1. Product and Company Identification

Material name: Alpha-Amylase Test Reagent (CNPG3)

Version #: 01

Issue date: 03-19-2013

Revision date: -

Supersedes date: -

CAS #: Mixture

Part No.: 80-3500-20; 80-3500-50; 80-3603-01; 80-3844-03; 80-5383-00; 80-5451-00

Product use: For the quantitative determination of alpha-amylose activity in serum and plasma; to assist in the diagnosis of acute pancreatitis. For In Vitro Diagnostic use only.

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: Liquid.

Appearance: Slight yellow liquid.

Emergency overview: WARNING

Causes skin, eye and respiratory tract irritation. May be harmful if absorbed through skin or swallowed. Physical and health hazard information on reagent mixtures have not been determined.

OSHA regulatory status: This product is hazardous according to OSHA 29 CFR 1910.1200.

Potential health effects

Routes of exposure

Skin contact. Eye contact. Inhalation. Ingestion.

Eyes

Causes eye irritation. Exposed individuals may experience eye tearing, redness, and discomfort.

Skin

Causes skin irritation. Symptoms of acute potassium thiocyanate exposure may be similar to acute cyanide toxicity: May be harmful if absorbed through skin.

Inhalation

Causes respiratory tract irritation. Symptoms of acute potassium thiocyanate exposure may be similar to acute cyanide toxicity: Acute inhalation may cause coughing, mucosal irritation and dyspnea (shortness of breath).

Ingestion

Symptoms of acute potassium thiocyanate exposure may be similar to acute cyanide toxicity: May be harmful if swallowed. Low oral doses of cyanides produce symptoms of weakness, headache, confusion, and occasionally nausea and vomiting.

Target organs

Potassium thiocyanate: central nervous system, cardiovascular system and thyroid.

Chronic effects

Symptoms of potassium thiocyanate intoxication may be similar to chronic cyanide toxicity. Subchronic and chronic effects of cyanide inhalation include: CNS effects, such as vertigo (dizziness), nystagmus (abnormal eye movement), nervousness, headache, weakness, loss of appetite, and changes in smell and taste; CVS effects, such as precordial (central chest) pain, EKG abnormalities, and breathing difficulties; GI tract effects, such as nausea, vomiting, and gastritis (stomach lining inflammation); enlarged thyroid/goiter; and skin effects, such as dermatitis, itching, scarlet rash, papules (bumps) and severe irritation of the nose and throat. Symptoms of chronic ingestion of cyanide include: CNS effects, such as neuropathies (nerve problems) and amylobia (lazy eye); and thyroid abnormalities. Subchronic dermal exposure symptoms include itching, rash, papules, dermatitis, skin and nail discoloration, diarrhea, headache, and body and limb numbness, weakness and pain.
3. Composition / Information on Ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS #</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium thiocyanate</td>
<td>333-20-0</td>
<td>7 - 9</td>
</tr>
<tr>
<td>MES (Methyl p-hydroxybenzoate)</td>
<td>145224-94-8</td>
<td>1 - 2</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: 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: 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.

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**
Slight yellow liquid.

**Physical state**
Liquid.

**Form**
Liquid.

**Color**
Slight yellow.

**Odor**
Not available.

**Odor threshold**
Not available.

**pH**
6.0-6.1

**Vapor pressure**
Not available.

**Vapor density**
Not available.

**Boiling point**
Not available.

**Melting point/Freezing point**
Not available.

**Solubility (water)**
Soluble.

**Specific gravity**
1.04

**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**
Polymerization will not occur.

11. Toxicological Information

**Toxicological data**

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium thiocyanate (CAS 333-20-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>854 mg/kg</td>
</tr>
</tbody>
</table>

**Sensitization**
Not classified.
Acute effects
May be harmful if absorbed through skin or swallowed.

Local effects
Causes skin, eye and respiratory tract irritation.

Chronic effects
Symptoms of potassium thiocyanate intoxication may be similar to chronic cyanide toxicity.

Carcinogenicity
Not classified.

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

Ecotoxicological data

<table>
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<tbody>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Aquatic Fish</td>
<td>LC50</td>
<td>Rainbow trout, donaldson trout (Oncorhynchus mykiss)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11 mg/l, 96 hours</td>
</tr>
</tbody>
</table>

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 a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 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 - Yes
  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)

Yes

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

Exempt

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) | No
Korea | Existing Chemicals List (ECL) | Yes
New Zealand | New Zealand Inventory | Yes
Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No
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: 2
  Flammability: 0
  Physical hazard: 0
NFPA ratings
Health: 2
Flammability: 0
Instability: 0

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