

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

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**Product identifier** CEDIA® Buprenorphine Calibrators and Control

**Synonyms** 100241 CEDIA® Buprenorphine Negative Calibrator  
100242 CEDIA® Buprenorphine 5 ng/mL Calibrator  
100243 CEDIA® Buprenorphine 20 ng/mL Calibrator  
100244 CEDIA® Buprenorphine 50 ng/mL Calibrator  
100245 CEDIA® Buprenorphine 75 ng/mL Calibrator  
100246 CEDIA® Buprenorphine Controls

**Trade names** CEDIA® Buprenorphine Calibrators and Control

**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.

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**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

**CLP/GHS signal word** Warning

## SECTION 2 - HAZARDS IDENTIFICATION ...continued

<b>CLP/GHS hazard statements</b>	None required
<b>CLP/GHS precautionary statements</b>	None required
<b>EU symbol/indication of danger</b>	None required
<b>Risk (R) Phrase(s)</b>	None required
<b>Safety Advice</b>	None required
<b>Other hazards</b>	<p>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.</p> <p>This product contains human urine and should be treated/handled as a potential biohazard. All such human 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.</p>
<b>US Signal word</b>	Caution
<b>US Hazard overview</b>	Mixture not yet fully tested. This product contains human urine and should be treated/handled as a potential biohazard.
<b>Note</b>	This product/mixture does not meet criteria for classification according to Directive 1999/45/EC, Regulation (EC) No 1272/2008 (EU CLP) and applicable US regulations, however it should be considered hazardous as it is potentially biohazardous. The pharmacological, toxicological, and ecological properties of this mixture have not been fully characterized. The CLP/GHS classifications are based on Regulation (EC) 1272/2008 and on the revised OSHA hazard communication standard. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 1999/45/EC.

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN</u> <u>CS#</u>	<u>Amount</u>	<u>EU</u> <u>Classification</u>	<u>GHS</u> <u>Classification</u>
Urine (Human)	N/A	N/A	≥99.9%	Not classified	Not classified
Sodium azide	26628-22-8	247-852-1	≤0.09%	Very Toxic - T+: R28, R32; N: R50/53	ATO2: H300; AA1: H400 , CA1: H410; EUH032

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

**Note** The ingredient(s) listed above are considered hazardous. Human urine is listed because it is a potential biohazard. The remaining components are non-hazardous and/or present at amounts below reportable limits. Product contains trace amounts of active pharmaceutical ingredient (<0.0001%). See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/ EEC and the CLP/GHS classification is based on Regulation (EC) 1272/2008.

### 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

**Specific hazards arising from the substance or mixture** No information identified. May emit toxic gases of carbon monoxide, carbon dioxide, and oxides of nitrogen.

**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** 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 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 ...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 should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls.
<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>	Liquid
<b>Color</b>	Light yellow
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	5.9-6.1
<b>Melting point/freezing point</b>	No information identified.
<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.

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

<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 (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.
<b>Conditions to avoid</b>	Avoid temperatures $\geq 25^{\circ}$ C.
<b>Incompatible materials</b>	No information identified.



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

**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

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Urine (Human)	--	--	--	--
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>
Urine (Human)	--	--	--
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. 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.

## 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 complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local or regional authorities for more information.
<b>Chemical safety assessment</b>	Not conducted.
<b>OSHA Hazardous</b>	Caution. Mixture not yet fully tested. This product contains human urine and should be treated/handled as a potential biohazard.
<b>WHMIS classification</b>	This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.
<b>TSCA status</b>	All components of mixture are on TSCA Inventory or are exempt.
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	Not listed.

## SECTION 16 - OTHER INFORMATION

<b>Full text of R phrases and EU Classifications</b>	T+ - Very toxic. R28 - Very toxic if swallowed. R32 - Contact with acids liberates very toxic gas N - Dangerous for the Environment. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
<b>Full text of H phrases, P phrases and GHS classification</b>	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.

## SECTION 16 - OTHER INFORMATION ...continued

<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 of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
<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>