Kit SDS Cover Sheet

Doc. ID: 439715-75: Rev. AK
Revised (year/month/day) 2015/05/08

Product Information

Product Name	Direct Bilirubin Reagent
Part Number	439715
Series Name	SYNCHRON Systems

Additional Product Information

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

Components

Description

Direct Bilirubin Reagent (Compartment A)
Direct Bilirubin Reagent (Compartment B)

Transport Information

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

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SAFETY DATA SHEET

Doc. ID: 439715-75 Rev. AK
Revised (year/month/day) 2015/05/08

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

1.1 Product Identifier

Product Name Direct Bilirubin Reagent (Compartment A)

Part Number Component of P/N 439715

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 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 Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

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

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Yellow; Clear; Liquid; Odorless

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

Skin Corrosion Category 1
Eye Damage Category 1
Skin Sensitization Category 1

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)

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Section 2 Hazards Identification (Continued)

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

Skin Corrosion Category 1
Eye Damage Category 1
Skin Sensitization Category 1

2.2 Label Elements

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

Hazardous Ingredients

Sulphanilic Acid
Hydrochloric Acid...%

Pictogram



Signal Word

DANGER

Hazard Statements

H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water.
P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.
P363 Wash contaminated clothing before reuse.
P405 Store locked up.
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.

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Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sulphanilic Acid CAS # 121-57-3 EINECS # 204-482-5 Index # 612-014-00-X	0.1 - 1	Xi;R36/38-43	Eye Irrit. 2 Skin Irrit. 2 Skin Sens. 1 H315; H317; H319	Eye Irrit. 2 Skin Irrit. 2 Skin Sens. 1 H315; H317; H319	
Hydrochloric Acid...% CAS # 7647-01-0 EINECS # 231-595-7 Index # 017-002-01-X	0.1 - 1	C;R34-37	Acute Tox. Oral 4 STOT SE 3 Skin Corr. 1B H302; H314; H335	Acute Tox. Oral 4 STOT SE 3 Skin Corr. 1B H302; H314; H335	

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 and obtain medical attention immediately.

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

Causes severe skin burns and eye damage.
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.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable aqueous solution.

5.1 Extinguishing Media — In case of fire use carbon dioxide (CO2), 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

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Section 5 Fire Fighting Measures (Continued)

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 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 tightly sealed 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.

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 Avoid inhaling, ingesting, and contact with eyes and skin.

7.2 Conditions for safe storage, including any incompatibilities

Store at 18 to 26°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

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Section 8 Exposure Controls and Personal Protection (Continued)

US OSHA

Hydrochloric Acid...%
CAS # 7647-01-0 — 5 ppm Ceiling; 7 mg/m3 Ceiling

ACGIH

Hydrochloric Acid...%
CAS # 7647-01-0 — 2 ppm Ceiling

DFG MAK

Hydrochloric Acid...%
CAS # 7647-01-0 — 4 ppm Peak; 6 mg/m3 Peak; 2 ppm TWA MAK; 3.0 mg/m3 TWA MAK

Ireland

Hydrochloric Acid...%
CAS # 7647-01-0 — 5 ppm TWA; 8 mg/m3 TWA; 10 ppm STEL; 15 mg/m3 STEL

IOELVs

Hydrochloric Acid...%
CAS # 7647-01-0 — 5 ppm TWA; 8 mg/m3 TWA; 10 ppm STEL; 15 mg/m3 STEL

NIOSH

Hydrochloric Acid...%
CAS # 7647-01-0 — 50 ppm IDLH

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. 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	Liquid	**Specific Gravity (Water=1.0)**	≈1.0 @20°C
Color	Yellow	**Solubility**	
Transparency	Clear	**Water**	Miscible

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Section 9 Physical and Chemical Properties (Continued)

Odor	Odorless	**Organic**	Not applicable
pH	1.3 -1.7	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition 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
Flammability Limits	Not applicable	**Explosive Properties**	Not applicable
Vapor Density	Not determined	**Oxidizing Properties**	Not applicable
Odor Threshold	Hydrochloric Acid...% no geometric mean air odor threshold		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to Avoid To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials No further relevant information available.

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

Sulphanilic Acid CAS # 121-57-3	Oral LD50 Rat 12300 mg/kg
Hydrochloric Acid...% CAS # 7647-01-0	Inhalation LC50 Rat 3124 ppm 1 h; Oral LD50 Rat 700 mg/kg; Dermal LD50 Rabbit >5010 mg/kg

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

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Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	Causes severe skin burns.
Serious eye damage/eye irritation	Causes serious eye damage.
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	No data available.
Reproductive Toxicity	No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard	No data available.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sulphanilic Acid CAS # 121-57-3	96 h LC50 Pimephales promelas: 77.8-129.6 mg/L [static]
Microtox	No information available.

Water Flea

Sulphanilic Acid CAS # 121-57-3	48 h EC50 Daphnia magna: 85.66 mg/L

Fresh Water Algae

Sulphanilic Acid CAS # 121-57-3	72 h EC50 Desmodesmus subspicatus: 91 mg/L

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.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

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

12.6 Other Adverse Effects No further relevant 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.

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, 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 Hydrochloric Acid...% is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Hydrochloric Acid...% is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Hydrochloric Acid...% is listed.

New Jersey Dept. of Health RTK List

Hydrochloric Acid...% is listed.

Pennsylvania RTK Hydrochloric Acid...% is listed.

EU Regulations

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

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

No ingredients listed.

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.

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Section 15 Regulatory Information (Continued)

PIN Not applicable

Ingredients on Ingredient Disclosure List

Hydrochloric Acid...%

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: 3** **Reactivity with Water: 0** **Contact: 3**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

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

C - Corrosive
Xi - Irritant
R34 Causes burns.
R37 Irritating to respiratory system.
R36/38 Irritating to eyes and skin.
R43 May cause sensitization by skin contact.
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Irrit. 2 - Eye Irritation Category 2
Skin Corr. 1B - Skin Corrosion Category 1B
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
H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
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
IARC - International Agency for Research on Cancer
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
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
EC50 - Effective Concentration, 50%
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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SAFETY DATA SHEET

Doc. ID: 439715-75 Rev. AK
Revised (year/month/day) 2015/05/08

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

1.1 Product Identifier

Product Name Direct Bilirubin Reagent (Compartment B)

Part Number Component of P/N 439715

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 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 Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

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

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture

Colorless; Transparent; 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)

2.2 Label Elements **According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS**

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 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: None

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

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

Eye Contact

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

Skin Contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. 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

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties

Nonflammable aqueous solution.

5.1 Extinguishing Media

In case of fire use carbon dioxide (CO2), 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)

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 No special precautions are necessary. Use good laboratory 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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Store at 18 to 26°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	None established
Ireland	None established
IOELVs	None established
NIOSH	None established

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Section 8 Exposure Controls and Personal Protection (Continued)

	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	Transparent	**Water**	Miscible
Odor	Odorless	**Organic**	Not applicable
pH	10.1 - 10.9	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
Boiling Point	Not determined		
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Not determined
Vapor Density	Not determined		
Odor Threshold	Not applicable		

9.2 Other Information No further relevant information available.

Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical Stability The product is stable in accordance with recommended storage conditions.

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

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

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

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

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory/skin sensitization

No data available.

Carcinogenicity

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

Germ cell mutagenicity

No data available.

Reproductive Toxicity

No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

Other Information

No further relevant information available.

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.

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Section 12 Ecological Information (Continued)

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 No further relevant 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.

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, 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 Sodium Nitrite is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Sodium Nitrite is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Sodium Nitrite is listed.

New Jersey Dept. of Health RTK List

Sodium Nitrite is listed.

Pennsylvania RTK Sodium Nitrite is listed.

EU Regulations

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

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

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Section 15 Regulatory Information (Continued)

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

Sodium Nitrite
Potassium Iodide

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: 0** **Reactivity with Water: 0** **Contact: 0**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
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
IARC - International Agency for Research on Cancer
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
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act

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Section 16 Other Information (Continued)

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

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