</b>	Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations



## **SAFETY DATA SHEET**

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

### **Section 14 Transport Information**

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

- 14.1 UN/ID Number:** Not regulated for transportation
- 14.2 Shipping Name:** Not regulated for transportation
- 14.3 Hazard Class:** Not regulated for transportation
- 14.4 Packing Group:** Not regulated for transportation
- 14.5 Environmental Hazards:** Not regulated for transportation
- 14.6 Special Precautions for user:** None
- 14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code:** Not applicable

### **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 (Section 313, Title III reporting requirements)**

No ingredients listed.

##### **CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4**

No ingredients listed.

##### **California Proposition 65**

##### **Chemical which is known to the State of California to cause cancer**

No ingredients listed.

##### **Chemical which is known to the State of California to cause development toxicity**

No ingredients listed.

##### **Chemical which is known to the State of California to cause male reproductive toxicity**

No ingredients listed.

##### **Chemical which is known to the State of California to cause female reproductive toxicity**

No ingredients listed.

##### **Massachusetts Right To Know (RTK) List**

CAS # 57-50-1                      Sucrose

##### **New Jersey Dept. of Health Right To Know (RTK) List**

No ingredients listed.

# SAFETY DATA SHEET

Document ID: B00389-75 Version 07  
Revision Date (year/month/day) 2020/05/26  
Last Revision Date (year/month/day) 2019/03/12

## Section 15 Regulatory Information (Continued)

### Pennsylvania Right To Know (RTK) List

CAS # 57-50-1                      Sucrose

### EU Regulations

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

### Water Hazard Class (Germany)

WGK 2, water endangering

### 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.

### 15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

*Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.*

## Section 16 Other Information

<b>Beckman Coulter Safety Rating</b>	<b>Flammability: 0</b> <b>Health: 2</b> <b>Reactivity with Water: 0</b> <b>Physical Contact: 2</b>	Code 0=None 1=Slight 2=Caution 3=Severe
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### Revision Changes

Updated E-mail address in Sec. 1.3.  
Update of product hazard classifications and label elements in Sec. 2.  
Updated hazardous ingredients in Section 3.  
Updated Section 4, 11, 16.

### Document version and issue/revision date

Revision Date (year/month/day) 2020/05/26  
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### Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1  
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3  
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2  
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

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## Section 16 Other Information (Continued)

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Skin Irrit. 2 - Skin Irritation Category 2  
Skin Sens. 1A - Skin Sensitization Category 1A  
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.  
H330 - Fatal 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

ACGIH - American Conference of Governmental Industrial Hygienists  
ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail  
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  
IARC - International Agency for Research on Cancer  
IATA DGR - International Air Transport Association Dangerous Goods Regulation  
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  
NTP - National Toxicology Program  
OSHA - Occupational Safety and Health Administration  
PBT - Persistent bioaccumulative and toxic substances  
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  
WHMIS - Workplace Hazardous Material Information System  
vPvB - Very persistent and very bioaccumulative substances  
LD50 - Lethal Dose, 50%  
LC50 - Lethal Concentration, 50%

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