

# SAFETY DATA SHEET

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### Contact information

#### General

**Thermo**

SCIENTIFIC

Microgenics Corporation

46500 Kato Road

Fremont, CA 94538

Main: (510) 979-5000

Fax: (510) 979-5002

E-mail: techservice.mgc@thermofisher.com

#### Emergency telephone number

Chemtrec (24-hour availability):

+1 (800) 424-9300 (USA and Canada)

+1 (703) 527-3887 (International; Collect calls accepted)

+1 (202) 483-7616 (Europe)

**Product identifier** CEDIA<sup>®</sup> Digitoxin Assay - Powder Reagents

**Synonyms** EA & ED Reagents for following Assays:  
100004, CEDIA<sup>®</sup> Digitoxin

**Trade names** CEDIA<sup>®</sup> Digitoxin Assay

**Chemical family** Mixture

**Relevant identified uses of the substance or mixture and uses advised against** *In vitro* diagnostic kit.

**Note** The pharmacological, toxicological, and ecological properties of this product/mixture have not been fully characterized. This data sheet will be updated as more data become available.

## SECTION 2 - HAZARDS IDENTIFICATION

### Classification of the substance or mixture

**Globally Harmonized System [GHS]** Irritant (skin) - Category 2. Irritant (eye) - Category 2. Respiratory Sensitizer - Category 1. Skin Sensitizer - Category 1.

**Other/Supplemental** Mixture not yet fully tested.

### Label elements

## SECTION 2 - HAZARDS IDENTIFICATION ...continued

### GHS hazard pictogram



### GHS signal word

Danger

### GHS hazard statements

H315 - Causes skin irritation. H317 - May cause allergic skin reaction. H319 - Causes serious eye irritation. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. EUH032 - Contact with acids liberates very toxic gas.

### GHS precautionary statements

P261 - Avoid breathing mist or vapor. P264 - Wash hands thoroughly after handling. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/eye protection/face protection. P285 - In case of inadequate ventilation wear respiratory protection. P302 + P352 - If on skin: Wash with plenty of soap and water. P304 + P341 - IF INHALED: If breathing is difficult, remove victim 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. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P337 + P313 - If eye irritation persists: Get medical advice/attention. P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P362 - Take off contaminated clothing and wash before reuse. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

### Other hazards

The potential health hazards associated with exposure/handling of this mixture are unknown; no data specific for the mixture were identified. The following data describe the hazards of individual ingredients, where applicable.

The mixture contains bovine serum albumin which has been associated with occupational sensitization. Material produced in compliance with USDA and/or CPMP/BWP/1230/98 (Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products). This is a CPMP/BWP/1230/98 Category IV material: it does not contain nor is it derived from specified risk materials as defined in Commission decision 97/534/EC (or successive amendments).

Because the mixture contains a protein, it may cause an allergic skin or respiratory reaction (e.g., potential to cause anaphylaxis). In a workplace setting, the likelihood of systemic effects following accidental ingestion is low, due to the rapid breakdown of proteins in the digestive tract. Although antibody particles are fairly large proteins, it is not known if systemic effects can occur following accidental inhalation. Proteins, in general, can cause skin and/or respiratory sensitization.

## SECTION 2 - HAZARDS IDENTIFICATION ...continued

**Note** This mixture is classified as hazardous according to Regulation EC No 1272/2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA). The pharmacological, toxicological and ecological properties of this mixture have not been fully characterized.

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN</u> <u>CS#</u>	<u>Amount</u>	<u>GHS</u> <u>Classification</u>
Bovine serum albumin	9048-46-8	N/A	≤31%	SS1: H317, RS1: H334
Sodium phosphate, dibasic, anhydrous	7558-79-4	231-448-7	≤19%	SI2: H315; EI2: H319
Sodium phosphate, monobasic	7558-80-7	231-449-2	≤12%	SI2: H315; EI2: H319
Donkey serum	N/A	N/A	≤10%	RS1: H334; SS1: H317
Sodium azide	26628-22-8	247-852-1	≤1%	ATO2: H300; AA1: H400 , CA1: H410; EUH032
Drug-specific antibody	N/A	N/A	≤9%	SS1: H317; RS1: H334

**Note** The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of CLP/GHS classifications. Product contains low levels of active pharmaceutical ingredients (≤0.2%) and trace levels of antibody conjugate (≤0.0003%). The GHS classification is based on Regulation (EC) 1272/2008 and Hazard Communication Standard No. 1910.1200.

## SECTION 4 - FIRST AID MEASURES

### Description of first aid measures

<b>Immediate Medical Attention Needed</b>	Yes
<b>Eye Contact</b>	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Skin Contact</b>	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Inhalation</b>	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

#### SECTION 4 - FIRST AID MEASURES ...continued

<b>Ingestion</b>	If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
<b>Protection of first aid responders</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed</b>	See Sections 2 and 11
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

#### SECTION 5 - FIREFIGHTING MEASURES

<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
<b>Specific hazards arising from the substance or mixture</b>	No information identified. May emit toxic gases of carbon monoxide, carbon dioxide, and oxides of nitrogen.
<b>Flammability/Explosivity</b>	No explosivity or flammability data identified. High airborne concentrations of finely divided organic particles can potentially explode if ignited.
<b>Advice for firefighters</b>	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

#### SECTION 6 - ACCIDENTAL RELEASE MEASURES

<b>Personal precautions, protective equipment and emergency procedures</b>	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.
<b>Methods and material for containment and cleaning up</b>	DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter into solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container for disposal in accordance with applicable waste disposal regulations (see section 13). Decontaminate the area twice with an appropriate solvent (see section 9).

## SECTION 6 - ACCIDENTAL RELEASE MEASURES ...continued

**Reference to other sections** See Sections 8 and 13 for more information.

## SECTION 7 - HANDLING AND STORAGE

**Precautions for safe handling** Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing dust.

**Conditions for safe storage including any incompatibilities** Store at 2-8 °C in a well-ventilated area, away from incompatible materials. Keep container upright and tightly closed.

**Specific end use(s)** No information identified.

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control

### Parameters/Occupational

### Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Bovine serum albumin	--	--	--
Sodium phosphate, dibasic, anhydrous	--	--	--
Sodium phosphate, monobasic	--	--	--
Donkey serum	--	--	--

**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

**Control  
Parameters/Occupational  
Exposure Limit Values  
...continued**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Sodium azide	ACGIH, Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, U.S.-California OSHA, United Kingdom	OEL-STEL	0.3 mg/m <sup>3</sup>
	New Zealand, Portugal	Ceiling	0.29 mg/m <sup>3</sup>

**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

**Control  
Parameters/Occupational  
Exposure Limit Values  
...continued**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Sodium azide	ACGIH,	OEL-TWA	0.1 mg/m <sup>3</sup>
	Australia,		
	Austria,		
	Belgium,		
	Bulgaria,		
	Croatia,		
	Cyprus, Czech		
	Republic,		
	Denmark,		
	Estonia,		
Finland,			
France, Greece,			
Hungary,			
Ireland, Italy,			
Latvia,			
Lithuania,			
Malta,			
Netherlands,			
Poland,			
Romania,			
Slovakia,			
Slovenia,			
Spain, Sweden,			
U.S.-California			
OSHA, United			
Kingdom			
NIOSH,	Ceiling	0.3 mg/m <sup>3</sup>	
U.S.-California			
OSHA			
Germany	OEL-STEL	0.4 mg/m <sup>3</sup>	
Germany	OEL-TWA	0.2 mg/m <sup>3</sup>	
Drug-specific antibody	--	--	--

**Exposure/Engineering  
controls**

Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at dust-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling.

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued

<b>Respiratory protection</b>	Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine handling tasks, an approved and properly fitted air-purifying respirator with appropriate HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with appropriate HEPA filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.
<b>Hand protection</b>	Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
<b>Skin protection</b>	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Environmental Exposure Controls</b>	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
<b>Other protective measures</b>	Wash hands in the event of contact with this product/mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

<b>Appearance</b>	Lyophilized powder
<b>Color</b>	White to off-white
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	Not applicable
<b>Melting point/freezing point</b>	No information identified.



## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	No information identified.
<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified.
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	Soluble in water
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (n-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular weight</b>	Not applicable (Mixture)
<b>Molecular formula</b>	Not applicable (Mixture)

## SECTION 10 - STABILITY AND REACTIVITY

<b>Reactivity</b>	Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.
<b>Chemical stability</b>	Stable when stored as recommended.
<b>Possibility of hazardous reactions</b>	Not expected to occur.

## SECTION 10 - STABILITY AND REACTIVITY ...continued

<b>Conditions to avoid</b>	Avoid excessive heat.
<b>Incompatible materials</b>	No information identified.
<b>Hazardous decomposition products</b>	No information identified.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### Information on toxicological effects

**Route of entry** May be absorbed by inhalation, skin contact and ingestion.

#### Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Bovine serum albumin	--	--	--	--
Sodium phosphate, dibasic, anhydrous	LD <sub>50</sub>	Oral	Rat	17 g/kg
Sodium phosphate, monobasic	LD <sub>50</sub>	Oral	Rabbit	8290 mg/kg
	LD <sub>50</sub>	Intramuscular	Rat	250 mg/kg
Donkey serum	--	--	--	--
Sodium azide	LD <sub>50</sub>	Oral	Rat	27 mg/kg
	LD <sub>50</sub>	Oral	Mouse	27 mg/kg
	LD <sub>50</sub>	Dermal	Rabbit	20 mg/kg
Drug-specific antibody	--	--	--	--

**Additional acute toxicity information** No studies identified.

**Irritation/Corrosion** No studies identified.

**Sensitization** No studies identified. As bovine serum albumin (BSA) is derived from animal (foreign) protein, there is potential for the material to cause an allergic response in humans. Occupational exposure to BSA has caused some cases of allergic sensitization in workers handling this material.

**STOT-single exposure** No studies identified.

**STOT-repeated exposure/Repeat-dose toxicity** No studies identified.

**Reproductive toxicity** No studies identified.

**Developmental toxicity** No studies identified.

**Genotoxicity** No studies identified.

## SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

<b>Carcinogenicity</b>	No studies identified. This mixture is not listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
<b>Aspiration hazard</b>	No data available.
<b>Human health data</b>	See "Section 2 - Other Hazards"
<b>Additional information</b>	The toxicological properties of this mixture have not been fully characterized.

## SECTION 12 - ECOLOGICAL INFORMATION

### Toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Bovine serum albumin	--	--	--
Sodium phosphate, dibasic, anhydrous	--	--	--
Sodium phosphate, monobasic	--	--	--
Donkey serum	--	--	--
Sodium azide	LC <sub>50</sub> /96h	Oncorhynchus mykiss	0.8 mg/L
	LC <sub>50</sub> /96h	Lepomis macrochirus	0.7 mg/L
	LC <sub>50</sub> /96h	Pimephales promelas	5.46 mg/L
Drug-specific antibody	--	--	--

**Additional toxicity information** Sodium azide is toxic to aquatic organisms and should not be allowed to accumulate in metal piping as it has the potential to form explosive mixtures.

**Persistence and Degradability** No data available.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Results of PBT and vPvB assessment** No data available.

**Other adverse effects** No data available.

**Note** The environmental characteristics of this product/mixture have not been fully investigated. The above data are for the active ingredient and/or any other ingredient(s) where applicable. Although present at low concentrations, disposal should consider that sodium azide is present. Releases to the environment should be avoided.

## SECTION 13 - DISPOSAL CONSIDERATIONS

**Waste treatment methods** Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

## SECTION 14 - TRANSPORT INFORMATION

**Transport** Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

**UN number** None assigned.

**UN proper shipping name** None assigned.

**Transport hazard classes and packing group** None assigned.

**Environmental hazards** Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.

**Special precautions for users** Mixture not fully tested - avoid exposure.

**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

## SECTION 15 - REGULATORY INFORMATION

**Safety, health and environmental regulations/legislation specific for the substance or mixture** This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.

**Chemical safety assessment** Not conducted.

**WHMIS classification** This product/mixture has been classified in accordance with the hazard criteria of the Hazardous Products Regulations and the SDS contains all of the information required by those regulations.

## SECTION 15 - REGULATORY INFORMATION ...continued

<b>TSCA status</b>	Not listed
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	Not listed.
<b>Additional information</b>	No other information identified.

## SECTION 16 - OTHER INFORMATION

**Full text of H phrases and GHS classifications** SI2 - Skin irritant Category 2. H315 - Causes skin irritation. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction. EI2 - Eye irritant Category 2. H319 - Causes serious eye irritation. RS1 - Respiratory Sensitizer Category 1. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled. ATO2 - Acute Toxicity (Oral) Category 2. H300 - Fatal if swallowed. AA1 - Aquatic toxicity (acute) - Category 1. H400 - Very toxic to aquatic life. CA1 - Chronic Aquatic Toxicity Category 1. H410 - Very toxic to aquatic life with long lasting effects. EUH032 - Contact with acids liberates very toxic gas.

**Sources of data** Information from published literature and internal company data.

**Abbreviations** ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

**Issue Date** 17 July 2015

**Revisions** This is the first version of this SDS.

## SECTION 16 - OTHER INFORMATION ...continued

### **Disclaimer**

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical/diagnostic product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

# SAFETY DATA SHEET

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### Contact information

#### General

**Thermo**

SCIENTIFIC

Microgenics Corporation

46500 Kato Road

Fremont, CA 94538

Main: (510) 979-5000

Fax: (510) 979-5002

E-mail: [techservice.mgc@thermofisher.com](mailto:techservice.mgc@thermofisher.com)

#### Emergency telephone number

Chemtrec (24-hour availability):

+1 (800) 424-9300 (USA and Canada)

+1 (703) 527-3887 (International; Collect calls accepted)

+1 (202) 483-7616 (Europe)

#### Product identifier

CEDIA® Digitoxin Assay - Liquid Reagents

#### Synonyms

**EARB & EDRB Reagents for following Assays:**

100004, CEDIA® Digitoxin Assay

#### Trade names

CEDIA® Digitoxin Assay

#### Chemical family

Mixture

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

*In vitro* diagnostic kit.

#### Note

The pharmacological, toxicological, and ecological properties of this product/mixture have not been fully characterized. This data sheet will be updated as more data become available.

## SECTION 2 - HAZARDS IDENTIFICATION

### Classification of the substance or mixture

#### Globally Harmonized System [GHS]

Aquatic toxicity (chronic) - Category 3.

#### Other/Supplemental

Mixture not yet fully tested.

### Label elements

## SECTION 2 - HAZARDS IDENTIFICATION ...continued

<b>GHS hazard pictogram</b>	None required
<b>GHS signal word</b>	Warning
<b>GHS hazard statements</b>	H412 - Harmful to aquatic life with long lasting effects. EUH032 - Contact with acids liberates very toxic gas.
<b>GHS precautionary statements</b>	P273 - Avoid release to the environment. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.
<b>Other hazards</b>	The potential health hazards associated with exposure/handling of this mixture are unknown; no data specific for the mixture were identified. The following data describe the hazards of individual ingredients, where applicable.
<b>Note</b>	This mixture is classified as hazardous according to Regulation EC No 1272/2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA). The pharmacological, toxicological and ecological properties of this mixture have not been fully characterized.

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN CS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Ethylene glycol	107-21-1	203-473-3	≤3%	ATO4: H302
Sodium azide	26628-22-8	247-852-1	≤0.2%	ATO2: H300; AA1: H400 , CA1: H410; EUH032
Sodium lauroylsarcosinate	137-16-6	25-281-5	≤0.1%	AT12: H330; SI2: H315; EI2: H319

<b>Note</b>	The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications. Product contains low levels of active pharmaceutical ingredients (≤0.001%). The GHS classification is based on Regulation (EC) 1272/2008 and Hazard Communication Standard No. 1910.1200.
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## SECTION 4 - FIRST AID MEASURES

### Description of first aid measures

<b>Immediate Medical Attention Needed</b>	Yes
<b>Eye Contact</b>	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.



## SECTION 4 - FIRST AID MEASURES ...continued

<b>Skin Contact</b>	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Inhalation</b>	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
<b>Ingestion</b>	If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
<b>Protection of first aid responders</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed</b>	See Sections 2 and 11
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

## SECTION 5 - FIREFIGHTING MEASURES

<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
<b>Specific hazards arising from the substance or mixture</b>	No information identified. May emit toxic gases of carbon monoxide, carbon dioxide, and oxides of nitrogen.
<b>Flammability/Explosivity</b>	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.
<b>Advice for firefighters</b>	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

<b>Personal precautions, protective equipment and emergency procedures</b>	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES ...continued

**Methods and material for containment and cleaning up** DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9).

**Reference to other sections** See Sections 8 and 13 for more information.

## SECTION 7 - HANDLING AND STORAGE

**Precautions for safe handling** Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing vapor/mist/spray.

**Conditions for safe storage including any incompatibilities** Store at 2-8 °C in a well-ventilated area, away from incompatible materials. Keep container upright and tightly closed.

**Specific end use(s)** No information identified.

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

**Note** Dispose of broken vials/syringes in a sharps container.

### Control Parameters/Occupational Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Ethylene glycol	ACGIH	TLV/Ceiling	100 mg/m <sup>3</sup>
	Austria, Germany	TWA 8-HR	10 ppm; 26 mg/m <sup>3</sup>
	Austria, Germany	STEL (8 x 5 min)	20 ppm; 52 mg/m <sup>3</sup>

**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

**Control  
Parameters/Occupational  
Exposure Limit Values  
...continued**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Ethylene glycol	Bulgaria, Croatia, Cyprus, Estonia, France, Hungary, Ireland, Italy, Latvia, Luxembourg, Malta, Netherlands, Romania, Slovak Republic, Slovenia, Spain, United Kingdom	TWA 8-HR	20 ppm; 52 mg/m <sup>3</sup>
	Bulgaria, Croatia, Cyprus, Estonia, France, Hungary, Ireland, Italy, Latvia, Luxembourg, Malta, Netherlands, Romania, Slovak Republic, Slovenia, Spain, United Kingdom	STEL	40 ppm; 104 mg/m <sup>3</sup>
	Czech Republic	TWA 8-HR	50 mg/m <sup>3</sup>
	Czech Republic, Italy, Portugal	Ceiling	100 mg/m <sup>3</sup>

**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

**Control  
Parameters/Occupational  
Exposure Limit Values  
...continued**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Ethylene glycol	Denmark	TWA 8-HR	10 ppm; 26 mg/m <sup>3</sup> ; 10 mg/m <sup>3</sup> (vapor)
	Finland	TWA 8-HR	20 ppm, 50 mg/m <sup>3</sup>
	Finland	STEL	40 ppm; 100 mg/m <sup>3</sup>
	Greece	TWA 8-HR; STEL	50 ppm (vapor); 125 mg/m <sup>3</sup> (vapor)
	Lithuania, Sweden	TWA 8-HR	10 ppm (aerosol and vapor); 25 mg/m <sup>3</sup> (aerosol and vapor)
	Lithuania, Sweden	STEL	20 ppm (aerosol and vapor); 50 mg/m <sup>3</sup> (aerosol and vapor)
	NIOSH	Ceiling	50 ppm
	Poland	TWA 8-HR	15 mg/m <sup>3</sup>
	Poland	STEL	50 mg/m <sup>3</sup>
	US-OSHA	Ceiling (vacated)	50 ppm; 125 mg/m <sup>3</sup>

**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

**Control Parameters/Occupational Exposure Limit Values  
...continued**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Sodium azide	ACGIH, Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, U.S.-California OSHA, United Kingdom	OEL-STEL	0.3 mg/m <sup>3</sup>
	New Zealand, Portugal	Ceiling	0.29 mg/m <sup>3</sup>

**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

**Control  
Parameters/Occupational  
Exposure Limit Values  
...continued**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Sodium azide	ACGIH, Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, U.S.-California OSHA, United Kingdom	OEL-TWA	0.1 mg/m <sup>3</sup>
	NIOSH, U.S.-California OSHA	Ceiling	0.3 mg/m <sup>3</sup>
	Germany	OEL-STEL	0.4 mg/m <sup>3</sup>
	Germany	OEL-TWA	0.2 mg/m <sup>3</sup>
Sodium lauroylsarcosinate	--	--	--

**Exposure/Engineering  
controls**

Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at aerosol/mist-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling.

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued

<b>Respiratory protection</b>	Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine handling tasks, an approved and properly fitted air-purifying respirator with appropriate HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with appropriate HEPA filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.
<b>Hand protection</b>	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
<b>Skin protection</b>	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Environmental Exposure Controls</b>	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
<b>Other protective measures</b>	Wash hands in the event of contact with this product/mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

<b>Appearance</b>	Clear liquid
<b>Color</b>	Colorless
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	6-8
<b>Melting point/freezing point</b>	No information identified.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	No information identified.
<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified.
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	Miscible with water.
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (<i>n</i>-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular weight</b>	Not applicable (Mixture)
<b>Molecular formula</b>	Not applicable (Mixture)

## SECTION 10 - STABILITY AND REACTIVITY

<b>Reactivity</b>	Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.
<b>Chemical stability</b>	Stable when stored as recommended.
<b>Possibility of hazardous reactions</b>	Not expected to occur.



## SECTION 10 - STABILITY AND REACTIVITY ...continued

<b>Conditions to avoid</b>	Avoid extreme temperatures.
<b>Incompatible materials</b>	No information identified.
<b>Hazardous decomposition products</b>	No information identified.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### Information on toxicological effects

**Route of entry** May be absorbed by inhalation, skin contact and ingestion.

#### Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Ethylene glycol	LD <sub>50</sub>	Oral	Rat	4700 mg/kg
	LD <sub>50</sub>	Oral	Mouse	5500 mg/kg
	LD <sub>50</sub>	Oral	Guinea Pig	6610 mg/kg
	LD <sub>50</sub>	Oral	Dog	5500 mg/kg
	LD <sub>50</sub>	Oral	Cat	1650 mg/kg
Sodium azide	LD <sub>50</sub>	Oral	Rat	27 mg/kg
	LD <sub>50</sub>	Oral	Mouse	27 mg/kg
	LD <sub>50</sub>	Dermal	Rabbit	20 mg/kg
Sodium lauroylsarcosinate	LD <sub>50</sub>	Inhalation	Rat	0.05-0.5 mg/L

**Irritation/Corrosion** No studies identified.

**Sensitization** No studies identified.

**STOT-single exposure** No studies identified.

**STOT-repeated exposure/Repeat-dose toxicity** Ethylene glycol was administered orally via drinking water to rats at doses of up to 4.0% in females and 2.0% in males. In the high-dose groups, 8/10 females and 2/10 males died prior to termination of the study. Body weights for both males and females were reduced in a dose-dependent manner. Leukocyte counts were also significantly reduced in a dose-related manner in females. In the kidney, there were dose-related increases in incidence and severity of renal tubular dilation, degeneration, acute inflammation, and presence of oxalate crystals.

**Reproductive toxicity** No studies identified.

**Developmental toxicity** No studies identified.

**Genotoxicity** No studies identified.

## SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

<b>Carcinogenicity</b>	No studies identified. None of the components of this mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
<b>Aspiration hazard</b>	No data available.
<b>Human health data</b>	See "Section 2 - Other Hazards"
<b>Additional information</b>	The toxicological properties of this mixture have not been fully characterized.

## SECTION 12 - ECOLOGICAL INFORMATION

### Toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Ethylene glycol	EC <sub>50</sub> /96h	Pseudothrauxis subcapitata (green algae)	6500-13000 mg/L
	LC <sub>50</sub> /96h	Oncorhynchus mykiss, rainbow trout	41000 mg/L
	LC <sub>50</sub> /96h	Oncorhynchus mykiss, rainbow trout	40761 mg/L [static]
	LC <sub>50</sub> /96h	Lepomis macrochirus, bluegill sunfish	27540 mg/L [static]
	LC <sub>50</sub> /96h	Pimephales promelas (fathead minnow)	40000-60000 mg/L [static]
	LC <sub>50</sub> /96h	Poecilia reticulata, freshwater fish	16000 mg/L [static]
Sodium azide	EC <sub>50</sub> /48h	Daphnia magna	46300 mg/L
	LC <sub>50</sub> /96h	Oncorhynchus mykiss	0.8 mg/L
	LC <sub>50</sub> /96h	Lepomis macrochirus	0.7 mg/L
Sodium lauroylsarcosinate	LC <sub>50</sub> /96h	Pimephales promelas	5.46 mg/L
	EC <sub>50</sub> (96h)	Danio rerio (zebra fish)	107 mg/L
	LC <sub>50</sub> (48h)	Daphnia magna	29.7 mg/L
	EC <sub>50</sub> (72 h)	Desmodesmus subspicatus (green algae)	79 mg/L
	NOEC (respiration inhibition test)	Bacteria (unspecified)	100 mg/L

<b>Additional toxicity information</b>	Sodium azide is toxic to aquatic organisms and should not be allowed to accumulate in metal piping as it has the potential to form explosive mixtures.
<b>Persistence and Degradability</b>	No data available.
<b>Bioaccumulative potential</b>	No data available.

## SECTION 12 - ECOLOGICAL INFORMATION ...continued

<b>Mobility in soil</b>	No data available.
<b>Results of PBT and vPvB assessment</b>	Not performed.
<b>Other adverse effects</b>	No data available.
<b>Note</b>	The environmental characteristics of this product/mixture have not been fully investigated. The above data are for the active ingredient and/or any other ingredient(s) where applicable. Although present at low concentrations, disposal should consider that sodium azide is present. Releases to the environment should be avoided.

## SECTION 13 - DISPOSAL CONSIDERATIONS

<b>Waste treatment methods</b>	Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.
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## SECTION 14 - TRANSPORT INFORMATION

<b>Transport</b>	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
<b>UN number</b>	None assigned.
<b>UN proper shipping name</b>	None assigned.
<b>Transport hazard classes and packing group</b>	None assigned.
<b>Environmental hazards</b>	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
<b>Special precautions for users</b>	Mixture not fully tested - avoid exposure.
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

## SECTION 15 - REGULATORY INFORMATION

<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
<b>Chemical safety assessment</b>	Not conducted.
<b>WHMIS classification</b>	CA3: H412, EUH032. This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations and the SDS contains all of the information required by those regulations.
<b>TSCA status</b>	Not listed
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	Not listed.
<b>Additional information</b>	No other information identified.

## SECTION 16 - OTHER INFORMATION

<b>Full text of H phrases and GHS classifications</b>	SI2 - Skin irritant Category 2. H315 - Causes skin irritation. EI2 - Eye irritant Category 2. H319 - Causes serious eye irritation. ATI2 - Acute Toxicity (Inhalation) Category 2. H330 - Fatal if inhaled. ATO2 - Acute Toxicity (Oral) Category 2. H300 - Fatal if swallowed. AA1- Aquatic toxicity (acute) - Category 1. H400 - Very toxic to aquatic life. CA1 - Aquatic toxicity (chronic) - Category 1. H410 - Very toxic to aquatic life with long lasting effects. CA3 - Aquatic toxicity (chronic) - Category 3. H412 - Harmful to aquatic life with long lasting effects. EUH032 - Contact with acids liberates very toxic gas.
<b>Sources of data</b>	Information from published literature and internal company data.
<b>Abbreviations</b>	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STEL - Short Term Exposure Limit; TDG - Transportation

## SECTION 16 - OTHER INFORMATION ...continued

<b>Abbreviations</b> ...continued	of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
<b>Issue Date</b>	17 July 2015
<b>Revisions</b>	This is the first version of this SDS.
<b>Disclaimer</b>	<p>The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical/diagnostic product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.</p>

# SAFETY DATA SHEET

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### Contact information

#### General

**Thermo**

SCIENTIFIC

Microgenics Corporation

46500 Kato Road

Fremont, CA 94538

Main: (510) 979-5000

Fax: (510) 979-5002

E-mail: [techservice.mgc@thermofisher.com](mailto:techservice.mgc@thermofisher.com)

#### Emergency telephone number

Chemtrec (24-hour availability):

+1 (800) 424-9300 (USA and Canada)

+1 (703) 527-3887 (International; Collect calls accepted)

+1 (202) 483-7616 (Europe)

#### Product identifier

CEDIA<sup>®</sup> Digitoxin Assay - Calibrators

#### Synonyms

CEDIA<sup>®</sup> Digitoxin Assay - **High and Low Calibrators for 100004**, CEDIA<sup>®</sup> Digitoxin Assay

#### Trade names

CEDIA<sup>®</sup> Digitoxin Assay

#### Chemical family

Mixture

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

*In vitro* diagnostic kit.

#### Note

The pharmacological, toxicological, and ecological properties of this product/mixture have not been fully characterized. This data sheet will be updated as more data become available.

#### Issue Date

17 July 2015

## SECTION 2 - HAZARDS IDENTIFICATION

### Classification of the substance or mixture

#### Globally Harmonized System [GHS]

Acute Toxicity (Oral) Category 4. Aquatic toxicity (chronic) - Category 3.

#### Other/Supplemental

Mixture not yet fully tested.

### Label elements

## SECTION 2 - HAZARDS IDENTIFICATION ...continued

### GHS hazard pictogram



**GHS signal word** Warning

**GHS hazard statements** H302 - Harmful if swallowed. H412 - Harmful to aquatic life with long lasting effects. EUH032 - Contact with acids liberates very toxic gas

**GHS precautionary statements** P264 - Wash hands thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P273 - Avoid release to the environment. P301+P312: IF SWALLOWED: Call a Poison Center or doctor/physician if you feel unwell. P330 - Rinse mouth. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

**Other hazards** The potential health hazards associated with exposure/handling of this mixture are unknown; no data specific for the mixture were identified. The following data describe the hazards of individual ingredients, where applicable.

This product/mixture contains human source material (human serum) and should be treated/handled as a potential biohazard. All such human serum has been derived from donors tested individually and shown by FDA approved methods to be free from antibodies to Human Immune Deficiency Virus and Hepatitis B and C. As no test method can offer complete assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions.

**Note** This mixture is classified as hazardous according to Regulation EC No 1272/2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA). The pharmacological, toxicological and ecological properties of this mixture have not been fully characterized.

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN</u>	<u>Amount</u>	<u>GHS</u>
		<u>CS#</u>		<u>Classification</u>
Human Source Material	N/A	N/A	≤97%	Not classified
Sodium azide	26628-22-8	247-852-1	≤1.3%	ATO2: H300; AA1: H400 , CA1: H410; EUH032

### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS ...continued

**Note** The ingredient(s) listed above are considered hazardous. Human serum is listed because it is a potential biohazard. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications. Product also contains trace amounts of active pharmaceutical ingredients (<0.005%) and methanol (<0.003%). The GHS classification is based on Regulation (EC) 1272/2008 and Hazard Communication Standard No. 1910.1200.

### SECTION 4 - FIRST AID MEASURES

#### Description of first aid measures

<b>Immediate Medical Attention Needed</b>	Yes
<b>Eye Contact</b>	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Skin Contact</b>	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Inhalation</b>	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
<b>Ingestion</b>	If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
<b>Protection of first aid responders</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed</b>	See Sections 2 and 11
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

### SECTION 5 - FIREFIGHTING MEASURES

**Extinguishing media** Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.



## SECTION 5 - FIREFIGHTING MEASURES ...continued

<b>Specific hazards arising from the substance or mixture</b>	No information identified. May emit toxic gases of carbon monoxide, carbon dioxide, and oxides of nitrogen.
<b>Flammability/Explosivity</b>	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.
<b>Advice for firefighters</b>	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

<b>Personal precautions, protective equipment and emergency procedures</b>	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.
<b>Methods and material for containment and cleaning up</b>	DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9).
<b>Reference to other sections</b>	See Sections 8 and 13 for more information.

## SECTION 7 - HANDLING AND STORAGE

<b>Precautions for safe handling</b>	This material should be handled at the Biosafety Level 2 (BSL2) consistent with the U.S. Department of Health and Human Services, the U.S. Public Health Service, Centers for Disease Control (CDC), and National Institute of Health (NIH) Guidelines "Biosafety in Microbiological and Biomedical Laboratories" (December 2009, HHS Publication No. (CDC) 21-1112). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing mist/spray.
<b>Conditions for safe storage including any incompatibilities</b>	Store at 2-8 °C in a well-ventilated area, away from incompatible materials. Keep container upright and tightly closed.
<b>Specific end use(s)</b>	No information identified.



**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

**Control  
Parameters/Occupational  
Exposure Limit Values  
...continued**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Sodium azide	ACGIH, Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, U.S.-California OSHA, United Kingdom	OEL-TWA	0.1 mg/m <sup>3</sup>
	NIOSH, U.S.-California OSHA	Ceiling	0.3 mg/m <sup>3</sup>
	Germany	OEL-STEL	0.4 mg/m <sup>3</sup>
	Germany	OEL-TWA	0.2 mg/m <sup>3</sup>

**Exposure/Engineering  
controls**

Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at aerosol/mist-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling.

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued

<b>Respiratory protection</b>	Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine handling tasks, an approved and properly fitted air-purifying respirator with appropriate HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with appropriate HEPA filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.
<b>Hand protection</b>	Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
<b>Skin protection</b>	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Environmental Exposure Controls</b>	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
<b>Other protective measures</b>	Wash hands in the event of contact with this product/mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

<b>Appearance</b>	Clear liquid
<b>Color</b>	Colorless
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	No information identified.
<b>Melting point/freezing point</b>	No information identified.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	No information identified.
<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified.
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	Miscible with water.
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (<i>n</i>-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular weight</b>	Not applicable (Mixture)
<b>Molecular formula</b>	Not applicable (Mixture)

## SECTION 10 - STABILITY AND REACTIVITY

<b>Reactivity</b>	Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.
<b>Chemical stability</b>	Stable when stored as recommended.
<b>Possibility of hazardous reactions</b>	Not expected to occur.

## SECTION 10 - STABILITY AND REACTIVITY ...continued

<b>Conditions to avoid</b>	Avoid extreme temperatures.
<b>Incompatible materials</b>	No information identified.
<b>Hazardous decomposition products</b>	No information identified.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### Information on toxicological effects

**Route of entry** May be absorbed by inhalation, skin contact and ingestion.

#### Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Human Source Material	--	--	--	--
Sodium azide	LD <sub>50</sub>	Oral	Rat	27 mg/kg
	LD <sub>50</sub>	Oral	Mouse	27 mg/kg
	LD <sub>50</sub>	Dermal	Rabbit	20 mg/kg

**Irritation/Corrosion** No studies identified.

**Sensitization** No studies identified.

**STOT-single exposure** No studies identified.

**STOT-repeated exposure/Repeat-dose toxicity** No studies identified.

**Reproductive toxicity** No studies identified.

**Developmental toxicity** No studies identified.

**Genotoxicity** No studies identified.

**Carcinogenicity** No studies identified. None of the components of this mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

**Aspiration hazard** No data available.

**Human health data** See "Section 2 - Other Hazards"

**Additional information** The toxicological properties of this mixture have not been fully characterized.

## SECTION 12 - ECOLOGICAL INFORMATION

### Toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Human Source Material	--	--	--
Sodium azide	LC <sub>50</sub> /96h	Oncorhynchus mykiss	0.8 mg/L
	LC <sub>50</sub> /96h	Lepomis macrochirus	0.7 mg/L
	LC <sub>50</sub> /96h	Pimephales promelas	5.46 mg/L

**Additional toxicity information** Sodium azide is toxic to aquatic organisms and should not be allowed to accumulate in metal piping as it has the potential to form explosive mixtures.

**Persistence and Degradability** No data available.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Results of PBT and vPvB assessment** Not performed.

**Other adverse effects** No data available.

**Note** The environmental characteristics of this product/mixture have not been fully investigated. The above data are for the active ingredient and/or any other ingredient(s) where applicable. Although present at low concentrations, disposal should consider that sodium azide is present. Releases to the environment should be avoided.

## SECTION 13 - DISPOSAL CONSIDERATIONS

**Waste treatment methods** Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

## SECTION 14 - TRANSPORT INFORMATION

**Transport** Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

**UN number** None assigned.

**UN proper shipping name** None assigned.

## SECTION 14 - TRANSPORT INFORMATION ...continued

<b>Transport hazard classes and packing group</b>	None assigned.
<b>Environmental hazards</b>	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
<b>Special precautions for users</b>	Mixture not fully tested - avoid exposure.
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

## SECTION 15 - REGULATORY INFORMATION

<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
<b>Chemical safety assessment</b>	Not conducted.
<b>WHMIS classification</b>	ATO4: H302; CA3: H412. This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations and the SDS contains all of the information required by those regulations.
<b>TSCA status</b>	Not listed
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	Not listed.
<b>Additional information</b>	No other information identified.

## SECTION 16 - OTHER INFORMATION

<b>Full text of H phrases and GHS classifications</b>	ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. ATO2 - Acute Toxicity (Oral) Category 2. H300 - Fatal if swallowed. AA1- Aquatic toxicity (acute) - Category 1. H400 - Very toxic to aquatic life. CA1 - Aquatic toxicity (chronic) - Category 1. H410 - Very toxic to aquatic life with long lasting effects. CA3 - Aquatic toxicity (chronic) - Category 3. H412 - Harmful to aquatic life with long lasting effects. EUH032 - Contact with acids liberates very toxic gas.
<b>Sources of data</b>	Information from published literature and internal company data.



## SECTION 16 - OTHER INFORMATION ...continued

<b>Abbreviations</b>	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
<b>Issue Date</b>	17 July 2015
<b>Revisions</b>	This is the second version of this SDS.
<b>Disclaimer</b>	<p>The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical/diagnostic product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.</p>