## SAFETY DATA SHEET

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

#### **Contact information**

General

# Thermo

**Microgenics Corporation** 

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

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

+1 (202) 483-7616 (Europe)

**Product identifier** 

CEDIA<sup>TM</sup> Technology - Powders (Group 1)

**Synonyms** 

#### **EA & ED Reagents for following Assays:**

10016409, CEDIA Benzodiazepine Assay 100085, CEDIA Benzodiazepine Assay 100094, CEDIA Benzodiazepine Assay 1775561, CEDIA Benzodiazepine Assay 10017365, CEDIA Barbiturate Assay 100084, CEDIA Barbiturate Assay 100093, CEDIA Barbiturate Assay 1661213, CEDIA Barbiturate Assay 100190, CEDIA Buprenorphine Assay 100240, CEDIA Buprenorphine Assay 10015658, CEDIA Buprenorphine Assay 100006, CEDIA Carbamazepine II Assay,

10016413, CEDIA Cocaine Assay 100086, CEDIA Cocaine Assay 100095, CEDIA Cocaine Assay 1661230, CEDIA Cocaine Assay 1732137, CEDIA LSD Assay

10016425, CEDIA Methadone Assay 100088, CEDIA Methadone Assay 100097, CEDIA Methadone Assay 1730916, CEDIA Methadone Assay

10016421, CEDIA Methadone Metabolite (EDDP) Assay 100087, CEDIA Methadone Metabolite (EDDP) Assay 100096, CEDIA Methadone Metabolite (EDDP) Assay 1868217, CEDIA Methadone Metabolite (EDDP) Assay

10016433, CEDIA Multi-Level THC Assay 100091, CEDIA Multi-Level THC Assay 100100, CEDIA Multi-Level THC Assay 1661256, CEDIA Multi-Level THC Assay

100015, CEDIA N-acetylprocainamide (NAPA) Assay

10018485SDS CEDIA Technology – Group 1A SDS Revision date: 11 January 2019, Version: 10 **Synonyms Continued** 

10016429, CEDIA Opiate Assay 100089, CEDIA Opiate Assay

10098, CEDIA Opiate Assay

1661248, CEDIA Opiate Assay

1815296, CEDIA Opiate 2K Assay

100090, CEDIA Opiate 2K Assay

100099, CEDIA Opiate 2K Assay

100172, CEDIA Phencyclidine (PCP) Assay

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1815784, CEDIA Phencyclidine (PCP) Assay

100003, CEDIA Phenobarbital II Assay

100002, CEDIA Phenytoin II Assay

100014, CEDIA Procainamide Assay

100170, CEDIA Propoxyphene Assay

100171, CEDIA Propoxyphene Assay

1661523, CEDIA Propoxyphene Assay

1815555, CEDIA Sample Check Assay

10016443, CEDIA Sample Check Assay

100008, CEDIA Theophylline II Assay

10014734, CEDIA Cocaine OFT Assay

10014740, CEDIA Cocaine OFT Assay

10018590, CEDIA Cocaine OFT Assay

10014764, CEDIA Cocaine OFT Assay

10021745, CEDIA Cocaine OFT Assay

10011931, CEDIA Amphetamine OFT Assay

10011932, CEDIA Amphetamine OFT Assay

10018579, CEDIA Amphetamine OFT Assay

10014947, CEDIA Amphetamine OFT Assay

10021729, CEDIA Amphetamine OFT Assay

10011934, CEDIA Methamphetamine OFT Assay

10011936, CEDIA Methamphetamine OFT Assay

10018595, CEDIA Methamphetamine OFT Assay

10014949, CEDIA Methamphetamine OFT Assay

10021753, CEDIA Methamphetamine OFT Assay

10010612, CEDIA Opiate OFT Assay

10010659, CEDIA Opiate OFT Assay

10018600, CEDIA Opiate OFT Assay

10014873, CEDIA Opiate OFT Assay

10021778, CEDIA Opiate OFT Assay

10010619, CEDIA PCP OFT Assay

10010665, CEDIA PCP OFT Assay

10018605, CEDIA PCP OFT Assay

10014888, CEDIA PCP OFT Assay

10021786, CEDIA PCP OFT Assay

10020849, CEDIA Buprenorphine II Assay

10020850, CEDIA Buprenorphine II Assay

10022971, CEDIA AB-PINACA Assay

10022977, CEDIA AB-PINACA Assay

10022949, CEDIA UR-144/XLR-11 Assay

10022955, CEDIA UR-144/XLR-11 Assay

**Trade names** CEDIA<sup>TM</sup> Technology

**Chemical family** Mixture

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

Criminal, Forensic, and Justice kits

**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]

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

H317 - May cause allergic skin reaction. 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. 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. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Other hazards

No data specific for the mixture were identified. The mixture contains bovine serum 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 antibodies 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.

Note

This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

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

Ingredient	CAS#	EINECS/ELIN CS#	Amount Amount	GHS Classification
Bovine serum albumin	9048-46-8	N/A	≤56%	SS1: H317; RS1: H334
Potassium phosphate monobasic	7778-77-0	231-913-4	≤3%	SI2: H315; EI2: H319
Potassium phosphate dibasic	7758-11-4	231-834-5	≤3%	SI2: H315; EI2: H319
Sodium azide	26628-22-8	247-852-1	≤2%	ATO2: H300; AA1: H400; CA1: H410; EUH032
Drug-specific antibody	N/A	N/A	0 - 0.5%	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. Product also contains trace levels of antibody conjugate (≤0.01%). See Section 16 for full text of GHS classifications.

#### **SECTION 4 - FIRST AID MEASURES**

Description of first aid measures

Immediate Medical Attention Needed Yes

**Eye Contact** 

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.

**Skin Contact** 

Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

Inhalation

**Ingestion** 

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.

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.

Protection of first aid responders

See Section 8 for Exposure Controls/Personal Protection recommendations.

Most important symptoms and effects, both acute and delayed

See Sections 2 and 11

Indication of immediate medical attention and special treatment needed, if necessary

Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

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#### **SECTION 5 - FIREFIGHTING MEASURES**

**Extinguishing media** Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for

surrounding fire and materials.

Specific hazards arising from the substance or mixture

No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, and potassium-containing compounds.

**Flammability/Explosivity** No explosivity or flammability data identified. High airborne concentrations of

finely divided organic particles can potentially explode if ignited.

**Advice for firefighters** 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

Personal precautions, protective equipment and emergency procedures 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.

**Environmental precautions** Do not empty into drains. Avoid release to the environment.

Methods and material for containment and cleaning up

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).

**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**

CompoundIssuerTypeOELBovine serum albumin----Potassium phosphate----monobasic----

Potassium phosphate dibasic

Sodium azide ACGIH, OEL-STEL 0.3 mg/m<sup>3</sup>

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

New Zealand, Ceiling

Portugal

10018485SDS CEDIA Technology – Group 1A SDS Revision date: 11 January 2019, Version: 10  $0.29 \text{ mg/m}^3$ 

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

#### **Control**

# Parameters/Occupational Exposure Limit Values

...continued

Compound	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>		
Sodium azide	ACGIH,	OEL-TWA	$0.1 \text{ mg/m}^3$		
	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.SCalifornia				
	OSHA, United				
	Kingdom				
	NIOSH,	Ceiling	$0.3 \text{ mg/m}^3$		
	U.SCalifornia				
	OSHA				
	Germany	OEL-STEL	$0.4 \text{ mg/m}^3$		
	Germany	OEL-TWA	$0.2 \text{ mg/m}^3$		
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. Laboratory operations should be conducted within a laboratory hood or biological safety cabinet if feasible. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling.

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

Respiratory protection

Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. If handling outside of containment device, an approved and properly fitted air-purifying respirator with HEPA filters should be considered to provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with HEPA filters or combination filters or a positive-pressure airsupplied 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.

**Hand protection** 

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.

Skin protection

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.

Eye/face protection

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.

**Controls** 

Environmental Exposure 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.

Other protective measures

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

> Lyophilized powder **Appearance**

EA Reagent - White to off-white Color

ED Reagent - Yellow to Orange

Odor No information identified. Odor threshold No information identified.

pН Not applicable

Melting point/freezing

point

No information identified.

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

boiling range

**Initial boiling point and** No information identified.

No information identified. Flash point

No information identified. **Evaporation rate** 

Flammability (solid, gas) No information identified.

Upper/lower No information identified.

flammability or explosive

limits

No information identified Vapor pressure

No information identified. Vapor density

No information identified. Relative density

Soluble in water. Water solubility

Solvent solubility No information identified.

Partition coefficient

(n-octanol/water)

No information identified.

**Auto-ignition** 

temperature

No information identified.

**Decomposition** 

temperature

No information identified.

Viscosity No information identified.

**Explosive properties** No information identified.

No information identified. **Oxidizing properties** 

Other information

Molecular formula Not applicable (Mixture)

Molecular weight Not applicable (Mixture)

#### SECTION 10 - STABILITY AND REACTIVITY

Sodium azide may react with lead or copper plumbing to form highly explosive Reactivity

metal azides.

Chemical stability Stable when stored as recommended.

Possibility of hazardous

reactions

Not expected to occur.

Conditions to avoid Avoid excessive heat.

**Incompatible materials** No information identified.

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

Hazardous decomposition

No information identified.

products

#### SECTION 11 - TOXICOLOGICAL INFORMATION

**Note** No data for this product/mixture were identified. The following data describe the

active ingredient and/or the individual ingredients where applicable.

## **Information on toxicological effects**

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

**Acute toxicity** 

<u>Compound</u>	<u>Type</u>	Route	<u>Species</u>	<u>Dose</u>
Bovine serum albumin				
Potassium phosphate monobasic	$LD_{50}$	Oral	Mouse	2820 mg/kg
	$LD_{50}$	Oral	Rat	3200 mg/kg
	$LD_{50}$	Dermal	Rabbit	>4640 mg/kg
Potassium phosphate dibasic	$LD_{50}$	Oral	Rat	>2000 mg/kg
Sodium azide	$LD_{50}$	Oral	Rat	27 mg/kg
	$LD_{50}$	Oral	Mouse	27 mg/kg
	$LD_{50}$	Dermal	Rabbit	20 mg/kg
Drug-specific antibody				

**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** Oral doses of up to 1000 mg/kg/day potassium phosphate dibasic were not

associated with reproductive toxicity in rats; the NOAEL was 1000 mg/kg/day.

**Developmental toxicity** Oral doses of up to 1000 mg/kg/day potassium phosphate dibasic were not

associated with developmental toxicity in rats; the NOAEL was 1000 mg/kg/day.

**Genotoxicity** Potassium phosphate dibasic was negative for genotoxic effects in an *in vitro* 

bacterial cell mutagenicity assay (Ames) and in an in vitro chromosomal

aberration test.

**Carcinogenicity** No studies identified. None of the components of the 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.

#### SECTION 11 - TOXICOLOGICAL INFORMATION ... continued

**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>	Concentration
Bovine serum albumin			
Potassium phosphate monobasic	LC50 (24 h)	Dreissena polymorpha (zebra mussel)	92-169 mg/L
Potassium phosphate dibasic	LC <sub>50</sub> (96 h)	Oryzias latipes (Japanese rice fish)	> 100 mg/L
	$EC_{50}$ (48 h)	Daphnia magna (water flea)	118.9 mg/L
	EC <sub>50</sub> /72h	Pseduokirchneriella subcapitata	>100 mg/L
	(growth rate reduction)	(green algae)	
	EC <sub>50</sub> /72h (biomass)	Pseduokirchneriella subcapitata (green algae)	60 mg/L
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

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. Rinse waters resulting

from spill cleanups should be discharged in an environmentally safe manner.

## **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

Avoid release to the environment.

Transport in bulk according Not applicable.

to Annex II of

MARPOL73/78 and the IBC

Code

#### **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.

**TSCA status** All components of mixture are on TSCA Inventory or are exempt.

SARA section 313 Not listed.

California proposition 65 Not listed.

#### SECTION 15 - REGULATORY INFORMATION ... continued

Additional information

Federal German Government Water Hazard Classification:

WHC 3

#### **SECTION 16 - OTHER INFORMATION**

Full text of H phrases and GHS classifications

SI2 - Skin irritant Category 2. H315 - Causes skin irritation. 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. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction. 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. 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; PBT -Persistent, Bioaccumulative, and Toxic; 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; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**Issue Date** 

11 January 2019

Revisions

This is the fourth version of this SDS.

**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.

## **SECTION 16 - OTHER INFORMATION** ... continued

Disclaimer ... continued

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

**Microgenics Corporation** 

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**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>TM</sup> Technology - Group A (Liquids)

**Synonyms** 

#### **EA & ED Reagents for following Assays:**

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10014734, CEDIA Cocaine OFT Assay

10014740, CEDIA Cocaine OFT Assay

10018590, CEDIA Cocaine OFT Assay

10014764, CEDIA Cocaine OFT Assay

10021745, CEDIA Cocaine OFT Assay

10011931, CEDIA Amphetamine OFT Assay

10011932, CEDIA Amphetamine OFT Assay

10018579, CEDIA Amphetamine OFT Assay

10014947, CEDIA Amphetamine OFT Assay

10021729, CEDIA Amphetamine OFT Assay

10011934, CEDIA Methamphetamine OFT Assay

10011936, CEDIA Methamphetamine OFT Assay

10018595, CEDIA Methamphetamine OFT Assay

10014949, CEDIA Methamphetamine OFT Assay

10021753, CEDIA Methamphetamine OFT Assay

10010612, CEDIA Opiate OFT Assay

10010659, CEDIA Opiate OFT Assay

10018600, CEDIA Opiate OFT Assay

10014873, CEDIA Opiate OFT Assay

10021778, CEDIA Opiate OFT Assay

10010619, CEDIA PCP OFT Assay

10010665, CEDIA PCP OFT Assay

10018605, CEDIA PCP OFT Assay

10014888, CEDIA PCP OFT Assay

10021786, CEDIA PCP OFT Assay

10020849, CEDIA Buprenorphine II Assay 10020850, CEDIA Buprenorphine II Assay

10022971, CEDIA AB-PINACA Assay (CJF)

10022977, CEDIA AB-PINACA Assay (CJF)

10023433, CEDIA AB-PINACA Assay (CE)

10023439, CEDIA AB-PINACA Assay (CE)

10022949, CEDIA UR-144/XLR-11 Assay

10022955, CEDIA UR-144/XLR-11 Assay

Trade names

CEDIA<sup>TM</sup> Technology

**Chemical family** Mixture

Relevant identified uses of the substance or mixture and uses advised against In vitro diagnostic kit. Contains multiple liquid reagents packaged as separate

vials. Criminal, Forensic, and Justice kits

**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]

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

H317 - May cause allergic skin reaction. 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. 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. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Other hazards

No data specific for the mixture were identified. The mixture contains bovine serum 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 antibodies 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.

Note

This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

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

<u>Ingredient</u>	CAS#	EINECS/ELIN	Amount	GHS .
MOPS	1132-61-2	<u>CS#</u> 214-478-5	≤3.0%	Classification SI2: H315; EI2: H319; STOT-SE3: H335
Potassium phosphate dibasic	7758-11-4	231-834-5	≤2.1%	SI2: H315; EI2: H319
Bovine serum	N/A	N/A	≤1.0%	SS1: H317;
Sodium azide	26628-22-8	247-852-1	0.1 – 0.3%	RS1: H334 ATO2: H300; AA1: H400;
Drug-specific antibody	N/A	N/A	0 – 0.1%	CA1: H410; EUH032 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 GHS classifications.

#### **SECTION 4 - FIRST AID MEASURES**

Description of first aid measures

Immediate Medical
Attention Needed

Yes

Attention Needed

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.

Skin Contact

**Eye Contact** 

Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

Inhalation

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.

Ingestion

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.

Protection of first aid responders

See Section 8 for Exposure Controls/Personal Protection recommendations.

Most important symptoms and effects, both acute and delayed

See Sections 2 and 11

Indication of immediate medical attention and special treatment needed, if Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

necessary

#### **SECTION 5 - FIREFIGHTING MEASURES**

**Extinguishing media** Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for

surrounding fire and materials.

Specific hazards arising from the substance or mixture

No information identified. May emit toxic gases of carbon monoxide, carbon dioxide, oxides of nitrogen, and potassium-containing compounds.

Flammability/Explosivity No explosivity or flammability data identified. As product is an aqueous solution,

it is not expected to be flammable or explosive.

**Advice for firefighters** 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

Personal precautions, protective equipment and emergency procedures 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.

**Environmental precautions** Do not empty into drains. Avoid release to the environment.

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 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

#### **Control**

## **Parameters/Occupational**

## **Exposure Limit Values**

Compound<br/>MOPSIssuer<br/>--Type<br/>--OELPotassium phosphate dibasic----Bovine serum------

Sodium azide ACGIH, OEL-STEL 0.3 mg/m<sup>3</sup>

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

New Zealand, Ceiling

 $0.29 \text{ mg/m}^3$ 

Portugal

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

#### **Control**

# Parameters/Occupational Exposure Limit Values

...continued

Compound	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>		
Sodium azide	ACGIH,	OEL-TWA	$0.1 \text{ mg/m}^3$		
	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.SCalifornia				
	OSHA, United				
	Kingdom				
	NIOSH,	Ceiling	$0.3 \text{ mg/m}^3$		
	U.SCalifornia				
	OSHA				
	Germany	OEL-STEL	$0.4 \text{ mg/m}^3$		
	Germany	OEL-TWA	$0.2 \text{ mg/m}^3$		
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 aerosol/mist-generating points. Laboratory operations should be conducted within a laboratory hood or biological safety cabinet if feasible. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling.

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

**Respiratory protection** Choice of respiratory protection should be appropriate to the task and the level of

existing engineering controls. If handling outside of containment device, an approved and properly fitted air-purifying respirator with HEPA filters should be considered to provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with HEPA filters or combination filters or a positive-pressure airsupplied 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.

**Hand protection** 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.

Skin protection 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.

Wear safety glasses with side shields, chemical splash goggles, or full face shield, Eye/face protection

> 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.

**Controls** 

Environmental Exposure 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.

Other protective measures

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

> Clear liquid **Appearance**

Colorless Color

No information identified. Odor **Odor threshold** No information identified.

рH 6-8

Melting point/freezing

point

No information identified.

boiling range

**Initial boiling point and** No information identified.

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

Flash point No information identified.

**Evaporation rate** No information identified.

Flammability (solid, gas) No information identified.

Upper/lower No information identified.

flammability or explosive

limits

Vapor pressure No information identified

No information identified. Vapor density

No information identified. **Relative density** 

Water solubility Miscible with water.

Solvent solubility No information identified.

**Partition coefficient** 

(n-octanol/water)

No information identified.

**Auto-ignition** temperature

No information identified.

**Decomposition** 

temperature

No information identified.

Viscosity No information identified. **Explosive properties** No information identified.

**Oxidizing properties** No information identified.

Other information

Molecular formula Not applicable (Mixture)

Molecular weight Not applicable (Mixture)

#### SECTION 10 - STABILITY AND REACTIVITY

Sodium azide may react with lead or copper plumbing to form highly explosive Reactivity

metal azides.

Chemical stability Stable when stored as recommended.

Possibility of hazardous

reactions

Not expected to occur.

Conditions to avoid Avoid excessive heat.

**Incompatible materials** No information identified.

**Hazardous decomposition** 

No information identified.

products

#### 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>	Route Property of the Route	<u>Species</u>	<u>Dose</u>
MOPS				
Potassium phosphate dibasic	$LD_{50}$	Oral	Rat	>2000 mg/kg
Bovine serum				
Sodium azide	$LD_{50}$	Oral	Rat	27 mg/kg
	$LD_{50}$	Oral	Mouse	27 mg/kg
	$LD_{50}$	Dermal	Rabbit	20 mg/kg
Drug-specific antibody				

**Irritation/Corrosion** No studies identified.

**Sensitization** No studies identified. As bovine serum is derived from animal (foreign) protein,

there is potential for the material to cause an allergic response in humans. Occupational exposure to bovine serum 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.

**Carcinogenicity** No studies identified. None of the components of the 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.

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#### **SECTION 12 - ECOLOGICAL INFORMATION**

#### **Toxicity**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	Concentration
MOPS			
Potassium phosphate dibasic	LC <sub>50</sub> (96 h)	Oryzias latipes (Japanese rice fish)	> 100 mg/L
	$EC_{50}$ (48 h)	Daphnia magna (water flea)	118.9 mg/L
	EC <sub>50</sub> /72h (growth rate reduction)	Pseduokirchneriella subcapitata (green algae)	>100 mg/L
	EC <sub>50</sub> /72h (biomass)	Pseduokirchneriella subcapitata (green algae)	60 mg/L
Bovine 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 potentialNo data available.Mobility in soilNo data available.Description of DRT and a DarkNot performed.

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. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner.

#### **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

Avoid release to the environment.

Transport in bulk according Not applicable.

to Annex II of

MARPOL73/78 and the IBC

Code

#### **SECTION 15 - REGULATORY INFORMATION**

Safety, health and environmental irregulations/legislation in

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.

**TSCA status** All components of mixture are on TSCA Inventory or are exempt.

SARA section 313 Not listed.

California proposition 65 Not listed.

**Additional information** Federal German Government Water Hazard Classification:

WHC 3

#### **SECTION 16 - OTHER INFORMATION**

## Full text of H phrases and GHS classifications

SI2 - Skin irritant Category 2. H315 - Causes skin irritation. EI2 - Eye irritant Category 2. H319 - Causes serious eye irritation. STOT-SE3 - Specific Target Organ Toxicity Following Single Exposure Category 3. H335 - May cause respiratory irritation. RS1 - Respiratory Sensitizer Category 1. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction. 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. 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; PBT -Persistent, Bioaccumulative, and Toxic; 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; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**Issue Date** 

11 January 2019

Revisions

This is the third version of this SDS.

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,

## SECTION 16 - OTHER INFORMATION ... continued

**Disclaimer** ...continued

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.