SAFETY DATA SHEET

MICROGENICS
Part of Thermo Fisher Scientific

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

Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538
Main: 510) 979-5000
Fax: 425-205-2901
E-mail:
Techservice.mgc@thermofisher.com

Emergency telephone number (Chemtrec): 1-(800) 424-9300 (US and Canada)
1-(703) 527-3887
International access (collect calls accepted)
1-(202) 483-7616 Europe

Product identifier CEDIA® Buprenorphine Calibrators & Controls

Synonyms 100241 CEDIA® Buprenorphine Calibrator (0 ng/mL),
100242 CEDIA® Buprenorphine Calibrator (5 ng/mL),
100243 CEDIA® Buprenorphine Calibrator (20 ng/mL),
100244 CEDIA® Buprenorphine Calibrator (50 ng/mL),
100245 CEDIA® Buprenorphine Calibrator (75 ng/mL),
100246 CEDIA® Buprenorphine Control, Low, (3.0 ng/mL),
100246 CEDIA® Buprenorphine Control, High (7.0 ng/mL)

Trade names CEDIA® Buprenorphine Calibrators and Controls

Chemical family Mixture

Relevant identified uses of the substance or mixture and uses advised against 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 Date12/3/2012 Revision Date 12/3/2012

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Regulation (EC) 1272/2008 [GHS] Mixture not yet fully tested.

Directive 67/548/EEC or 1999/45/EC Mixture not yet fully tested.

Label elements

CLP/GHS hazard pictogram None required

SECTION 2 - HAZARDS IDENTIFICATION …continued

CLP/GHS signal word	Warning
CLP/GHS hazard statements	Not applicable as product mixture is not classified according to GHS or CLP.
CLP/GHS precautionary statements	No precautionary statements required as product mixture is not classified under GHS or CLP.
Other hazards	This product contains human urine and should be treated/handled as a potential biohazard. The urine 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.
US Signal word	Warning
US Hazard overview	Mixture not yet fully tested. This product contains human urine and should be treated/handled as a potential biohazard.
Note	The pharmacological, toxicological, and ecological properties of this mixture have not been fully characterized. See Section 16 for full text of EU and GHS classifications. The GHS classifications are based on Regulation (EC) 1272/2008.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	EINECS/ELINCS#	Amount	EU Classification	GHS Classification
Urine (Human)	N/A	N/A	80-90%	Not classified	Not classified
Sodium azide	26628-22-8	247-852-1	0.07-0.09%	Very Toxic - T+: R28, R32; N: R50/53	ATO2: H300; AA1: H400 , CA1: H410; EUH032
Buprenorphine	52485-79-7	N/A	1-800 ppb	Xn: R22, R63	ATO4: H302; RT2: H361

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 EU and GHS classifications. The pharmacological, toxicological, and ecological properties of this mixture have not been fully characterized. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed	No. If exposed or concerned: Get medical advice/attention.
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	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 necessary	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.
Specific hazards arising from the substance or mixture	No information identified. May emit toxic fumes of carbon monoxide and carbon dioxide.
Flammability/Explosivity	No explosivity or flammability data identified. Not expected to be flammable or explosive.
Advice for firefighters	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. 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	Surround spill with absorbents and place a damp cloth or towel over the area to minimize entry 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, such as 5% chlorine bleach solution.
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	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 dust/mist/spray.
Conditions for safe storage including any incompatibilities	Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling. Avoid ingestion and inhalation. Use with adequate ventilation. 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	Issuer	Type	OEL
Urine (Human)	--	--	--
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^3

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION …continued

Control Parameters/Occupational Exposure Limit Values
…continued

Compound	Issuer	Type	OEL
	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/m³
	New Zealand, Portugal	Ceiling	0.29 mg/m³
	NIOSH, U.S.-California OSHA	Ceiling	0.3 mg/m³
	Germany	OEL-STEL	0.4 mg/m³
	Germany	OEL-TWA	0.2 mg/m³
Buprenorphine	--	--	--

DNELs/PNECs None identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION …continued

Exposure/Engineering controls	None normally required. When practicable, handle material in enclosed or contained processes or in processes with effective local exhaust ventilation.
Respiratory protection	When possible, handle material in enclosed processes or containers. If it is properly handled with effective ventilation or containment, respiratory protection should not be needed.
Hand protection	Wear nitrile, rubber or other impervious gloves if skin contact is possible. If 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.
Environmental Exposure Controls	Disposal should consider that sodium azide is present (but at concentrations that would not make the product classified as hazardous to the environment). Sodium azide is toxic to aquatic organisms and should not be allowed to accumulate in metal piping and/or drains as it has the potential to form explosive mixtures. 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

Appearance	Clear liquid
Color	Amber
Odor	No information identified.
Odor threshold	No information identified.
pH	5-8
Melting point/freezing point	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES …continued

Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	Miscible in 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 weight	No information identified.
Molecular formula	No information identified.

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Stable when stored as recommended.
Possibility of hazardous reactions	Not expected to occur.
Conditions to avoid	Avoid temperatures ≥ 25° C.

SECTION 10 - STABILITY AND REACTIVITY …continued

Incompatible materials No information identified.

Hazardous decomposition products 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

Compound	Type	Route	Species	Dose
Urine (Human)	--	--	--	--
Sodium azide	LD_{50}	Oral	Rat	27 mg/kg
	LD_{50}	Oral	Mouse	27 mg/kg
	LD_{50}	Dermal	Rabbit	20 mg/kg
Buprenorphine	LD_{50}	Oral	Mouse	260 mg/kg
	LD_{50}	Oral	Rat	>600 mg/kg
	LD_{50}	Intravenous (IV)	Mouse	24 mg/kg
	LD_{50}	Intravenous (IV)	Rat	31 mg/kg
	LD_{50}	Dermal	Rat	>100 mg/kg
	LD_{50}	Inhalation	Rat	>0.93 mg/L

Irritation/Corrosion Buprenorphine was mildly irritating to rabbit skin.

Sensitization Buprenorphine was not a sensitizer or phototoxicant when tested in guinea pigs.

STOT-single exposure No studies identified.

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

Reproductive toxicity Buprenorphine did not impair fertility in rats treated with oral, intramuscular (IM), or subcutaneous (SC) doses of buprenorphine (up to 80, 5, and 5 mg/kg/day, respectively).

Developmental toxicity Buprenorphine caused skeletal abnormalities in rats and rabbits treated parenterally at ≥1 and ≥5 mg/kg/day, respectively. Additionally, fetal developmental delays and increased resorptions were seen in studies with rats and/or rabbits. Buprenorphine was also shown to delay parturition in the rat. Buprenorphine did not cause a statistically significant increase in birth defects in rats and rabbits administered IM or SC doses as high as 5 mg/kg/day, IV doses up to 0.8 mg/kg/day, or oral doses up to 160 mg/ kg/day (rats only).

SECTION 11 - TOXICOLOGICAL INFORMATION …continued

Genotoxicity Buprenorphine was not mutagenic in yeast, bacterial, and cultured mammalian cells; it was not clastogenic in Chinese hamster ovary, bone marrow, and sperm cells. Equivocal results were obtained in the Ames bacterial mutagenicity assay. Buprenorphine was positive in an *E. coli* survival test, a DNA synthesis inhibition test in mice (*in vitro* and *in vivo*), and an unscheduled DNA synthesis test in mice.

Carcinogenicity No studies identified. This product/mixture and its ingredients are not 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 Mixture not yet fully tested.

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Urine (Human)	--	--	--
Sodium azide	LC_{50}/96h	Oncorhynchus mykiss	0.8 mg/L
	LC_{50}/96h	Lepomis macrochirus	0.7 mg/L
	LC_{50}/96h	Pimephales promelas	5.46 mg/L
Buprenorphine	NOEC/21 days (survival)	Daphnia magna	1.950 mg/L
	NOEC/21 days (growth)	Daphnia magna	0.883 mg/L
	NOEC/21 days (repro)	Daphnia magna	0.883 mg/L
	NOEC/33 days (growth)	Pimephales promelas, fathead minnow	0.462 mg/L
	NOEC/33 days (survival)	Pimephales promelas, fathead minnow	0.137 mg/L
	NOEC/33 days (hatch)	Pimephales promelas, fathead minnow	0.137 mg/L
	NOEC (72h)	Pseduokirchneriella subcapitata (green algae)	0.319 mg/L

Additional toxicity information Buprenorphine has no significant bioaccumulation potential, as indicated by the measured log Kow value of 3.11 at pH 7 and, more significantly, a measured mean bioconcentration factor of 57. In a 35-day study with the rainbow trout at concentrations of 1.0 and 10.0 µg/L total radioactivity was measured in edible, non-edible and whole fish tissue. The highest mean bioconcentration factor for buprenorphine was in the non-edible portion of fish at the higher exposure concentration. This value was 57.

Persistence and Degradability No data available.

Bioaccumulative potential No data available.

SECTION 12 - ECOLOGICAL INFORMATION …continued

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. Disposal should consider that sodium azide is present (but at concentrations that would not make the product classified as hazardous to the environment). 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. 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 complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines.
Chemical safety assessment	Not conducted.
OSHA Hazardous	Warning. Mixture not fully tested.
WHMIS classification	This product is not classified as hazardous under the hazard criteria of the Controlled Products Regulations. The SDS contains all of the information required by those regulations.
TSCA status	Not listed
SARA section 313	Not listed.
California proposition 65	Not listed.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	Xn - Harmful. R22 - Harmful if swallowed. R63 - Possible risk of harm to the unborn child.
Full text of H phrases, P phrases and GHS classification	ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. RT2 - Reproductive toxicity Category 2. H361d - Suspected of damaging the unborn child.
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 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 Labelling 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

SECTION 16 - OTHER INFORMATION …continued

Abbreviations …continued

NTP - National Toxicology Program OEL - Occupational Exposure Limit OSHA - Occupational Safety and Health Administration PBT - Persistent, Bioaccumulative and Toxic PNEC - Predicted No Effect Concentration PPB – parts per billion SARA - Superfund Amendments and Reauthorization Act STEL - Short Term Exposure Limit TDG - Transport Dangerous Goods TSCA - Toxic Substances Control Act TWA - Time Weighted Average WHMIS - Workplace Hazardous Materials Information System

Revision

This is the forth draft 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 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.