1. Product and Company Identification

Material name: OSOM® hCG Serum Control - Positive

Version #: 01

Issue date: 09-04-2012

Revision date: -

Supersedes date: -

CAS #: Mixture

Kit number: 138

Product use: Component of OSOM® hCG Serum Control Set (Catalog # 138). For use in quality control testing with the OSOM® hCG Combo Test. For In Vitro Diagnostic use only.

Synonym(s): hCG Serum Positive Control

Manufacturer information

Corporate Headquarters: Sekisui Diagnostics, LLC
31 New York Avenue, Framingham, MA 01701 USA
www.sekisuidiagnostics.com
Phone: 800-332-1042

Emergency Telephone Numbers:
Americas: 1-760-476-3962
Europe, Middle East & Africa: +1-760-476-3961
Asia Pacific: +1-760-476-3960
Access code: 333512

2. Hazards Identification

Physical state: Liquid.

Appearance: Clear, yellowish liquid.

Emergency overview: Physical and health hazard information on reagent mixtures have not been determined. Contains animal source material of U.S. origin. 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.

OSHA regulatory status: This product is not hazardous according to OSHA 29CFR 1910.1200.

Potential health effects

Routes of exposure

- Skin contact. Eye contact.
- Eyes: May cause eye irritation.
- Skin: May cause skin irritation.
- Inhalation: In high concentrations, vapors may be irritating to the respiratory system.
- Ingestion: May cause discomfort if swallowed.

Target organs: Eyes.

Chronic effects: No data available.

Signs and symptoms

Ingestion may cause irritation and malaise.

Potential environmental effects: The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS #</th>
<th>Percent</th>
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<tbody>
<tr>
<td>Sodium azide</td>
<td>26628-22-8</td>
<td>&lt; 0.2</td>
</tr>
<tr>
<td>Horse Serum</td>
<td>N/A</td>
<td>~99.8</td>
</tr>
</tbody>
</table>
Composition comments

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First Aid Measures

First aid procedures

Eye contact
In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact
Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists.

Inhalation
Move to fresh air. Call a physician if symptoms develop or persist.

Ingestion
Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Get medical attention if irritation develops and persists.

Notes to physician
Provide general supportive measures and treat symptomatically.

General advice
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.

Extinguishing media

Suitable extinguishing media
Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media
None known.

Protection of firefighters

Specific hazards arising from the chemical
When heated to decomposition, may produce hydrazoic acid fumes.

Protective equipment and precautions for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions
Use standard firefighting procedures and consider the hazards of other involved materials.

Hazardous combustion products
Carbon oxides.

6. Accidental Release Measures

Personal precautions
Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions
Do not allow to enter drains, sewers or watercourses. This mixture 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 for containment
Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up
Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Other information
Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water. Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling
Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care. Observe good industrial hygiene practices.

Storage
Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits
No exposure limits noted for ingredient(s).

Exposure guidelines
Follow standard monitoring procedures.

Engineering controls
Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors.
Personal protective equipment

Eye / face protection  Wear approved safety glasses or goggles.
Skin protection  Remove contaminated clothing promptly.
Respiratory protection  In case of inadequate ventilation or risk of inhalation of vapors, use suitable respiratory equipment.

General hygiene considerations  Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance  Clear, yellowish liquid.
Physical state  Liquid.
Form  Liquid.
Color  Yellowish.
Odor  Not available.
Odor threshold  Not available.
pH  8.1 Approximate
Vapor pressure  Not available.
Vapor density  Not available.
Boiling point  Not available.
Melting point/Freezing point  Not available.
Solubility (water)  Soluble.
Specific gravity  1.06
Flash point  Not available.
Flammability limits in air, upper, % by volume  Not available.
Flammability limits in air, lower, % by volume  Not available.
Auto-ignition temperature  Not available.
Partition coefficient (n-octanol/water)  Not applicable.

10. Chemical Stability & Reactivity Information

Chemical stability  Material is stable under normal conditions.
Conditions to avoid  Heat, sparks, flames, elevated temperatures.
Incompatible materials  Strong oxidizing agents.
Hazardous decomposition products  No data available.
Possibility of hazardous reactions  Contact with acids liberates toxic gas.

11. Toxicological Information

Sensitization  Not classified.
Acute effects  May cause discomfort if swallowed.
Local effects  May cause skin and eye irritation.
Chronic effects  No data available.
Carcinogenicity  Not classifiable as to carcinogenicity to humans.
Epidemiology  No epidemiological data is available for this product.
Mutagenicity  Not classified.
Reproductive effects  Not classified.
Symptoms and target organs  Ingestion may cause irritation and malaise.
Further information  No other specific acute or chronic health impact noted.
12. Ecological Information

Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Environmental effects
An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulation / Accumulation
Not available.

Partition coefficient
Not applicable.

Mobility in environmental media
The product is soluble in water.

13. Disposal Considerations

Waste codes
The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal instructions
Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard 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. If preparation enters drain, flush with a large volume of water to prevent azide build-up.

Waste from residues / unused products
Dispose in accordance with all applicable regulations. Contract with a licensed chemical disposal agency.

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

DOT
Not regulated as a hazardous material by DOT.

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. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
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 (DEA) (21 CFR 1308.11-15)
Not controlled
Canadian regulations
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

WHMIS status
Non-controlled

Inventory status

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
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<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
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<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>Yes</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*A “Yes” indicates this product complies with the inventory requirements administered by the governing country(s)

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

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance
Not listed.

US. Massachusetts RTK - Substance List
Not regulated.

US. New Jersey Worker and Community Right-to-Know Act
Not regulated.

US. Pennsylvania RTK - Hazardous Substances
Not regulated.

Mexico regulations
This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions
Use in accordance with supplier's recommendations.

Further information
HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 0
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 0
Flammability: 0
Instability: 0

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 Sekisui Diagnostics 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 Sekisui Diagnostics has been advised of the possibility of such damages.
1. Product and Company Identification

Material name: OSOM® hCG Serum Control - Negative

Version #: 01
Issue date: 09-04-2012
Revision date: -
Supersedes date: -
CAS #: Mixture
Kit number: 138
Product use: Component of OSOM® hCG Serum Control Set (Catalog # 138). For use in quality control testing with the OSOM® hCG Combo Test. For In Vitro Diagnostic use only.

Synonym(s): hCG Serum Negative Control

Manufacturer information:
Corporate Headquarters: Sekisui Diagnostics, LLC
31 New York Avenue, Framingham, MA 01701 USA
www.sekisuidiagnostics.com
Phone: 800-332-1042

Emergency Telephone Numbers:
Americas 1-760-476-3962
Europe, Middle East & Africa +1-760-476-3961
Asia Pacific +1-760-476-3960
Access code 333512

2. Hazards Identification

Physical state: Liquid.
Appearance: Clear, yellowish liquid.

Emergency overview: Physical and health hazard information on reagent mixtures have not been determined. Contains animal source material of U.S. origin. 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.

OSHA regulatory status: This product is not hazardous according to OSHA 29CFR 1910.1200.

Potential health effects:

Routes of exposure:
Skin contact. Eye contact.

Eyes: May cause eye irritation.
Skin: May cause skin irritation.

Inhalation: In high concentrations, vapors may be irritating to the respiratory system.

Ingestion: May cause discomfort if swallowed.

Target organs: Eyes.

Chronic effects: No data available.

Signs and symptoms:
Ingestion may cause irritation and malaise.

Potential environmental effects: The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

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<th>Components</th>
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<td>Horse Serum</td>
<td>N/A</td>
<td>~99.8</td>
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4. First Aid Measures

First aid procedures

Eye contact
In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact
Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists.

Inhalation
Move to fresh air. Call a physician if symptoms develop or persist.

Ingestion
Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Get medical attention if irritation develops and persists.

Notes to physician
Provide general supportive measures and treat symptomatically.

General advice
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.

Extinguishing media
Suitable extinguishing media
Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media
None known.

Protection of firefighters
Specific hazards arising from the chemical
When heated to decomposition, may produce hydrazoic acid fumes.

Protective equipment and precautions for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions
Use standard firefighting procedures and consider the hazards of other involved materials.

Hazardous combustion products
Carbon oxides.

6. Accidental Release Measures

Personal precautions
Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions
Do not allow to enter drains, sewers or watercourses. This mixture 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 for containment
Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up
Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Other information
Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water. Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling
Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care. Observe good industrial hygiene practices.

Storage
Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits
No exposure limits noted for ingredient(s).

Exposure guidelines
Follow standard monitoring procedures.

Engineering controls
Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors.
Personal protective equipment

- **Eye / face protection**: Wear approved safety glasses or goggles.
- **Skin protection**: Remove contaminated clothing promptly.
- **Respiratory protection**: In case of inadequate ventilation or risk of inhalation of vapors, use suitable respiratory equipment.
- **General hygiene considerations**: Handle in accordance with good industrial hygiene and safety practice.

### 9. Physical & Chemical Properties

- **Appearance**: Clear, yellowish liquid.
- **Physical state**: Liquid.
- **Form**: Liquid.
- **Color**: Yellowish.
- **Odor**: Not available.
- **Odor threshold**: Not available.
- **pH**: 8.1 Approximate
- **Vapor pressure**: Not available.
- **Vapor density**: Not available.
- **Boiling point**: Not available.
- **Melting point/Freezing point**: Not available.
- **Solubility (water)**: Soluble.
- **Specific gravity**: 1.06
- **Flash point**: Not available.
- **Flammability limits in air, upper, % by volume**: Not available.
- **Flammability limits in air, lower, % by volume**: Not available.
- **Auto-ignition temperature**: Not available.
- **Partition coefficient (n-octanol/water)**: Not applicable.

### 10. Chemical Stability & Reactivity Information

- **Chemical stability**: Material is stable under normal conditions.
- **Conditions to avoid**: Heat, sparks, flames, elevated temperatures.
- **Incompatible materials**: Strong oxidizing agents.
- **Hazardous decomposition products**: No data available.
- **Possibility of hazardous reactions**: Contact with acids liberates toxic gas.

### 11. Toxicological Information

- **Sensitization**: Not classified.
- **Acute effects**: May cause discomfort if swallowed.
- **Local effects**: May cause skin and eye irritation.
- **Chronic effects**: No data available.
- **Carcinogenicity**: Not classifiable as to carcinogenicity to humans.
- **Epidemiology**: No epidemiological data is available for this product.
- **Mutagenicity**: Not classified.
- **Reproductive effects**: Not classified.
- **Symptoms and target organs**: Ingestion may cause irritation and malaise.
- **Further information**: No other specific acute or chronic health impact noted.
12. Ecological Information

Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Environmental effects
An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulation / Accumulation
Not available.

Partition coefficient
Not applicable.

Mobility in environmental media
The product is soluble in water.

13. Disposal Considerations

Waste codes
The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal instructions
Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contaminated instruments and surfaces should be disinfected in accordance with your employer’s chemical-specific and universal/standard 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. If preparation enters drain, flush with a large volume of water to prevent azide build-up.

Waste from residues / unused products
Dispose in accordance with all applicable regulations. Contract with a licensed chemical disposal agency.

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

DOT
Not regulated as a hazardous material by DOT.

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. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
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Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
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 (DEA) (21 CFR 1308.11-15)
Not controlled
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WHMIS status
Non-controlled

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*A “Yes” indicates this product complies with the inventory requirements administered by the governing country(s)

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

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listened substance
Not listed.

US. Massachusetts RTK - Substances List
Not regulated.

US. New Jersey Worker and Community Right-to-Know Act
Not regulated.

US. Pennsylvania RTK - Hazardous Substances
Not regulated.

Mexico regulations
This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions
Use in accordance with supplier’s recommendations.

Further information
HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 0  
Flammability: 0  
Physical hazard: 0

NFPA ratings
Health: 0  
Flammability: 0  
Instability: 0

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