

Alta Diagnostics, Inc.

LIQUID URINE *Dipstick* CONTROL

NEGATIVE AND POSITIVE CONTROLS FOR THE SEMIQUANTITATIVE ASSAYING OF HUMAN URINE

PRINCIPLE

The usefulness of Quality control materials for monitoring the accuracy and precision of clinical testing is well documented.

ALTA'S LIQUID URINE *DIPSTICK* CONTROL for the semiquantitative assay is a liquid, and stable for two years at refrigerated temperature of 2° - 8° C. The control is designed specifically to react with commercial dipsticks to register listed responses on the color pads. The control should be used like a patient sample to assist in the assessment of the listed analytical procedures.

ALTA LIQUID URINE CONTROL FOR DIPSTICK ASSAY

Store at 2° - 8° C. To use the product, remove from refrigerator and allow to come to room temperature. Remove the cap and squeeze gently to pour the drops as needed for assay. The LIQUID URINE *DIPSTICK* CONTROL is specifically designed and packaged to be stable in the liquid state for two years. This represents a major advancement in control technology, resulting in a product which offers ready to use convenience and long shelf life. The stable LIQUID URINE *DIPSTICK* CONTROL eliminates errors arising from lyophilization and pipeting as well as discrepancies due to uneven lyophilization or improper mixing.

WARNING: POTENTIAL BIOHAZARD MATERIAL. THIS PRODUCT CONTAINS HUMAN SOURCE MATERIALS. ALL HUMAN SOURCE MATERIALS USED IN THE PREPARATION HAVE BEEN FOUND NON-REACTIVE FOR HbSaG WHEN TESTED BY RIA, AND ALSO NEGATIVE FOR HIV-1 ANTIBODY WHEN TESTED BY ELISA. HOWEVER, NO KNOWN TEST METHOD CAN ASSURE THAT A PRODUCT DERIVED FROM HUMAN SOURCE DOES NOT CONTAIN HEPATITIS OR HIV-1 VIRUS.

WARNING: HANDLE AS IF CAPABLE OF TRANSMITTING INFECTION.

PROCEDURE

The LIQUID URINE *DIPSTICK* CONTROL should be used in the same manner as patient samples and routinely used for day – to – day quality control of the assay system.

ASSIGNMENT OF VALUES

The values assigned to each constituent are derived from the assay of multiple vials that are representative of the lot. These ranges should be used only as guidelines by the laboratory until it has established its own precision and accuracy parameters. The LIQUID URINE *DIPSTICK* CONTROL contains certain chemical analogs of the constituents, which stimulates the color reaction. The listed values are method dependent and different laboratories may observe variations as a result of differences in technique, instrument and/or reagent variations, method modifications and other systemic and random errors. These differences may result in the values to fall outside the suggested ranges.

LIMITATIONS OF THE PROCEDURE

The listed value and ranges were obtained using instruments, reagents and procedure available at the time of analysis. Any change in the reagents, methods or instrument methodology by the manufacturer may result in different values. Consult manufacturer's instructions for the procedure for further information. Laboratories employing methods other than those listed should establish their own mean value and ranges and determine if there is any interaction and/or interference from the system.

SPECIFIC PERFORMANCE CHARACTERISTICS

The values listed detail the characteristics of the ALTA LIQUIDURINE *DIPSTICK* CONTROL, and outline the reliability and usefulness of the product in clinical quality control.

PRODUCT STABILITY

The product is stable for 2 years if kept at 2° - 8° C and used as directed.

This product is warranted to perform as described in its labeling and in the product literature. Alta Diagnostics, Inc. disclaims any implied warranty or merchantability or fitness for any other purpose, and in no event shall be liable for any consequential damages arising out of the aforesaid express warranty.

800-359-9691

10/25/11

SAFETY DATA SHEET

SDS

1. Product and Company Identification

Trade Name: Urine Dipstick Control
Revision Date: 04/17/2017
Version #: 01
CAS #: Mixture
Product Code: 301-01,301-02,301-12,303-12,301-1,301-2
Product Use: Laboratory quality control material
Synonyms: Human Urine
Manufacturer/Supplier: Alta Diagnostics, Inc.
Physical Address: 3123 Research Way, Ste 214 Carson City, NV 89706 USA www.altadiagnostics.com
Telephone: 775-283-5780, Fax 775-283-5787

2. Hazards Identification

Physical State: Liquid
Appearance: Yellow to amber liquid
Emergency Overview: CAUTION! May cause skin and eye irritation
OSHA regulatory status: This product is not hazardous according to ISHA 29CFR 1910, 1200
Potential Health Effects
Routes of exposure: Eye contact, skin contact
Eyes: May cause eye irritation. Exposed individuals may experience eye tearing, redness and discomfort
Skin: May cause skin irritation. This product contains a small amount of sensitizing substance, which may provoke an allergic reaction among sensitive individuals in contact with skin.
Inhalation: In high concentrations, vapors may be irritating to the respiratory system
Ingestion: May cause discomfort if swallowed
Target organs: Eye
Chronic effects: No data available
Signs and symptoms: Contact may cause irritation with redness, tearing and pain
Potential environmental effects: This product is not classified as environmentally hazardous. However, this does not exclude the possibility that large amount of frequent spills can have a harmful or damaging effect on the environment.

3. Composition/Information on Ingredients

Components	CAS#	%
Sodium Azide	26628-22-8	<1
2-Methyl-4-isothiazolin-3-one	2682-20-4	<1
5-Chloro-2-methyl-4-isothiazol-3-one	26172-55-4;	<1

Composition Comments: All concentrations are in percent by weight.

4. First Aid Measures

First Aid Procedures
Eye contact: Flush thoroughly with water for at least 15 minutes. If eye irritation persists get medical advice.
Skin Contact: Wash with soap and water. Get medical attention if discomfort continues.
Inhalation: Move into fresh air and keep at rest. Get medical attention if any discomfort continues.
Ingestion: Rinse mouth thoroughly with water provided subject is conscious. Get medical attention.
General Notes: Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties: This product is not flammable or combustible
Extinguishing media
Suitable: foam, carbon dioxide or dry powder
Unsuitable: Do not use water jet as an extinguisher, as this will spread fire.
Protection of firefighters
Specific hazards arising from the chemical: None known

Protective equipment and precautions for firefighters: Selection of respiratory protection for the fire fighting: Follow the general fire precaution indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions specific methods: In the event of fire and/or explosion, do not breathe fumes.

6. Accidental Release Measures

Personal Precautions: Avoid contact with skin and eyes. Wear suitable protective clothing. For personal protection, see section 8 of the MSDS
Environmental precautions: Do not discharge into drains, water courses or onto the ground. Stop leak if possible without any risk.
Methods for cleaning up: Dike the spilled material, where this is possible. Collect and dispose of spillage as indicated in section 13 of the MSDS.

7. Handling and Storage

Handling: Use local exhaust ventilation. Avoid inhalation of vapors and contact with skin and eyes. Wear appropriate personal protective equipment. Wash hands after handling. Observe good industrial hygiene practices.
Storage: Store away from incompatible materials

8. Exposure Controls/Personal Protection

Occupational exposure limits: No exposure limits noted for ingredient(s)
Engineering controls: Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of vapors

Personal protective equipment:
Eye/face protection: Wear approved safety goggles
Skin protection: Wear appropriate chemical resistant clothing to prevent the possibility of skin contact
Respiratory protection: If engineering controls do not maintain airborne concentrations recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established) an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134
General hygiene considerations: Always observe good personal hygiene, such as washing after handling the material and eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and Chemical Properties

Appearance: Yellow to amber liquid
Color: Amber yellow
Odor: None
Odor Threshold: Not available
Physical state: Liquid
Form: Liquid
pH: Not available
Melting point: Not available
Freezing point: Not available
Boiling point: Not available
Flash point: Not available
Evaporation rate: Not available
Flammability limits in air, upper, % by volumes: Not available
Flammability limits in air, lower, % by volume: Not available
Vapor pressure: Not available
Vapor density: Not available
Specific gravity: Not available
Solubility (water): Not available
Partition coefficient (n-octanol/water): Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available

10. Chemical Stability and Reactivity Information

Chemical stability: Stable under normal temperature conditions
Conditions to avoid: Heat, sparks, flames
Incompatible materials: Unknown
Hazardous decomposition products: Unknown
Possibility of hazardous reactions: Hazardous polymerization does not occur

11. Toxicological Information

Acute effects: May cause discomfort if swallowed
Local effect: May cause skin and eye irritation
Sensitization: This product contains a small amount of sensitizing substance which may provoke an allergic reaction among sensitive individuals when product comes in contact with skin
Chronic effects: No data available
Carcinogenicity: Not classified as a carcinogen in humans
Mutagenicity: No data available
Reproductive effects: No data available
Symptoms and target organs: Contact may cause irritation with redness, tearing and pain
Further information: No other specific or chronic health impact noted.

12. Ecological information

Ecotoxicity: The product contains a substance which is very toxic to aquatic organisms
Persistence and degradability: The product is not readily biodegradable
Bioaccumulation/accumulation: No data available
Partition coefficient (n-octanol/water): Not available
Mobility in environmental media: Unknown

13. Disposal Considerations

Disposal instructions: Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations
Waste from residues/unused products: Dispose in accordance with local regulations
Contaminated packaging: Empty containers should be taken to an approved waste-handling site for recycling or disposal

14. Transport Information

DOT: Not regulated as dangerous goods
IATA: Not regulated as dangerous goods
IMDG: Not regulated as dangerous goods
TDG: Not regulated as dangerous goods

15. Regulatory Information

US federal regulations: This product is not hazardous according to OSHA 29CFR 1910.1200. All components are on the USA EPA TSCA Inventory List.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D): Not regulated
CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4): None
Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate hazard – No
Delayed hazard – No
Fire hazard – No
Pressure hazard – No
Reactivity hazard – No
Section 302 extremely hazardous substance (40 CFR 355, Appendix A): No
Section 311/312 (40 CFR 370): No
Drug enforcement Administration: Not controlled (DEA)(21 CFR 1308.11-15)
Canadian regulations: This product has been classified in accordance with the hazard criteria of the CPR on the MSDS contains all of the information required by the CPR
WHMIS status: Non-controlled

Inventory Status:
United States

Country(s) or Region	Inventory Name	On inventory (yes/no)
United States	Toxic substance Control Act (TSCA) Inventory	yes
*A "Yes" indicated that all components of this product comply with the inventory requirements administered by the governing country(s)		

State regulations: This product does not contain a chemical which is known to the State of California to cause cancer, birth defects or other reproductive harm

16. Other Information

HMIS * ratings:
Health – 1
Flammability – 0
Physical hazard – 0
NFPA ratings:
Health – 1
Flammability – 0
Physical hazard – 0

Disclaimer: The information in the sheet was written based on the best knowledge and experience currently available.

X. SPECIAL NOTICE ABOUT BIOLOGICAL HAZARD FOR MATERIALS OF HUMAN ORIGIN

The FDA and CDC emphasize the importance of practicing good microbiological laboratory techniques when handling products manufactured from human source materials. The FDA recommends the use of Biosafety Level 2 techniques prescribed in the CDC/NIH manual of "Biosafety in Microbiological and Biochemical Laboratories, 1984". It is known that some materials negative for HbsAg by radioimmunoassay is potentially infectious and should be treated as if capable of infecting the handlers. The possibility of contracting Human Immunodeficiency Virus (HIV - 1) infection from human material should be taken seriously. Hepatitis virus or other infectious agents are absent from the materials used in the production of in vitro diagnostic products. However, it must be noted that "there has been no known reported cases of HIV - 1 transmission by contact with in vitro diagnostic products" (FDA letter of December 6, 1985).

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Alta Diagnostics shall not be held liable for any damage resulting from handling or from contact with the above product.

URINE *DIPSTICK* CONTROL

CHEMSTRIP™

DAYS OF THE MONTH

		DAYS OF THE MONTH																															Q.C. FACTOR	TOTAL	MEAN			
ANALYTE	RANGE	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31						
SPECIFIC GRAVITY	1.000																																					
	1.005																																					
	1.010																																					
	1.015																																					
	1.020																																					
	1.025																																					
	1.030																																					
PH	5																																					
	6																																					
	7																																					
	8																																					
	9																																					
LEUKOCYTES	NEG																																					
	Tr																																					
	+ - SM																																					
	++ - MOD																																					
	+++ - LG																																					
NITRITE	NEG																																					
	POS																																					
PROTEIN	NEG																																					
	Tr																																					
	+ - 30 mg/dl																																					
	++ - 100 mg/dl																																					
GLUCOSE	+++ - 500 mg/dl																																					
	NORMAL																																					
	50 mg/dl																																					
	100 mg/dl																																					
	250 mg/dl																																					
KETONES	500 mg/dl																																					
	1000 mg/dl																																					
	NEG																																					
	+ - SM																																					
UROBILINOGEN	++ - MOD																																					
	+++ - LG																																					
	NORMAL - 0.2 mg/dl																																					
	1 mg/dl																																					
	2 mg/dl																																					
BILIRUBIN	4 mg/dl																																					
	8 mg/dl																																					
	12 mg/dl																																					
	NEG																																					
BLOOD	+ - SM																																					
	++ - MOD																																					
	+++ - LG																																					
	NEG																																					
BLOOD	ABOUT 10 - Tr																																					
	ABOUT 50 - SM																																					
	ABOUT 125 - MOD																																					
	ABOUT 250 - LG																																					

To record results of the URINE DIPSTICK CONTROL enter an (x) in the appropriate box each day for each analyte. At the end of the month, multiply the number of (x) in a given row by the Q.C. FACTOR and enter the total in the TOTAL COLUMN. Determine the MEAN for each analyte by dividing the sum of the totals for each analyte by the total number of (x) marks for that analyte.

SAFETY DATA SHEET

SDS

1. Product and Company Identification

Trade Name: Liquid Urine Control for Microscopic & High Specific Gravity
Revision Date: 04/18/2017
Version #: 01
CAS #: Mixture
Product Code: 301-3, 301-4
Product Use: Laboratory quality control material
Synonyms: Urine Microscopic
Manufacturer/Supplier: Alta Diagnostics, Inc.
Physical Address: 3123 Research Way, Ste 214 Carson City, NV 89706 USA www.altadiagnostics.com
Telephone: 775-283-5780, Fax 775-283-5787

2. Hazards Identification

Physical State: Liquid
Appearance: Yellow to amber liquid
Emergency Overview: CAUTION! May cause skin and eye irritation
OSHA regulatory status: This product is not hazardous according to ISHA 29CFR 1910, 1200
Potential Health Effects
Routes of exposure: Eye contact, skin contact
Eyes: May cause eye irritation. Exposed individuals may experience eye tearing, redness and discomfort
Skin: May cause skin irritation. This product contains a small amount of sensitizing substance, which may provoke an allergic reaction among sensitive individuals in contact with skin.
Inhalation: In high concentrations, vapors may be irritating to the respiratory system
Ingestion: May cause discomfort if swallowed
Target organs: Eye
Chronic effects: No data available
Signs and symptoms: Contact may cause irritation with redness, tearing and pain
Potential environmental effects: This product is not classified as environmentally hazardous. However, this does not exclude the possibility that large amount of frequent spills can have a harmful or damaging effect on the environment.

3. Composition/Information on Ingredients

Components	CAS#	%
Sodium Azide	26628-22-8	<1
2-Methyl-4-isothiazolin-3-one	2682-20-4	<1
5-Chloro-2-methyl-4-isothiazol-3-one	26172-55-4;	<1

Composition Comments: All concentrations are in percent by weight.

4. First Aid Measures

First Aid Procedures
Eye contact: Flush thoroughly with water for at least 15 minutes. If eye irritation persists get medical advice.
Skin Contact: Wash with soap and water. Get medical attention if discomfort continues.
Inhalation: Move into fresh air and keep at rest. Get medical attention if any discomfort continues.
Ingestion: Rinse mouth thoroughly with water provided subject is conscious. Get medical attention.
General Notes: Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties: This product is not flammable or combustible
Extinguishing media
Suitable: foam, carbon dioxide or dry powder
Unsuitable: Do not use water jet as an extinguisher, as this will spread fire.
Protection of firefighters
Specific hazards arising from the chemical: None known

Protective equipment and precautions for firefighters: Selection of respiratory protection for the fire fighting: Follow the general fire precaution indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions specific methods: In the event of fire and/or explosion, do not breathe fumes.

6. Accidental Release Measures

Personal Precautions: Avoid contact with skin and eyes. Wear suitable protective clothing. For personal protection, see section 8 of the MSDS
Environmental precautions: Do not discharge into drains, water courses or onto the ground. Stop leak if possible without any risk.
Methods for cleaning up: Dike the spilled material, where this is possible. Collect and dispose of spillage as indicated in section 13 of the MSDS.

7. Handling and Storage

Handling: Use local exhaust ventilation. Avoid inhalation of vapors and contact with skin and eyes. Wear appropriate personal protective equipment. Wash hands after handling. Observe good industrial hygiene practices.
Storage: Store away from incompatible materials

8. Exposure Controls/Personal Protection

Occupational exposure limits: No exposure limits noted for ingredient(s)
Engineering controls: Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of vapors

Personal protective equipment:
Eye/face protection: Wear approved safety goggles
Skin protection: Wear appropriate chemical resistant clothing to prevent the possibility of skin contact
Respiratory protection: If engineering controls do not maintain airborne concentrations recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established) an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134
General hygiene considerations: Always observe good personal hygiene, such as washing after handling the material and eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and Chemical Properties

Appearance: Yellow to amber liquid
Color: Amber yellow
Odor: None
Odor Threshold: Not available
Physical state: Liquid
Form: Liquid
pH: Not available
Melting point: Not available
Freezing point: Not available
Boiling point: Not available
Flash point: Not available
Evaporation rate: Not available
Flammability limits in air, upper, % by volumes: Not available
Flammability limits in air, lower, % by volume: Not available
Vapor pressure: Not available
Vapor density: Not available
Specific gravity: Not available
Solubility (water): Not available
Partition coefficient (n-octanol/water): Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available

10. Chemical Stability and Reactivity Information

Chemical stability: Stable under normal temperature conditions
Conditions to avoid: Heat, sparks, flames
Incompatible materials: Unknown
Hazardous decomposition products: Unknown
Possibility of hazardous reactions: Hazardous polymerization does not occur

11. Toxicological Information

Acute effects: May cause discomfort if swallowed
Local effect: May cause skin and eye irritation
Sensitization: This product contains a small amount of sensitizing substance which may provoke an allergic reaction among sensitive individuals when product comes in contact with skin
Chronic effects: No data available
Carcinogenicity: Not classified as a carcinogen in humans
Mutagenicity: No data available
Reproductive effects: No data available
Symptoms and target organs: Contact may cause irritation with redness, tearing and pain
Further information: No other specific or chronic health impact noted.

12. Ecological information

Ecotoxicity: The product contains a substance which is very toxic to aquatic organisms
Persistence and degradability: The product is not readily biodegradable
Bioaccumulation/accumulation: No data available
Partition coefficient (n-octanol/water): Not available
Mobility in environmental media: Unknown

13. Disposal Considerations

Disposal instructions: Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations
Waste from residues/unused products: Dispose in accordance with local regulations
Contaminated packaging: Empty containers should be taken to an approved waste-handling site for recycling or disposal

14. Transport Information

DOT: Not regulated as dangerous goods
IATA: Not regulated as dangerous goods
IMDG: Not regulated as dangerous goods
TDG: Not regulated as dangerous goods

15. Regulatory Information

US federal regulations: This product is not hazardous according to OSHA 29CFR 1910.1200. All components are on the USA EPA TSCA Inventory List.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D): Not regulated
CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4): None
Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate hazard – No
Delayed hazard – No
Fire hazard – No
Pressure hazard – No
Reactivity hazard – No
Section 302 extremely hazardous substance (40 CFR 355, Appendix A): No
Section 311/312 (40 CFR 370): No
Drug enforcement Administration: Not controlled (DEA)(21 CFR 1308.11-15)
Canadian regulations: This product has been classified in accordance with the hazard criteria of the CPR on the MSDS contains all of the information required by the CPR
WHMIS status: Non-controlled

Inventory Status:
United States

Country(s) or Region	Inventory Name	On inventory (yes/no)
United States	Toxic substance Control Act (TSCA) Inventory	yes
*A "Yes" indicated that all components of this product comply with the inventory requirements administered by the governing country(s)		

State regulations: This product does not contain a chemical which is known to the State of California to cause cancer, birth defects or other reproductive harm

16. Other Information

HMIS * ratings:
Health – 1
Flammability – 0
Physical hazard – 0
NFPA ratings:
Health – 1
Flammability – 0
Physical hazard – 0

Disclaimer: The information in the sheet was written based on the best knowledge and experience currently available.

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SAFETY DATA SHEET

SDS

1. Product and Company Identification

Trade Name: Liquid Human Urine Control
Revision Date: 04/17/2017
Version #: 01
CAS #: Mixture
Product Code: 323-16-01, 323-16-02, 323-16-12, 323-17-01, 323-17-02, 323-17-12
Product Use: Laboratory quality control material
Synonyms: Human Urine
Manufacturer/Supplier: Alta Diagnostics, Inc.
Physical Address: 3123 Research Way, Ste 214 Carson City, NV 89706 USA www.altadiagnostics.com
Telephone: 775-283-5780, Fax 775-283-5787

2. Hazards Identification

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Skin: May cause skin irritation. This product contains a small amount of sensitizing substance, which may provoke an allergic reaction among sensitive individuals in contact with skin.
Inhalation: In high concentrations, vapors may be irritating to the respiratory system
Ingestion: May cause discomfort if swallowed
Target organs: Eye
Chronic effects: No data available
Signs and symptoms: Contact may cause irritation with redness, tearing and pain
Potential environmental effects: This product is not classified as environmentally hazardous. However, this does not exclude the possibility that large amount of frequent spills can have a harmful or damaging effect on the environment.

3. Composition/Information on Ingredients

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Unsuitable: Do not use water jet as an extinguisher, as this will spread fire.
Protection of firefighters
Specific hazards arising from the chemical: None known

Protective equipment and precautions for firefighters: Selection of respiratory protection for the fire fighting: Follow the general fire precaution indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
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Physical state: Liquid
Form: Liquid
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Freezing point: Not available
Boiling point: Not available
Flash point: Not available
Evaporation rate: Not available
Flammability limits in air, upper, % by volumes: Not available
Flammability limits in air, lower, % by volume: Not available
Vapor pressure: Not available
Vapor density: Not available
Specific gravity: Not available
Solubility (water): Not available
Partition coefficient (n-octanol/water): Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available

10. Chemical Stability and Reactivity Information

Chemical stability: Stable under normal temperature conditions
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Further information: No other specific or chronic health impact noted.

12. Ecological information

Ecotoxicity: The product contains a substance which is very toxic to aquatic organisms
Persistence and degradability: The product is not readily biodegradable
Bioaccumulation/accumulation: No data available
Partition coefficient (n-octanol/water): Not available
Mobility in environmental media: Unknown

13. Disposal Considerations

Disposal instructions: Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations
Waste from residues/unused products: Dispose in accordance with local regulations
Contaminated packaging: Empty containers should be taken to an approved waste-handling site for recycling or disposal

14. Transport Information

DOT: Not regulated as dangerous goods
IATA: Not regulated as dangerous goods
IMDG: Not regulated as dangerous goods
TDG: Not regulated as dangerous goods

15. Regulatory Information

US federal regulations: This product is not hazardous according to OSHA 29CFR 1910.1200. All components are on the USA EPA TSCA Inventory List.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D): Not regulated
CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4): None
Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate hazard – No
Delayed hazard – No
Fire hazard – No
Pressure hazard – No
Reactivity hazard – No
Section 302 extremely hazardous substance (40 CFR 355, Appendix A): No
Section 311/312 (40 CFR 370): No
Drug enforcement Administration: Not controlled (DEA)(21 CFR 1308.11-15)
Canadian regulations: This product has been classified in accordance with the hazard criteria of the CPR on the MSDS contains all of the information required by the CPR
WHMIS status: Non-controlled

Inventory Status:
United States

Country(s) or Region	Inventory Name	On inventory (yes/no)
United States	Toxic substance Control Act (TSCA) Inventory	yes
*A "Yes" indicated that all components of this product comply with the inventory requirements administered by the governing country(s)		

State regulations: This product does not contain a chemical which is known to the State of California to cause cancer, birth defects or other reproductive harm

16. Other Information

HMIS ® ratings:
Health – 1
Flammability – 0
Physical hazard – 0
NFPA ratings:
Health – 1
Flammability – 0
Physical hazard – 0

Disclaimer: The information in the sheet was written based on the best knowledge and experience currently available.

X. SPECIAL NOTICE ABOUT BIOLOGICAL HAZARD FOR MATERIALS OF HUMAN ORIGIN

The FDA and CDC emphasize the importance of practicing good microbiological laboratory techniques when handling products manufactured from human source materials. The FDA recommends the use of Biosafety Level 2 techniques prescribed in the CDC/NIH manual of "Biosafety in Microbiological and Biochemical Laboratories, 1984". It is known that some materials negative for HbsAg by radioimmunoassay is potentially infectious and should be treated as if capable of infecting the handlers. The possibility of contracting Human Immunodeficiency Virus (HIV - 1) infection from human material should be taken seriously. Hepatitis virus or other infectious agents are absent from the materials used in the production of in vitro diagnostic products. However, it must be noted that "there has been no known reported cases of HIV - 1 transmission by contact with in vitro diagnostic products" (FDA letter of December 6, 1985).

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Alta Diagnostics shall not be held liable for any damage resulting from handling or from contact with the above product.

SAFETY DATA SHEET

SDS

1. Product and Company Identification

Trade Name: Liquid Human Spinal Fluid Control
Revision Date: 04/17/2017
Version #: 01
CAS #: Mixture
Product Code: 323-26-01, 323-26-02, 323-26-12, 323-27-01, 323-27-02, 323-27-12
Product Use: Laboratory quality control material
Synonyms: Spinal Fluid
Manufacturer/Supplier: Alta Diagnostics, Inc.
Physical Address: 3123 Research Way, Ste 214 Carson City, NV 89706 USA www.altadiagnostics.com
Telephone: 775-283-5780, Fax 775-283-5787

2. Hazards Identification

Physical State: Liquid
Appearance: Yellow to amber liquid
Emergency Overview: CAUTION! May cause skin and eye irritation
OSHA regulatory status: This product is not hazardous according to ISHA 29CFR 1910, 1200
Potential Health Effects
Routes of exposure: Eye contact, skin contact
Eyes: May cause eye irritation. Exposed individuals may experience eye tearing, redness and discomfort
Skin: May cause skin irritation. This product contains a small amount of sensitizing substance, which may provoke an allergic reaction among sensitive individuals in contact with skin.
Inhalation: In high concentrations, vapors may be irritating to the respiratory system
Ingestion: May cause discomfort if swallowed
Target organs: Eye
Chronic effects: No data available
Signs and symptoms: Contact may cause irritation with redness, tearing and pain
Potential environmental effects: This product is not classified as environmentally hazardous. However, this does not exclude the possibility that large amount of frequent spills can have a harmful or damaging effect on the environment.

3. Composition/Information on Ingredients

Components	CAS#	%
Sodium Azide	26628-22-8	<1
2-Methyl-4-isothiazolin-3-one	2682-20-4	<1
5-Chloro-2-methyl-4-isothiazol-3-one	26172-55-4;	<1

Composition Comments: All concentrations are in percent by weight.

4. First Aid Measures

First Aid Procedures
Eye contact: Flush thoroughly with water for at least 15 minutes. If eye irritation persists get medical advice.
Skin Contact: Wash with soap and water. Get medical attention if discomfort continues.
Inhalation: Move into fresh air and keep at rest. Get medical attention if any discomfort continues.
Ingestion: Rinse mouth thoroughly with water provided subject is conscious. Get medical attention.
General Notes: Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties: This product is not flammable or combustible
Extinguishing media
Suitable: foam, carbon dioxide or dry powder
Unsuitable: Do not use water jet as an extinguisher, as this will spread fire.
Protection of firefighters
Specific hazards arising from the chemical: None known

Protective equipment and precautions for firefighters: Selection of respiratory protection for the fire fighting: Follow the general fire precaution indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions specific methods: In the event of fire and/or explosion, do not breathe fumes.

6. Accidental Release Measures

Personal Precautions: Avoid contact with skin and eyes. Wear suitable protective clothing. For personal protection, see section 8 of the MSDS
Environmental precautions: Do not discharge into drains, water courses or onto the ground. Stop leak if possible without any risk.
Methods for cleaning up: Dike the spilled material, where this is possible. Collect and dispose of spillage as indicated in section 13 of the MSDS.

7. Handling and Storage

Handling: Use local exhaust ventilation. Avoid inhalation of vapors and contact with skin and eyes. Wear appropriate personal protective equipment. Wash hands after handling. Observe good industrial hygiene practices.
Storage: Store away from incompatible materials

8. Exposure Controls/Personal Protection

Occupational exposure limits: No exposure limits noted for ingredient(s)
Engineering controls: Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of vapors

Personal protective equipment:
Eye/face protection: Wear approved safety goggles
Skin protection: Wear appropriate chemical resistant clothing to prevent the possibility of skin contact
Respiratory protection: If engineering controls do not maintain airborne concentrations recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established) an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134
General hygiene considerations: Always observe good personal hygiene, such as washing after handling the material and eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and Chemical Properties

Appearance: Yellow to amber liquid
Color: Amber yellow
Odor: None
Odor Threshold: Not available
Physical state: Liquid
Form: Liquid
pH: Not available
Melting point: Not available
Freezing point: Not available
Boiling point: Not available
Flash point: Not available
Evaporation rate: Not available
Flammability limits in air, upper, % by volumes: Not available
Flammability limits in air, lower, % by volume: Not available
Vapor pressure: Not available
Vapor density: Not available
Specific gravity: Not available
Solubility (water): Not available
Partition coefficient (n-octanol/water): Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available

10. Chemical Stability and Reactivity Information

Chemical stability: Stable under normal temperature conditions
Conditions to avoid: Heat, sparks, flames
Incompatible materials: Unknown
Hazardous decomposition products: Unknown
Possibility of hazardous reactions: Hazardous polymerization does not occur

11. Toxicological Information

Acute effects: May cause discomfort if swallowed
Local effect: May cause skin and eye irritation
Sensitization: This product contains a small amount of sensitizing substance which may provoke an allergic reaction among sensitive individuals when product comes in contact with skin
Chronic effects: No data available
Carcinogenicity: Not classified as a carcinogen in humans
Mutagenicity: No data available
Reproductive effects: No data available
Symptoms and target organs: Contact may cause irritation with redness, tearing and pain
Further information: No other specific or chronic health impact noted.

12. Ecological information

Ecotoxicity: The product contains a substance which is very toxic to aquatic organisms
Persistence and degradability: The product is not readily biodegradable
Bioaccumulation/accumulation: No data available
Partition coefficient (n-octanol/water): Not available
Mobility in environmental media: Unknown

13. Disposal Considerations

Disposal instructions: Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations
Waste from residues/unused products: Dispose in accordance with local regulations
Contaminated packaging: Empty containers should be taken to an approved waste-handling site for recycling or disposal

14. Transport Information

DOT: Not regulated as dangerous goods
IATA: Not regulated as dangerous goods
IMDG: Not regulated as dangerous goods
TDG: Not regulated as dangerous goods

15. Regulatory Information

US federal regulations: This product is not hazardous according to OSHA 29CFR 1910.1200. All components are on the USA EPA TSCA Inventory List.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D): Not regulated
CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4): None
Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate hazard – No
Delayed hazard – No
Fire hazard – No
Pressure hazard – No
Reactivity hazard – No
Section 302 extremely hazardous substance (40 CFR 355, Appendix A): No
Section 311/312 (40 CFR 370): No
Drug enforcement Administration: Not controlled (DEA)(21 CFR 1308.11-15)
Canadian regulations: This product has been classified in accordance with the hazard criteria of the CPR on the MSDS contains all of the information required by the CPR
WHMIS status: Non-controlled

Inventory Status:
United States

Country(s) or Region	Inventory Name	On inventory (yes/no)
United States	Toxic substance Control Act (TSCA) Inventory	yes
*A "Yes" indicated that all components of this product comply with the inventory requirements administered by the governing country(s)		

State regulations: This product does not contain a chemical which is known to the State of California to cause cancer, birth defects or other reproductive harm

16. Other Information

HMIS ® ratings:
Health – 1
Flammability – 0
Physical hazard – 0
NFPA ratings:
Health – 1
Flammability – 0
Physical hazard – 0

Disclaimer: The information in the sheet was written based on the best knowledge and experience currently available.

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The FDA and CDC emphasize the importance of practicing good microbiological laboratory techniques when handling products manufactured from human source materials. The FDA recommends the use of Biosafety Level 2 techniques prescribed in the CDC/NIH manual of "Biosafety in Microbiological and Biochemical Laboratories, 1984". It is known that some materials negative for HbsAg by radioimmunoassay is potentially infectious and should be treated as if capable of infecting the handlers. The possibility of contracting Human Immunodeficiency Virus (HIV - 1) infection from human material should be taken seriously. Hepatitis virus or other infectious agents are absent from the materials used in the production of in vitro diagnostic products. However, it must be noted that "there has been no known reported cases of HIV - 1 transmission by contact with in vitro diagnostic products" (FDA letter of December 6, 1985).

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SAFETY DATA SHEET

SDS

1. Product and Company Identification

Trade Name: Microalbumin Control
Revision Date: 04/17/2017
Version #: 01
CAS #: Mixture
Product Code: 302-01, 302-02, 302-12, 302-1, 302-2
Product Use: Laboratory quality control material
Synonyms: Urine Microalbumin
Manufacturer/Supplier: Alta Diagnostics, Inc.
Physical Address: 3123 Research Way, Ste 214 Carson City, NV 89706 USA www.altadiagnostics.com
Telephone: 775-283-5780, Fax 775-283-5787

2. Hazards Identification

Physical State: Liquid
Appearance: Yellow to amber liquid
Emergency Overview: CAUTION! May cause skin and eye irritation
OSHA regulatory status: This product is not hazardous according to ISHA 29CFR 1910, 1200
Potential Health Effects
Routes of exposure: Eye contact, skin contact
Eyes: May cause eye irritation. Exposed individuals may experience eye tearing, redness and discomfort
Skin: May cause skin irritation. This product contains a small amount of sensitizing substance, which may provoke an allergic reaction among sensitive individuals in contact with skin.
Inhalation: In high concentrations, vapors may be irritating to the respiratory system
Ingestion: May cause discomfort if swallowed
Target organs: Eye
Chronic effects: No data available
Signs and symptoms: Contact may cause irritation with redness, tearing and pain
Potential environmental effects: This product is not classified as environmentally hazardous. However, this does not exclude the possibility that large amount of frequent spills can have a harmful or damaging effect on the environment.

3. Composition/Information on Ingredients

Components	CAS#	%
Sodium Azide	26628-22-8	<1
2-Methyl-4-isothiazolin-3-one	2682-20-4	<1
5-Chloro-2-methyl-4-isothiazol-3-one	26172-55-4;	<1

Composition Comments: All concentrations are in percent by weight.

4. First Aid Measures

First Aid Procedures
Eye contact: Flush thoroughly with water for at least 15 minutes. If eye irritation persists get medical advice.
Skin Contact: Wash with soap and water. Get medical attention if discomfort continues.
Inhalation: Move into fresh air and keep at rest. Get medical attention if any discomfort continues.
Ingestion: Rinse mouth thoroughly with water provided subject is conscious. Get medical attention.
General Notes: Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties: This product is not flammable or combustible
Extinguishing media
Suitable: foam, carbon dioxide or dry powder
Unsuitable: Do not use water jet as an extinguisher, as this will spread fire.
Protection of firefighters
Specific hazards arising from the chemical: None known

Protective equipment and precautions for firefighters: Selection of respiratory protection for the fire fighting: Follow the general fire precaution indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions specific methods: In the event of fire and/or explosion, do not breathe fumes.

6. Accidental Release Measures

Personal Precautions: Avoid contact with skin and eyes. Wear suitable protective clothing. For personal protection, see section 8 of the MSDS
Environmental precautions: Do not discharge into drains, water courses or onto the ground. Stop leak if possible without any risk.
Methods for cleaning up: Dike the spilled material, where this is possible. Collect and dispose of spillage as indicated in section 13 of the MSDS.

7. Handling and Storage

Handling: Use local exhaust ventilation. Avoid inhalation of vapors and contact with skin and eyes. Wear appropriate personal protective equipment. Wash hands after handling. Observe good industrial hygiene practices.
Storage: Store away from incompatible materials

8. Exposure Controls/Personal Protection

Occupational exposure limits: No exposure limits noted for ingredient(s)
Engineering controls: Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of vapors

Personal protective equipment:
Eye/face protection: Wear approved safety goggles
Skin protection: Wear appropriate chemical resistant clothing to prevent the possibility of skin contact
Respiratory protection: If engineering controls do not maintain airborne concentrations recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established) an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134
General hygiene considerations: Always observe good personal hygiene, such as washing after handling the material and eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and Chemical Properties

Appearance: Yellow to amber liquid
Color: Amber yellow
Odor: None
Odor Threshold: Not available
Physical state: Liquid
Form: Liquid
pH: Not available
Melting point: Not available
Freezing point: Not available
Boiling point: Not available
Flash point: Not available
Evaporation rate: Not available
Flammability limits in air, upper, % by volumes: Not available
Flammability limits in air, lower, % by volume: Not available
Vapor pressure: Not available
Vapor density: Not available
Specific gravity: Not available
Solubility (water): Not available
Partition coefficient (n-octanol/water): Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available

10. Chemical Stability and Reactivity Information

Chemical stability: Stable under normal temperature conditions
Conditions to avoid: Heat, sparks, flames
Incompatible materials: Unknown
Hazardous decomposition products: Unknown
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Local effect: May cause skin and eye irritation
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Chronic effects: No data available
Carcinogenicity: Not classified as a carcinogen in humans
Mutagenicity: No data available
Reproductive effects: No data available
Symptoms and target organs: Contact may cause irritation with redness, tearing and pain
Further information: No other specific or chronic health impact noted.

12. Ecological information

Ecotoxicity: The product contains a substance which is very toxic to aquatic organisms
Persistence and degradability: The product is not readily biodegradable
Bioaccumulation/accumulation: No data available
Partition coefficient (n-octanol/water): Not available
Mobility in environmental media: Unknown

13. Disposal Considerations

Disposal instructions: Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations
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TDG: Not regulated as dangerous goods

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CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4): None
Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate hazard – No
Delayed hazard – No
Fire hazard – No
Pressure hazard – No
Reactivity hazard – No
Section 302 extremely hazardous substance (40 CFR 355, Appendix A): No
Section 311/312 (40 CFR 370): No
Drug enforcement Administration: Not controlled (DEA)(21 CFR 1308.11-15)
Canadian regulations: This product has been classified in accordance with the hazard criteria of the CPR on the MSDS contains all of the information required by the CPR
WHMIS status: Non-controlled

Inventory Status:
United States

Country(s) or Region	Inventory Name	On inventory (yes/no)
United States	Toxic substance Control Act (TSCA) Inventory	yes
*A "Yes" indicated that all components of this product comply with the inventory requirements administered by the governing country(s)		

State regulations: This product does not contain a chemical which is known to the State of California to cause cancer, birth defects or other reproductive harm

16. Other Information

HMIS * ratings:
Health – 1
Flammability – 0
Physical hazard – 0
NFPA ratings:
Health – 1
Flammability – 0
Physical hazard – 0

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