

1. Product and Company Identification

Material name	DC-UIBC-Calibrator
Version #	01
Issue date	01-16-2013
Revision date	-
Supersedes date	-
CAS #	Mixture
Product code	SE-090
Product use	For in vitro diagnostic use as a calibrator in clinical chemistry assays for UIBC (Unsaturated Iron Binding Capacity). DC-UIBC-CAL may be used to check the linearity over the reportable patient range of UIBC assays.
Manufacturer information	
Corporate Headquarters	Sekisui Diagnostics, LLC 4 Hartwell Place, Lexington, MA 02421, 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	Solid.
Appearance	Off-white lyophilized powder.
Emergency overview	Exercise the normal precautions required for handling all laboratory reagents. The human serum in this product has been prepared exclusively from the blood of donors tested individually and shown by FDA-approved methods to be free from HBsAg and antibodies to HCV and HIV. However, as no test method can rule out the potential risk of infection with absolute certainty, the material should be treated just as carefully as a patient sample. In the event of exposure, the directives of the responsible Health Authorities should be followed. The bovine serum was collected in the United States at USDA inspected facilities from animals which have been found to be free of signs of infections and contagious disease.
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	May cause irritation to the mucous membranes and upper respiratory tract.
Ingestion	May be harmful if swallowed.
Target organs	Eyes. Skin.
Chronic effects	No data available.
Signs and symptoms	Direct contact with skin and eyes may cause irritation.
Potential environmental effects	The product components are 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

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

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 Material may burn when exposed to sufficient heat.

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 Fire will generate toxic and irritating gases.

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 No data available.

6. Accidental Release Measures

Personal precautions Avoid dust formation. 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.

Methods for containment Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up Sweep up or vacuum up spillage and collect in suitable container for disposal. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Other information Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling Provide appropriate exhaust ventilation at places where dust is formed. Avoid contact with skin and eyes. Wash thoroughly after handling. 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 Observe occupational exposure limits and minimize the risk of inhalation of dust and fumes.

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 dust, use a suitable NIOSH approved respirator with an appropriate particulate filter.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Off-white lyophilized powder.
Physical state	Solid.
Form	Lyophilized powder.
Color	Off-white.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
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.

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	Heat, flames and sparks.
Incompatible materials	No data available.
Hazardous decomposition products	No data available.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

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	Direct contact with skin and eyes may cause irritation.
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.

Mobility in environmental media No data available.

13. Disposal Considerations

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.

Waste from residues / unused products Dispose in accordance with all applicable 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 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

Country(s) or region	Inventory name	On inventory (yes/no)*
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

Country(s) or region	Inventory name	On inventory (yes/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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