

SECTION 1: PRODUCT & SUPPLIER IDENTIFICATION**Lin-Zhi International (LZI), Inc.**

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Product Name: Urinalysis Norbuprenorphine Calibrators and Controls
Catalog Numbers: A53687, A66824, A68825, A68826, A68827, A68828, A68829, A68830
Description: Norbuprenorphine urine based calibrators and controls for use in combination with the buprenorphine urinalysis enzyme immunoassay (EIA) product catalog number A53684. The products are contained in dropper bottles, packaged in small boxes, distributed by Beckman Coulter, and manufactured for use on their Synchron® Systems. For further information, please refer to the product inserts included inside of the EIA box or go to www.lin-zhi.com for the product inserts specifically for calibrators and/or controls.

SECTION 2: HAZARDS IDENTIFICATION

Classification: The product is not considered a hazardous mixture, but it is potentially biohazardous because it contains processed human urine. It contains a trace quantity amount ($< 0.1\%$ w/v) of sodium azide (NaN_3 , CAS No. 26628-22-8) which is added as a preservative. Trace amounts of acids and bases have been used only during product processing and to balance the pH of the product. Testing of the product itself to determine health hazards has not been performed. The product does not contain carcinogens.

Labeling: The product label states the product contains sodium azide (0.09%) as preservative.

Symbol: N/A

Hazard Statement: N/A

Precautionary Statements: Although sodium azide is only $< 0.1\%$ w/v of the product, the Precautions and Warning section of the product insert states:

- *Harmful if swallowed.*
- *The calibrators / controls contain sodium azide preservative, which may react with lead or copper plumbing to form potentially explosive metal azide. When disposing such liquids always flush with a large volume of water to prevent azide build-up.*
- *The calibrators / controls are prepared from non-sterile human urine. They are not tested by licensed reagents for the presence of antibodies to human immunodeficiency viruses, the hepatitis antigens, and/or anti-hepatitis antibodies. They should be handled as potentially infectious. Always apply good laboratory practice to avoid any skin contact or ingestion.*
- *Do not use the calibrators / controls beyond their expiration dates.*

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

There is no hazardous ingredient present in the product which is above its appropriate cutoff levels according to the Globally Harmonized System (GHS). The cutoff level for ingredients causing respiration/skin sensitization, reproductive toxicity, carcinogenicity, and category 1 mutagenicity is $\geq 0.1\%$. The cutoff level for all other hazard classes is $\geq 1\%$. Therefore no components need to be disclosed according the applicable regulations. The products do contain processed human urine which has not been tested for the presence of antibodies to the human immunodeficiency virus or hepatitis antigens/antibodies. The products should be handled as potentially biohazardous using standard biosafety precautions.

SECTION 4: FIRST AID MEASURES

Potential Routes of Exposure: Skin contact, eye contact, and accidental ingestion. Inhalation is highly unlikely.

Skin contact: Wash affected area thoroughly with soap and water. Remove contaminated clothing and shoes.

Eye contact: Flush with plenty of water for at least 15 minutes.

Ingestion: If swallowed, wash out mouth with water and drink plenty of water.

If adverse symptoms are experienced, contact a physician as a precautionary measure.

SECTION 5: FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Typical media is suitable.

Unsuitable extinguishing media: None are known.

Specific hazards in case of fire: None are known.

Special protective equipment and precaution for fire fighters: Use the typical equipment and precautions. There is a recommendation to wear self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions: If the liquid product is spilled, take the proper precautions to minimize exposure to it by wearing the appropriate personal protective equipment (PPE).

Cleaning Methods: Quarantine the spill area and minimize spreading of spilled liquid. Soak up the liquid with a suitable absorbent material such as a mat pad. Clean the spill area thoroughly with soap and water. When disposing of the product by means of plumbing, always flush with a large volume of water to prevent long-term sodium azide accumulation in the metal plumbing. Observe and obey federal, state, and local laws and ordinances regarding proper disposal practices.

Environmental Precautions: Collect the spilled liquid, absorbent material, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations. Prevent runoff into sewers, storm drains, surface waters, and soil.

SECTION 7: HANDLING AND STORAGE

Handling: Wear PPE such as gloves, lab coats, and safety glasses as necessary. Avoid contact with eyes or skin.

Storage: Keep the product tightly closed. Store at 2-8°C. Do not expose to extreme temperatures.

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Occupational Exposure Limits: There are no established exposure limits for this product.

Personal Protective Equipment (PPE)

Eye Protection: Wear safety glasses with side shields. Have eye wash stations available as a precaution.

Skin Protection: Wear lab coat over clothing and gloves.

Respiratory Protection: Inhalation is unlikely.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

	<u>Calibrators</u>	<u>Controls</u>
<i>Physical state:</i>	Liquid	Liquid
<i>Appearance:</i>	Transparent	Transparent
<i>Odor</i>	No odor	No odor
<i>pH:</i>	~6.0 to 7.0	~6.0 to 7.0
<i>Flammable Liquid:</i>	No	No
<i>Solubility:</i>	Soluble in Water	Soluble in Water
<i>Specific Gravity:</i>	~1.0	~1.0

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Possibility of hazardous reactions: Although sodium azide is < 0.1% w/v of the product, sodium azide build up may occur over time in metal plumbing if the product is not properly disposed, leading to explosive and shock sensitive components. An extra precaution is to schedule a routine assessment of the plumbing system.

Conditions to Avoid: Sodium azide build up in metal plumbing may be avoided by flushing the product with a large volume of water when disposing of it. Additionally, introducing the product to acidic conditions below a pH of 4.8 should be avoided.

Materials to Avoid: None are known.

Hazardous Decomposition Products: None are known.

SECTION 11: TOXICOLOGICAL INFORMATION

Skin (Irritancy and Acute Toxicity): No data is available.

Eye (Irritancy and Acute Toxicity): No data is available.

Ingestion: No data is available.

Chronic Toxicity (Target Organ Effects): No data is available.

Mutagenicity: No data is available.

Inhalation: No data is available. Low risk of inhalation.

SECTION 12: ECOLOGICAL INFORMATION

Persistence and Degradability: No data is available.

Bio-accumulative potential: No data is available.

Mobility: No data is available.

Aquatic Toxicity: No data is available.

SECTION 13: DISPOSAL CONSIDERATION

The proper disposal method consists of running a large volume of water with the disposal of the product and/or product wastes in order to prevent sodium azide buildup in metal plumbing. Dispose of the product separately from other waste materials. Follow applicable local, state, and federal regulations for disposal, as some guidelines may require more precautionary measures for disposal of dilute sodium azide liquids, such as segregation of the waste products and treatment.

SECTION 14: TRANSPORT INFORMATION

The calibrators and controls are considered to be non-hazardous but potentially biohazardous for transport.

Proper Shipping Name: Urinalysis Norbuprenorphine Calibrators and Controls

Hazard Class: Non-hazardous but potentially biohazardous

Packing Group: N/A

Marine Pollutant: No

Note: These are perishable, liquid products. The products are packed with ice to maintain an approximately 2-8°C temperature range during transit.

SECTION 15: REGULATORY INFORMATION

The regulatory data in this section is not intended to be all-inclusive, only a selected regulation is represented.

European Inventory of Existing Commercial Chemical Substances / European List of Notified Chemical Substances (EINECS / ELINCS) No. for Sodium Azide: 247-852-1



SECTION 16: OTHER INFORMATION

SDS Revision: 0

SDS Preparation Date: February 12, 2015

Disclaimer: This information is accurate to the best of Lin-Zhi's knowledge. Since the products may be used under conditions beyond the company's control, LZI does not assume any responsibility for the results of such usage. With the information provided on this SDS, customers receiving LZI products shall make their own determination of the effects, properties, and measures pertaining to their usage conditions. No warranty or guarantee, expressed or implied, is made concerning the safe use of this product.