

## 1. Product and Company Identification

<b>Material name</b>	<b>Bile Acid Control, Level 1</b>
<b>Version #</b>	01
<b>Issue date</b>	04-18-2013
<b>Revision date</b>	-
<b>Supersedes date</b>	-
<b>CAS #</b>	Mixture
<b>Kit number</b>	SM-702-C1
<b>Product use</b>	For in vitro diagnostic use in calibration and quality control of serum assays.
<b>Manufacturer information</b>	
<b>Corporate Headquarters</b>	Sekisui Diagnostics, LLC 4 Hartwell Place, Lexington, MA 02421, USA www.sekisuidiagnostics.com Phone: 800-332-1042
<b>Emergency Telephone Numbers</b>	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

<b>Physical state</b>	Liquid.
<b>Appearance</b>	Pale yellow liquid.
<b>Emergency overview</b>	Physical and health hazard information on reagent mixtures have not been determined. Bovine source materials. Treat as potentially infectious. Bovine based products should be handled in accordance with good laboratory practices using appropriate precautions. The bovine material was obtained by USDA or foreign government facilities and have been found to be free of signs of infectious and contagious disease.
<b>OSHA regulatory status</b>	This product is not hazardous according to OSHA 29CFR 1910.1200.
<b>Potential health effects</b>	
<b>Routes of exposure</b>	Skin contact. Eye contact.
<b>Eyes</b>	May cause eye irritation.
<b>Skin</b>	May cause skin irritation.
<b>Inhalation</b>	May cause irritation to mucous membrane and respiratory system.
<b>Ingestion</b>	May cause discomfort if swallowed.
<b>Target organs</b>	Eyes. Skin.
<b>Chronic effects</b>	No data available.
<b>Signs and symptoms</b>	Direct contact with skin and eyes may cause irritation.
<b>Potential environmental effects</b>	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

<b>Eye contact</b>	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.
<b>Skin contact</b>	For skin contact flush with large amounts of water while removing contaminated clothing.
<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.

**Ingestion** If material is ingested, immediately contact a poison control center.  
**Notes to physician** Provide general supportive measures and treat symptomatically.

## 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** None known.

**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** 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** 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.

**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. Provide easy access to water supply and eye wash facilities.

**Personal protective equipment**

**Eye / face protection** Wear approved safety glasses or goggles.

**Skin protection** Wear lab coat or other protective garments. Remove contaminated clothing promptly.

**Respiratory protection** Under normal conditions, respirator is not normally required.

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

## 9. Physical & Chemical Properties

**Appearance** Pale yellow liquid.

**Physical state** Liquid.

**Form** Liquid.

**Color** Pale yellow.

**Odor** No distinctive odor.

**Odor threshold** Not available.

**pH** 6

<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Boiling point</b>	Not available.
<b>Melting point/Freezing point</b>	Not available.
<b>Solubility (water)</b>	Soluble.
<b>Specific gravity</b>	1
<b>Flash point</b>	Not available.
<b>Flammability limits in air, upper, % by volume</b>	Not available.
<b>Flammability limits in air, lower, % by volume</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.

## 10. Chemical Stability & Reactivity Information

<b>Chemical stability</b>	Stable at normal conditions.
<b>Conditions to avoid</b>	Heat, sparks, flames, elevated temperatures.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	No data available.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.

## 11. Toxicological Information

<b>Sensitization</b>	Not classified.
<b>Acute effects</b>	May cause discomfort if swallowed.
<b>Local effects</b>	May cause eye, skin and respiratory tract irritation.
<b>Chronic effects</b>	No data available.
<b>Carcinogenicity</b>	Not classifiable as to carcinogenicity to humans.
<b>Epidemiology</b>	No epidemiological data is available for this product.
<b>Mutagenicity</b>	Not classified.
<b>Reproductive effects</b>	Not classified.
<b>Symptoms and target organs</b>	Direct contact with skin and eyes may cause irritation.
<b>Further information</b>	Not available.

## 12. Ecological Information

<b>Ecotoxicity</b>	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.
<b>Environmental effects</b>	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulation / Accumulation</b>	Not available.
<b>Mobility in environmental media</b>	The product is completely soluble in water.

## 13. Disposal Considerations

<b>Disposal instructions</b>	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.
<b>Waste from residues / unused products</b>	Dispose in accordance with all applicable regulations.
<b>Contaminated packaging</b>	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. All components are on the U.S. EPA TSCA Inventory List.

#### 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

#### SARA 311/312 Hazardous chemical

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
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

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
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).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory 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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