

Kit SDS Cover Sheet

Doc. ID: 469188-75: Rev. AF Revised (year/month/day) 2015/05/08

Product Information

Product Name Phenytoin Reagent

Part Number 469188

Series Name SYNCHRON Systems

Additional Product Information

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

Components

Description Phenytoin Reagent (Compartment A)

Phenytoin Reagent (Compartment B) Phenytoin Reagent (Compartment C)

Transport Information

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



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

1.1 Product Identifier

Product Name Phenytoin Reagent (Compartment A)

Part Number Component of P/N 469188
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 EC REP Address

Beckman Coulter, Inc.

Beckman Coulter Eurocenter S.A.

250 S. Kraemer Blvd

22, rue Juste-Oliver, Case Postale 1044,

Brea, CA 92821, U.S.A. CH-1260 Nyon 1, Switzerland.
Tel: 800-854-3633 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; Clear; Liquid; Odorless

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

Eye Irritation Category 2

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)

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

Eye Irritation Category 2

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

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

Hazardous Ingredients

Polyoxyethylated Octyl Phenol

Pictogram



Signal Word

WARNING

Hazard Statements

H319 Causes serious eye irritation.

Precautionary Statements

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention. Product label will display most significant precautionary statements.

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

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-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Polyoxyethylated Octyl Phenol CAS # 9002-93-1 EINECS # Not available Index # Not available	< 3	Xn;R22-41 N;R51/53	Acute Tox. Oral 4 Aquatic Longterm 2 Eye Dam. 1 H302; H318; H411	Acute Tox. Oral 4 Aquatic Longterm 2 Eye Dam. 1 H302; H318; H411	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

- 2 Substance with Community workplace exposure limits
- 8 Present at concentration below the cut-off limits

See section 8 for available Occupational exposure limits

See Section 15 for additional regulatory information

See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not

breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact If product enters eyes, wash eyes gently under running water for 15 minutes

or longer, making sure that the eyelids are held open. If pain or irritation occur,

obtain medical attention.

Skin Contact In case of skin contact, flush with copious amounts of water for at least 15

minutes. If pain or irritation occur, obtain medical attention.

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

medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye irritation.

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

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.

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Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal PrecautionsObserve 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.

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

Sodium Azide 0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Sodium Azide 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

CAS # 26628-22-8

CAS # 26628-22-8

Sodium Azide 0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous

CAS # 26628-22-8 absorption

IOELVs

Ireland

Sodium Azide Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH None established

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Section 8 Exposure Controls and Personal Protection (Continued)

Japan None established

8.2 Exposure controls

Engineering ControlsNo 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 phys	ical and chemical prop	perties	
	Physical State	Liquid	Specific Gravity (Water=1.0)	≈1.014 @20°C
	Color	Colorless	Solubility	
	Transparency	Clear	Water	Miscible
	Odor	Odorless	Organic	Not applicable
	рН	7.0-7.2	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	Not applicable		
9.2	Other Information	No further relevant i	nformation available.	

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Section 10 Stability and Reactivity

10.1 Reactivity No further relevant information available.

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

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing

drains may result in the build up of shock sensitive compounds.

10.4 Conditions to Avoid Avoid contact with incompatible materials.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

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

Polyoxyethylated Octyl Phenol

CAS # 9002-93-1

Oral LD50 Rat 1800 mg/kg

Sodium Azide CAS # 26628-22-8 Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20

mg/kg

Primary Routes of Exposure

Eye contact, ingestion, inhalation, and skin contact.

Skin Corrosion/Irritation

No data available.

Serious eye damage/eye

irritation

Causes serious eye irritation.

Respiratory/skin sensitization No data available.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient

listed as carcinogen 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.

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Section 11 Toxicological Information (Continued)

Other Information

No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Sodium Azide 96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus:

CAS # 26628-22-8 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]

MicrotoxNo information available.Water FleaNo information available.Fresh Water AlgaeNo 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 contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to

enter sewer/surface or ground water.

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. Sodium azide preservative may form explosive compounds in metal drain lines.

See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in

accordance with appropriate local regulations.

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

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Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313 Ethylene Oxide is subject to reporting requirements of Section 313, Title III of

SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA.

0.1 % de minimis concentration

Sodium Azide is subject to reporting requirements of Section 313, Title III of

SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4 Ethylene Oxide is listed.

1,4-Dioxane is listed.

Sodium Azide is listed.

California Proposition 65 Ethylene Oxide has been identified by the State of California to cause cancer

and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals

identified by the State to cause cancer or reproductive harm.

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

cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause

cancer or reproductive harm.

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

to cause cancer.

Massachusetts MSL Ethylene Oxide is listed.

1,4-Dioxane is listed. Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Ethylene Oxide is listed. 1,4-Dioxane is listed. Sodium Azide is listed.

Pennsylvania RTK Ethylene Oxide is listed.

1,4-Dioxane is listed. Sodium Azide is listed.

EU Regulations

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

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

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

No ingredients listed.

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

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

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

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Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Ethylene Oxide 1,4-Dioxane

Polyoxyethylated Octyl Phenol

Sodium Azide

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

Revision Changes

Updated to GHS.

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

N - Dangerous for the environment

T+ - Very toxic

Xn - Harmful

R22 Harmful if swallowed.

R41 Risk of serious damage to eyes.

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in aquatic environment.

Aguatic Acute 1 - Aguatic Hazard Acute, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

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

Eye Dam. 1 - Eye Damage Category 1

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Aquatic Longterm 2 - Aquatic Hazard Long term, Category 2

H300 - Fatal if swallowed.

H302 - Harmful if swallowed.

H318 - Causes serious eye damage.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

H411 - Toxic to aquatic life with long lasting effects.

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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

LC50 - Lethal Concentration, 50%

LD50 - Lethal Dose, 50%

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

1.1 Product Identifier

Product Name Phenytoin Reagent (Compartment B)

Part Number Component of P/N 469188
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 EC REP Address

Beckman Coulter, Inc.

Beckman Coulter Eurocenter S.A.

250 S. Kraemer Blvd

22, rue Juste-Oliver, Case Postale 1044,

Brea, CA 92821, U.S.A. CH-1260 Nyon 1, Switzerland.
Tel: 800-854-3633 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

Clear to slightly yellow; Clear; Liquid; Odorless

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

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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)

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

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

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

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

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:	s Ingredients: Hazard Classification of Pure Ingredients		nts		
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

^{2 -} Substance with Community workplace exposure limits

See section 8 for available Occupational exposure limits See Section 15 for additional regulatory information

See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not

breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact If product enters eyes, wash eyes gently under running water for 15 minutes

or longer, making sure that the eyelids are held open. If pain or irritation occur,

obtain medical attention.

Skin Contact In case of skin contact, flush with copious amounts of water for at least 15

minutes. Remove contaminated clothing and shoes. If pain or irritation occur,

obtain medical attention.

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

medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

^{8 -} Present at concentration below the cut-off limits.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable 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).

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 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.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water

solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal

regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 **Precautions for safe handling** This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

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

Sodium Azide 0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

CAS # 26628-22-8 **DFG MAK**

Sodium Azide 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

CAS # 26628-22-8

Sodium Azide 0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous

CAS # 26628-22-8 absorption

IOELVs

Ireland

Sodium Azide Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH None established

Japan None established

8.2 Exposure controls

CAS # 26628-22-8

Engineering ControlsNo 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 ProtectionUnder normal conditions, the use of this product should not require respiratory

protection.

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Section 9 Physical and Chemical Properties

9.1	Information on basic physi	ysical and chemical properties			
	Physical State	Liquid	Specific Gravity (Water=1.0)	≈1.025 @20°C	
	Color	Clear to slightly yellow	Solubility		
	Transparency	Clear	Water	Miscible	
	Odor	Odorless	Organic	Not applicable	
	рН	7.0 - 7.2	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	Not applicable			
9.2	Other Information	No further relevant ir	formation 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 react	ions
		Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
10.4	Conditions to Avoid	Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.
10.5	Incompatible materials	Metals and metallic compounds
10.6	Hazardous Decomposition Pro	oducts

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

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20

CAS # 26628-22-8 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact.

> Specific paths of concern for potentially infectious materials are skin puncture. contact with broken skin, contact with mucous membranes and inhalation of

aerosolized material.

Skin Corrosion/Irritation No data available.

Serious eve damage/eve

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.

No data available. Germ cell mutagenicity No data available. Reproductive Toxicity

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 This product contains material of animal origin and should be considered as

potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: Sodium Azide CAS # 26628-22-8

0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]

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.

Doc. ID: 469188-75 Rev. AF Revised (year/month/day) 2015/05/08

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

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

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

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we

recommend that you contact the relevant (local) authorities and/or and approved

waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines.

See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in

accordance with appropriate local regulations.

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 Azide is subject to reporting requirements of Section 313, Title III of

SARA. 1.0 % de minimis concentration

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

California Proposition 65 No ingredients listed.

New Jersey Dept. of Health RTK List

Massachusetts MSL

Sodium Azide is listed.

Sodium Azide is listed.

Doc. ID: 469188-75 Rev. AF Revised (year/month/day) 2015/05/08

Section 15 Regulatory Information (Continued)

Pennsylvania RTK

Sodium Azide is listed.

EU Regulations

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

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

No ingredients listed.

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 Azide

Ingredients with unknown toxicological properties

Product is exempt

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

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

Section 16 Other Information

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

Updated to GHS.

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

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in

the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1 Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aguatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Doc. ID: 469188-75 Rev. AF Revised (year/month/day) 2015/05/08

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

LC50 - Lethal Concentration, 50%

LD50 - Lethal Dose, 50%

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

1.1 Product Identifier

Product Name Phenytoin Reagent (Compartment C)

Part Number Component of P/N 469188
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 EC REP Address

Beckman Coulter, Inc.

Beckman Coulter Eurocenter S.A.

250 S. Kraemer Blvd

22, rue Juste-Oliver, Case Postale 1044,

Brea, CA 92821, U.S.A. CH-1260 Nyon 1, Switzerland.
Tel: 800-854-3633 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

Milky white; Opaque; Liquid; Odorless

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

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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)

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

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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Section 2 Hazards Identification (Continued)

2.3 Other hazards

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

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

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			nts
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.2	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

^{2 -} Substance with Community workplace exposure limits

See section 8 for available Occupational exposure limits See Section 15 for additional regulatory information

See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation If product is inhaled, move exposed individual to fresh air. If individual is not

breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact If product enters eyes, wash eyes gently under running water for 15 minutes

or longer, making sure that the eyelids are held open. If pain or irritation occur,

obtain medical attention.

Skin Contact In case of skin contact, flush with copious amounts of water for at least 15

minutes. Remove contaminated clothing and shoes. If pain or irritation occur,

obtain medical attention.

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

medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

^{8 -} Present at concentration below the cut-off limits.

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Section 4 First Aid Measures (Continued)

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

Flammable Properties Nonflammable 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).

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 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.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures As a precautionary measure, treat spilled material with a 1:10 bleach/water

solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal

regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 **Precautions for safe handling** This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

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Section 7 Handling and Storage (Continued)

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

Sodium Azide 0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor) CAS # 26628-22-8

DFG MAK

Sodium Azide 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

CAS # 26628-22-8

Sodium Azide 0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL (as NaN3); Potential for cutaneous

CAS # 26628-22-8 absorption

IOELVs

Ireland

Sodium Azide Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH None established

Japan None established

8.2 Exposure controls

CAS # 26628-22-8

Engineering ControlsNo 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 ProtectionUnder normal conditions, the use of this product should not require respiratory

protection.

Revised (year/month/day) 2015/05/08

SAFETY DATA SHEET Doc. ID: 469188-75 Rev. AF

Section 9 Physical and Chemical Properties

	Gotton of Hydroan and Ghommoan Froporation				
9.1	Information on basic physi	cal and chemical pro	perties		
	Physical State	Liquid	Specific Gravity (Water=1.0)	≈1.009 @20°C	
	Color	Milky white	Solubility		
	Transparency	Opaque	Water	Miscible	
	Odor	Odorless	Organic	Not applicable	
	рН	7.1	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	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 react	ions
		Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
10.4	Conditions to Avoid	Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.
10.5	Incompatible materials	Metals and metallic compounds
10.6	Hazardous Decomposition Pro	oducts

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

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Sodium Azide Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20

CAS # 26628-22-8 mg/kg

Primary Routes of Exposure Common routes of entry include inhalation, ingestion and eye/skin contact.

> Specific paths of concern for potentially infectious materials are skin puncture. contact with broken skin, contact with mucous membranes and inhalation of

aerosolized material.

Skin Corrosion/Irritation No data available.

Serious eye damage/eye

irritation

No data available.

Respiratory/skin sensitization No data available.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient

listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

No data available. Germ cell mutagenicity

No data available. Reproductive Toxicity

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 This product contains material of animal origin and should be considered as

potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: Sodium Azide CAS # 26628-22-8

0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]

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.

Doc. ID: 469188-75 Rev. AF Revised (year/month/day) 2015/05/08

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

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal

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

Dispose of as potentially biohazardous waste and in compliance with

anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines.

See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

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

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

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

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

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Section 15 Regulatory Information (Continued)

CERCLA RG's, 40 CFR 302.4

Acetaldehyde is listed.

Ethylene Oxide is listed. 1,4-Dioxane is listed. Sodium Azide is listed.

California Proposition 65

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

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

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

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

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

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

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

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

Massachusetts MSL

Phenytoin (PHY) is listed. Acetaldehyde is listed. Ethylene Oxide is listed. 1,4-Dioxane is listed. Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Phenytoin (PHY) is listed. Acetaldehyde is listed. Ethylene Oxide is listed. 1,4-Dioxane is listed. Sodium Azide is listed.

Pennsylvania RTK

Phenytoin (PHY) is listed. Acetaldehyde is listed. Ethylene Oxide is listed. 1,4-Dioxane is listed. Sodium Azide is listed.

Doc. ID: 469188-75 Rev. AF Revised (year/month/day) 2015/05/08

Section 15 Regulatory Information (Continued)

EU Regulations

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

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

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

No ingredients listed.

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

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

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde Ethylene Oxide 1,4-Dioxane Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

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

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

Section 16 Other Information

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

Revision Changes

Updated to GHS.

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

N - Dangerous for the environment

T+ - Very toxic

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1 Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300 - Fatal if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Doc. ID: 469188-75 Rev. AF Revised (year/month/day) 2015/05/08

Section 16 Other Information (Continued)

Abbreviations and Acronyms

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CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System

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IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

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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.

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US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

LC50 - Lethal Concentration, 50%

LD50 - Lethal Dose, 50%

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