



Corporate Headquarters
Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Manufacturer/Distributor
Genzyme Diagnostics
6659 Top Gun Street
San Diego, CA 92121
USA

Phone: 858-452-3198

MATERIAL SAFETY DATA SHEETS

Catalog Number:	Kit Name:
134	OSOM[®] hCG Urine Control Set

Item Number:	Component Name:
1229	OSOM[®] hCG Urine Control – Positive I & II
1228	OSOM[®] hCG Urine Control – Negative

Note: The page numbers on the 2 individual MSDSs for this kit are specific to each document. There are a total of 15 pages including this cover sheet.



MATERIAL SAFETY DATA SHEET
OSOM® hCG Urine Control - Positive I & II

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® hCG Urine Control - Positive I & II

Synonym(s): hCG Urine Positive Control I; hCG Urine Positive Control II

Product Use: Component of OSOM® hCG Urine Control Set (Catalog # 134). For use in quality control testing with the OSOM® hCG-Urine Test, OSOM® Card Pregnancy Test, and OSOM® hCG Combo Test. For In Vitro Diagnostic Use Only.

Description: Aqueous solution containing purified hCG (glycoprotein hormone), salt, and preservative.

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San Diego, CA 92121
USA

Phone: 858-452-3198

Emergency Telephone Numbers

Genzyme (U.S.): 617-562-4555

CHEMTREC (U.S.): 800-424-9300

CHEMTREC (Outside U.S.): 703-527-3887

2. HAZARDS IDENTIFICATION

Precautionary Statements:

CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Harmful by ingestion. The human hCG in this preparation was tested by FDA-approved methods and found to be negative for the presence of hepatitis B virus surface antigen (HBsAg), human immunodeficiency virus (HIV) 1 & 2 and hepatitis C virus (HCV). However, because no test method can provide complete assurance that infectious agents are absent, this product should be handled as a potentially biohazardous material in accordance with universal/standard precautions. Preparation appearance: clear, colorless liquid.

Routes of Exposure:

Occupational exposure routes may include eye contact, skin contact and skin absorption.

Potential Health Effects:

- | | |
|------------------------|--|
| Inhalation | Aerosol inhalation may cause coughing and sore throat. |
| Eye | Eye exposure may cause irritation, redness and watering. |
| Skin | Skin contact may cause irritation, dryness and redness. Sodium azide may be absorbed through the skin and result in systemic effects. |
| Ingestion | Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness. |
| Chronic Effects | No data available. |
| Target Organs | Sodium azide: Cardiovascular and central nervous system. |

Regulatory Status:

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

Potential Environmental Effects:

Unknown.



MATERIAL SAFETY DATA SHEET
OSOM® hCG Urine Control - Positive I & II

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water EC R-Phrases: None	7732-18-5 EC Hazard Class: None	231-791-2	> 97
Human Chorionic Gonadotropin (hCG) EC R-Phrases: None	Not Assigned EC Hazard Class: None	Not Assigned	< 1
Sodium chloride EC R-Phrases: None	7647-14-5 EC Hazard Class: None	231-598-3	0.88
Sodium azide EC R-Phrases: R28, R32, R50, R53	26628-22-8 EC Hazard Class: T+, N	247-852-1	0.2

4. FIRST AID MEASURES

General Advice:

In the event of occupational exposure, follow company-specific bloodborne pathogen post-exposure requirements.

Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact:

In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, contact a poison control center or physician for instructions.

5. FIRE FIGHTING MEASURES

Flammable Properties:

Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media:

Carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:

Unknown.

Specific Hazards Arising from the Chemical:

None expected.

Standard Protective Equipment and Precautions for Firefighters:

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.



MATERIAL SAFETY DATA SHEET

OSOM® hCG Urine Control - Positive I & II

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

Environmental Precautions:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures for biohazardous spills. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7. HANDLING AND STORAGE

Handling:

Follow good laboratory hygiene practices. Follow universal/standard precautions when preparing or handling this material. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling. Avoid physical contact.

Storage:

Store at 2 to 8°C (36 to 46°F). Do not store with incompatible substances. See Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

ACGIH - Threshold Limits Values - Ceilings (TLV-C)

Sodium azide 26628-22-8 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (vapor, as hydrazoic acid)

Canada - Quebec - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.11 ppm Ceiling; 0.3 mg/m³ Ceiling

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - Skin Notations

Sodium azide 26628-22-8 possibility of significant uptake through the skin

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELs

Sodium azide 26628-22-8 0.3 mg/m³ STEL

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

Sodium azide 26628-22-8 0.1 mg/m³ TWA

Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations)

Sodium azide 26628-22-8 0.4 mg/m³ Peak (inhalable fraction)

Germany - DFG - Recommended Exposure Limits - MAK Values

Sodium azide 26628-22-8 0.2 mg/m³ MAK (inhalable fraction)

Germany - TRGS 900 - Occupational Exposure Limits - TWAs

Sodium azide 26628-22-8 0.2 mg/m³ TWA (exposure factor 2)

Israel - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (vapor, as Hydrazoic acid)

Korea - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.1 ppm Ceiling; 0.3 mg/m³ Ceiling

Engineering Controls:

This preparation is aqueous and non-volatile and is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with an eyewash fountain.

Personal Protective Equipment (PPE):

Respiratory A respirator is not required under normal conditions of use.

Eye/Face Wear appropriate protective chemical safety glasses.



MATERIAL SAFETY DATA SHEET

OSOM® hCG Urine Control - Positive I & II

Personal Protective Equipment (PPE):

Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colorless liquid	pH:	7.1 (approx.)
Odor:	Not available	Solubility:	Water-soluble
Boiling Point:	Not available	Vapor Pressure:	Not available
Melting Point:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
Freezing Point:	Not available	Vapor Density:	Not available
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not available		
Flash Point:	Not available		

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

Conditions to Avoid:

There are no physical conditions known to result in a hazardous situation.

Incompatible Materials:

Avoid strong oxidizing agents, acids, heavy metals and their salts.

Hazardous Decomposition Products:

Thermal decomposition may lead to release of irritating gases and vapors.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

The human source material in this preparation presents a risk for exposure to infectious agents.

Toxicology Data - Selected LD50s and LC50s

Sodium azide 26628-22-8 Oral LD50 Rat: 27 mg/kg; Dermal LD50 Rabbit: 20 mg/kg

Local Effects:

No data available.

Chronic Effects:

No data available.



MATERIAL SAFETY DATA SHEET

OSOM® hCG Urine Control - Positive I & II

Carcinogenicity:

ACGIH - Threshold Limits Values - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

Canada - Manitoba - Occupational Exposure Limits - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

Ecotoxicity - Freshwater Fish Species Data

Sodium azide 26628-22-8 96 Hr LC50 *Oncorhynchus mykiss*: 0.8 mg/L; 96 Hr LC50 *Lepomis macrochirus*: 0.7 mg/L; 96 Hr LC50 *Pimephales promelas*: 5.46 mg/L [flow-through]

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up. Remaining unused material and product waste should be treated as biohazardous/infectious waste and contaminated instruments and surfaces should be disinfected in accordance with your employer's universal/standard precautions.

Waste Classification:

U.S. - California - 22 CCR - Presumed Hazardous Wastes

Sodium azide 26628-22-8 Ignitable; Reactive

U.S. - RCRA (Resource Conservation & Recovery Act) - P Series Wastes - Acutely Toxic Wastes

Sodium azide 26628-22-8 waste number P105

14. TRANSPORT INFORMATION

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.



MATERIAL SAFETY DATA SHEET
OSOM® hCG Urine Control - Positive I & II

15. REGULATORY INFORMATION

US Federal Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

Inventory - United States - Section 8(b) Inventory (TSCA)

Sodium azide 26628-22-8 Present

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

Sodium azide 26628-22-8 1000 lb final RQ; 454 kg final RQ

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

Sodium azide 26628-22-8 1000 lb EPCRA RQ

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

Sodium azide 26628-22-8 500 lb TPQ (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solvent form)

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

Sodium azide 26628-22-8 1.0 % de minimis concentration

US State Regulations:

U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances

Sodium azide 26628-22-8 Present

International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Canada - WHMIS - Classifications of Substances

Sodium azide 26628-22-8 D1A

Canada - WHMIS - Ingredient Disclosure List

Sodium azide 26628-22-8 1 %

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification

Sodium azide 26628-22-8 T+;R28 R32 N;R50-53

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases

Sodium azide 26628-22-8 S:1/2-28-45-60-61

Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

Sodium azide 26628-22-8 ID Number 636, hazard class 2 - hazard to waters

Inventory - Australia - Inventory of Chemical Substances (AICS)

Sodium azide 26628-22-8 Present

Inventory - Canada - Domestic Substances List (DSL)

Sodium azide 26628-22-8 Present

Inventory - China

Sodium azide 26628-22-8 Present

Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Sodium azide 26628-22-8 247-852-1

Inventory - Japan Existing and New Chemical Substances (ENCS)

Sodium azide 26628-22-8 1-482

Inventory - Korea - Existing and Evaluated Chemical Substances

Sodium azide 26628-22-8 KE-31357

Canadian Hazardous Products:

WHMIS Status Exempt



MATERIAL SAFETY DATA SHEET
OSOM® hCG Urine Control - Positive I & II

European Communities Dangerous Substances/Preparations:

EC Hazard Class Xn - Harmful

Symbols



Risk Phrases

R22 Harmful if swallowed.
R32 Contact with acids liberates very toxic gas.

Safety Phrases

S35 This material and its container must be disposed of in a safe way.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

16. OTHER INFORMATION

Further Information:

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

MSDS Origination Date: January 14, 2005

Version #: 4

Revision Date: November 13, 2008

Disclaimer:

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Genzyme be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Genzyme has been advised of the possibility of such damages.



MATERIAL SAFETY DATA SHEET

OSOM® hCG Urine Control - Negative

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® hCG Urine Control - Negative

Synonym(s): hCG Urine Negative Control

Product Use: Component of OSOM® hCG Urine Control Set (Catalog # 134). For use in quality control testing with the OSOM® hCG-Urine Test, OSOM® Card Pregnancy Test, and OSOM® hCG Combo Test. For In Vitro Diagnostic Use Only.

Description: Aqueous solution containing salt and preservative.

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Manufacturer/Distributor

Genzyme Diagnostics

6659 Top Gun Street
San Diego, CA 92121
USA

Phone: 858-452-3198

Emergency Telephone Numbers

Genzyme (U.S.): 617-562-4555

CHEMTREC (U.S.): 800-424-9300

CHEMTREC (Outside U.S.): 703-527-3887

2. HAZARDS IDENTIFICATION

Precautionary Statements:

CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Harmful by ingestion. Preparation appearance: clear, colorless liquid.

Routes of Exposure:

Occupational exposure routes may include eye contact, skin contact and skin absorption.

Potential Health Effects:

Inhalation	Aerosol inhalation may cause coughing and sore throat.
Eye	Eye exposure may cause irritation, redness and watering.
Skin	Skin contact may cause irritation, dryness and redness. Sodium azide may be absorbed through the skin and result in systemic effects.
Ingestion	Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness.
Chronic Effects	No data available.
Target Organs	Sodium azide: Cardiovascular and central nervous system.

Regulatory Status:

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

Potential Environmental Effects:

Unknown.

3. COMPOSITION / INFORMATION ON INGREDIENTS



MATERIAL SAFETY DATA SHEET

OSOM® hCG Urine Control - Negative

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	98.92
EC R-Phrases: None	EC Hazard Class: None		
Sodium chloride	7647-14-5	231-598-3	0.88
EC R-Phrases: None	EC Hazard Class: None		
Sodium azide	26628-22-8	247-852-1	0.2
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		

4. FIRST AID MEASURES

Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact:

In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, contact a poison control center or physician for instructions.

5. FIRE FIGHTING MEASURES

Flammable Properties:

Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media:

Carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:

Unknown.

Specific Hazards Arising from the Chemical:

None expected.

Standard Protective Equipment and Precautions for Firefighters:

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

Environmental Precautions:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.



MATERIAL SAFETY DATA SHEET

OSOM® hCG Urine Control - Negative

Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7. HANDLING AND STORAGE

Handling:

Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:

Store at 2 to 8°C (36 to 46°F). Do not store with incompatible substances. See Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

ACGIH - Threshold Limits Values - Ceilings (TLV-C)

Sodium azide 26628-22-8 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (vapor, as hydrazoic acid)

Canada - Quebec - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.11 ppm Ceiling; 0.3 mg/m³ Ceiling

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - Skin Notations

Sodium azide 26628-22-8 possibility of significant uptake through the skin

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELs

Sodium azide 26628-22-8 0.3 mg/m³ STEL

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

Sodium azide 26628-22-8 0.1 mg/m³ TWA

Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations)

Sodium azide 26628-22-8 0.4 mg/m³ Peak (inhalable fraction)

Germany - DFG - Recommended Exposure Limits - MAK Values

Sodium azide 26628-22-8 0.2 mg/m³ MAK (inhalable fraction)

Germany - TRGS 900 - Occupational Exposure Limits - TWAs

Sodium azide 26628-22-8 0.2 mg/m³ TWA (exposure factor 2)

Israel - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.29 mg/m³ Ceiling (as NaN₃); 0.11 ppm Ceiling (vapor, as Hydrazoic acid)

Korea - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.1 ppm Ceiling; 0.3 mg/m³ Ceiling

Engineering Controls:

This preparation is aqueous and non-volatile and is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with an eyewash fountain.

Personal Protective Equipment (PPE):

Respiratory	A respirator is not required under normal conditions of use.
Eye/Face	Wear appropriate protective chemical safety glasses.
Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colorless liquid	pH:	7.1 (approx.)
Odor:	Not available	Solubility:	Water-soluble



MATERIAL SAFETY DATA SHEET

OSOM® hCG Urine Control - Negative

Boiling Point:	Not available	Vapor Pressure:	Not available
Melting Point:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
Freezing Point:	Not available	Vapor Density:	Not available
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not available		
Flash Point:	Not available		

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

Conditions to Avoid:

There are no physical conditions known to result in a hazardous situation.

Incompatible Materials:

Avoid strong oxidizing agents, acids, heavy metals and their salts.

Hazardous Decomposition Products:

Thermal decomposition may lead to release of irritating gases and vapors.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

Toxicology Data - Selected LD50s and LC50s

Sodium azide 26628-22-8 Oral LD50 Rat: 27 mg/kg; Dermal LD50 Rabbit: 20 mg/kg

Local Effects:

No data available.

Chronic Effects:

No data available.

Carcinogenicity:

ACGIH - Threshold Limits Values - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

Canada - Manitoba - Occupational Exposure Limits - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.



MATERIAL SAFETY DATA SHEET

OSOM® hCG Urine Control - Negative

12. ECOLOGICAL INFORMATION

Ecotoxicity:**Ecotoxicity - Freshwater Fish Species Data**

Sodium azide	26628-22-8	96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 Hr LC50 Lepomis macrochirus: 0.7 mg/L; 96 Hr LC50 Pimephales promelas: 5.46 mg/L [flow-through]
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Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up. Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

Waste Classification:**U.S. - California - 22 CCR - Presumed Hazardous Wastes**

Sodium azide	26628-22-8	Ignitable; Reactive
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U.S. - RCRA (Resource Conservation & Recovery Act) - P Series Wastes - Acutely Toxic Wastes

Sodium azide	26628-22-8	waste number P105
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14. TRANSPORT INFORMATION

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

Inventory - United States - Section 8(b) Inventory (TSCA)

Sodium azide	26628-22-8	Present
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U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

Sodium azide	26628-22-8	1000 lb final RQ; 454 kg final RQ
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U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

Sodium azide	26628-22-8	1000 lb EPCRA RQ
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U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

Sodium azide	26628-22-8	500 lb TPQ (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solvent form)
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U.S. - CERCLA/SARA - Section 313 - Emission Reporting

Sodium azide	26628-22-8	1.0 % de minimis concentration
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MATERIAL SAFETY DATA SHEET

OSOM® hCG Urine Control - Negative

US State Regulations:

U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances

Sodium azide 26628-22-8 Present

International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Canada - WHMIS - Classifications of Substances

Sodium azide 26628-22-8 D1A

Canada - WHMIS - Ingredient Disclosure List

Sodium azide 26628-22-8 1 %

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification

Sodium azide 26628-22-8 T+;R28 R32 N;R50-53

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases

Sodium azide 26628-22-8 S:1/2-28-45-60-61

Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

Sodium azide 26628-22-8 ID Number 636, hazard class 2 - hazard to waters

Inventory - Australia - Inventory of Chemical Substances (AICS)

Sodium azide 26628-22-8 Present

Inventory - Canada - Domestic Substances List (DSL)

Sodium azide 26628-22-8 Present

Inventory - China

Sodium azide 26628-22-8 Present

Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Sodium azide 26628-22-8 247-852-1

Inventory - Japan Existing and New Chemical Substances (ENCS)

Sodium azide 26628-22-8 1-482

Inventory - Korea - Existing and Evaluated Chemical Substances

Sodium azide 26628-22-8 KE-31357

Canadian Hazardous Products:

WHMIS Status Exempt

European Communities Dangerous Substances/Preparations:

EC Hazard Class Xn - Harmful

Symbols



Risk Phrases

R22 Harmful if swallowed.

R32 Contact with acids liberates very toxic gas.

Safety Phrases

S35 This material and its container must be disposed of in a safe way.

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

16. OTHER INFORMATION

Further Information:

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).



MATERIAL SAFETY DATA SHEET

OSOM® hCG Urine Control - Negative

MSDS Origination Date: January 14, 2005

Version #: 4

Revision Date: November 13, 2008

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