EasyRA SAFETY DATA SHEET
Buprenorphine Positive/Negative Control

1. IDENTIFICATION OF THE MIXTURE AND THE COMPANY

1.1 Identification of the mixture

Product Name: **Buprenorphine Negative Control (7 ng/mL)** Product Number: **14762**

Buprenorphine Positive Control (13 ng/mL) **14767**

1.2 Use of the Product: Urine based positive and negative controls for use in combination with drugs of abuse (DAU) urinalysis enzyme immunoassay (EIA) and enzymatic assay diagnostic reagents. The products are contained in dropper bottles and packaged in small boxes.

1.3 Company identification:

Address	Medica Corporation
	5 Oak Park Drive
	Bedford MA 01730 USA
Phone	+1-800-777-5983 or +1-781-275-4892
Email	sds@medicacorp.com
Website	www.medicacorp.com
FAX	+1-781-275-2731

In compliance with OSHA Hazard Communication Standard (29 CFR 1910.1200), a chemical is considered hazardous if it contains 1.0% or more of a hazardous compound or 0.1 % or more of a carcinogen. The product does NOT contain hazardous material(s) in excess of these amounts.

2. HAZARDS IDENTIFICATION

2.1 Mixture classification (see also § 15) Not Hazardous

2.2 Hazards not otherwise classified: The negative/positive 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.

2.3 Mixture ingredients of unknown toxicity: Not applicable

3. COMPOSTION/INFORMATION ON INGREDIENTS

Composition: 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.

3.1 Hazardous Components:

Chemical Name	EINECS/ ELINCS no.	CAS no.	Conc. % w/w	Classification 67/548/EEC	Classification 1272/2008/EC
Sodium Azide	247-852-1	26628-22-8	<0.1%	Not Hazardous Below 0.1% limit	Not Hazardous Below 0.1% limit

4. FIRST AID MEASURES

Ingestion:	If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.
Inhalation exposure:	Highly unlikely
Contact with skin:	Remove contaminated clothes and shoes. Wash affected area with plenty of water. Get medical advice if adverse symptoms appear.
Contact with eyes:	Flush with plenty of water for at least 15 minutes.

5. FIRE FIGHTING MEASURES

Suitable extinguishing means: Water spray or regular foam, CO2, dry powder; typical media is suitable.

Mean of extinguishing NOT to be used: Not known.

Known hazards caused by combustion: Not combustible

Equipment for self-protection: (fire fighters): Standard equipment; There is a recommendation to wear a self-contained breathing apparatus.

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).
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.

Cleaning procedure to recover spilled material: Quarantine the spill area and minimize the spreading of spilled liquid. Soak up the 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.

7. HANDLING AND STORAGE

7.1 Handling

Handling procedures:	Wear suitable protective clothing, gloves, eye protection.
Work/Hygienic practices:	Wash hands with soap and water after use.

7.2 Storage

Room ventilation:	Well ventilated workplace.
Special precautions: (see also § 8)	Keep product tightly closed. Do not expose to extreme temperatures
Recommended temperature:	Store at 2-8 °C.
Humidity, light and other environmental factors:	No limitations
Containers:	Keep individual bottles closed tightly.
Other storage precautions:	Keep away from food and drinks.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Exposure limit values

TLV/TWA:	No established exposure limits for this product.
TLV/STEL: TLV (US):	No established exposure limits for this product.
LV EU:	Not available

8.2 Personal Protective Equipment (PPE) and Handling

Respiratory protection:	Normal room ventilation.
Skin protection:	Protective clothing, rubber or polythene gloves.
Eye protection:	Safety glasses with side shields. Have eye wash stations available as precaution.
Hand protection:	Plastic gloves.
Other protective systems:	Personal protective equipment (PPE) useful for reducing individual exposure.
Environmental protection:	Avoid release into the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information Appearance: Aqueous saline solution

Appearance *R1, R2*:	Liquid solution
Odor *R1, R2*:	Odorless
Color *R1, R2*:	Colorless

9.2 Important health, safety and environmental information

Value Related to pH *R1*:	6.0 – 7.0
Value Related to pH *R2*:	6.0 – 7.0
Boiling point/range:	Not available
Flash point:	Not available
Vapor pressure:	Not available

Density:	1.0 g/cm^3 at 25° C
Solubility:	Soluble in Water
Water Solubility:	Completely miscible
Mixture Viscosity:	Not available
Vapor density:	Not available
Evaporation rate:	Not available

9.3 Other information

Melting point/range: Not available

10. STABILITY AND REACTIVITY INFORMATION

Stability: The product is stable until the expiration date shown on the box and on the labels when stored at 2 - 8°C.

10.1 Conditions to avoid: No data available.

10.2 Materials to avoid: Strong oxidizing agents, strong bases, strong acids.

10.3 Hazardous decomposition products: No data available.

11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetic effects (ADME)

Absorption: No data available

11.2 Acute toxicity Value mu. No data available

11.3 Irritation:

Skin: No data available

Eye: No data available

Inhalation: No data available; Low risk of inhalation.

11.4 Sensitization:

Skin sensitization: Not available

11.5 Prolonged exposure toxicity:

Micronucleus test: Not available

Teratogenesis: Not available

Carcinogenesis: Not available

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicology:

Ecotoxicology	Value	m.u.	Related to
Acute toxicity with fish:	Not known	Not known	
Acute toxicity with Dahnia Magna:	Not known	Not known	
Acute toxicology with algae:	Not known	Not known	

12.2 Mobility: Not available

12.3 Persistency and degradability: Not available

12.4 Bioaccumulation potential: Not available

12.5 Evaluation PBT result: Not available

12.6 Other toxic effects: Not available

13. DISPOSAL CONSIDERATIONS

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected. Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

14. TRANSPORT INFORMATION

Not classified for transport in accordance with ADR/RID, IMDG, IATA and DOT regulations. The control kit is considered to be non-hazardous but potentially biohazardous for transport.

15. REGULATORY INFORMATION

Regulatory information on labeling according to 67/548/EEC, to 1999/45/EEC Directive and to 1272/2008 Regulation (EC)(European reinforcement of GHS), and according to their following amendments/atp.

	According to 67/548/EEC and 1999/45/EEC Directives	According to 1272/2008/EC Regulation
Classification:	Not classified as dangerous	Not classified as hazardous
Labeling symbols: (signal word)	None	None
Labeling risk phrases: (hazard statements)	None	None
Labeling safety phrases: (precautionary statements)	None	None

Other labeling details: None

Safety precautions: Wear suitable protective clothing, gloves and eye/face protection.

Authorization: No

Restriction: No

Phrases R: None

Hazard Statements: None

16. OTHER INFORMATION

The contained information in this Safety Data Sheet (SDS) are in accordance with OSHA "Hazard Communication Standard" (HCS) under 29CFR 1910.1200(g) and EU Regulation No 1272/2008. Every effort has been made to adhere to the hazard criteria and content requirement of the US OSHA Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard Information and Packaging Regulations and UN Globally Harmonized System of Classification and Labeling of Chemicals.

Bibliographic references:

OSHA BRIEF: Hazard Communication Standard: Safety Data Sheets
EC1272/2008

Disclaimer:

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this MSDS are in accordance with Annex II of Regulation no.1907/2006 (REACH) and in accordance with ANSI "Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets – Preparation" (ANSI Z400.1-2004) as recommended by US OSHA.

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End of SDS