

1. Product and Company Identification

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| Material name | ImmunoCard STAT!® hCG Urine Control - Positive I & II |
| Version # | 01 |
| Issue date | 09-04-2012 |
| Revision date | - |
| Supersedes date | - |
| CAS # | Mixture |
| Kit number | 755625 |
| Product use | For use in quality control testing with the ImmunoCard STAT!® hCG Combo Test. For In Vitro Diagnostic use only. |
| Synonym(s) | hCG Urine Positive Control I; hCG Urine Positive Control II |
| 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

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| Physical state | Liquid. |
| Appearance | Clear, colorless liquid. |
| Emergency overview | Physical and health hazard information on reagent mixtures have not been determined. 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

| Components | CAS # | Percent |
|--------------|------------|---------|
| Sodium azide | 26628-22-8 | 0.2 |

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

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| 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

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| 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.

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| 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

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| Appearance | Clear, colorless liquid. |
| Physical state | Liquid. |
| Form | Liquid. |
| Color | Colorless. |
| Odor | Not available. |
| Odor threshold | Not available. |
| pH | 7.1 Approximate |
| Vapor pressure | Not available. |
| Vapor density | Not available. |
| Boiling point | Not available. |
| Melting point/Freezing point | Not available. |
| Solubility (water) | Soluble. |
| Specific gravity | Not available. |
| 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

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| 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

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| 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

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| 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. |

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| 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

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| 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

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| 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. |
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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)

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| Hazard categories | Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No |
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| Section 302 extremely hazardous substance (40 CFR 355, Appendix A) | No |
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| Section 311/312 (40 CFR 370) | No |
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| Drug Enforcement Administration (DEA) (21 CFR 1308.11-15) | Not controlled |
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| 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. |
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| WHMIS status | Non-controlled |
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Inventory status

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

*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

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