SAFETY DATA SHEET
KL-6 KIT
Standard antigen

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: KL-6 KIT [Standard antigen]
* KL-6 KIT (1 box) consists of 9 reagents (Standard antigen 6 concentrations ×1 vial, Sample diluent concentrate ×1 vial, Antibody coated cup ×1 pack, Reaction solution ×1 vial, Enzyme antibody conjugate concentrate ×1 vial, Enzyme substrate ×1 vial, Chromogen ×3 vials, Stop reaction solution ×1 vial, Wash solution concentrate ×1 vial). See also the SDSs of the other reagents (Sample diluent concentrate, Antibody coated cup, Reaction solution, Enzyme antibody conjugate concentrate, Enzyme substrate, Chromogen, Stop reaction solution, Wash solution concentrate) (No.S515828B, S515828C, S515828D, S515828E, S515828F, S515828G, S515828H, S515828I).

KL-6 KIT Standard antigen consists of 6 levels of concentration (Standard antigen 0 U/mL, 1 U/mL, 2.5 U/mL, 5 U/mL, 10 U/mL and 20 U/mL) × 1 vial each. Hazardous ingredients corresponding to GHS classification and their concentrations are common to the reagents (6 concentration levels).

Product code: 502515828
Identification of the supplier:
Name: SEKISUI MEDICAL CO., LTD.
Address: 3262-12 Yoshiwara, Ami-machi, Inashiki-gun, Ibaraki 300-1155, Japan
Contact: Compliance & Assurance Department Ami Quality Assurance Group
Phone number: +81-29-889-2242
Recommended uses: Research use only

Reference number: S515828A

2. HAZARDS IDENTIFICATION

GHS classification: No classification.
Other hazards: The product contains ingredients of human origin and bovine serum albumin, and should be handled as potentially infectious.

3. COMPOSITION/ INFORMATION ON INGREDIENTS

Single substance or mixture: Mixture

Hazardous ingredient

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS No.</th>
<th>Concentration or concentration range (mass fraction: %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide</td>
<td>26628-22-8</td>
<td>0.10</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

Inhalation: Remove to fresh air, and keep at rest in a position comfortable for breathing. Call a doctor if you feel unwell.
SAFETY DATA SHEET
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Skin contact : Immediately take off contaminated clothing. Wash the contaminated skin with running water.
Eye contact : Rinse cautiously with water for several minutes. Next, remove contact lenses if present and easy to do. Continue rinsing. Rinse with clean water for several minutes, and immediately get medical attention. During rinsing, open eyelids with fingers and rinse the eyeball and eyelids thoroughly.
Ingestion : Rinse mouth with water. Immediately call a doctor.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Use dry chemicals, carbon dioxide or dry sand for initial fire. For a large fire, cut off the air supply with foam.
Unsuitable extinguishing media : No information available
Protection of fire-fighters : Use personal protective equipment during fire-fighting.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment to avoid skin contact with the spill or inhalation of dust or gas.
Environmental precautions : Avoid releasing spilled product into rivers, etc. to prevent environmental impact. When the product is diluted with a large amount of water, avoid spilling the contaminated wastewater into the environment without proper treatment.
Methods and materials for containment and cleaning up : In the case of a small amount, absorb with dry sand, soil, sawdust or dustcloth, and collect in an empty sealable container. In the case of a large amount, prevent leaking by surrounding with soil, and lead to a safe place before treatment.

7. HANDLING AND STORAGE

Handling Technical measures : Avoid eye or skin contact and contamination of clothing. Do not subject the container to rough handling such as fall, drop, shock or friction.
Safety handling precautions : Handle with care as potentially infectious.
Contact avoidance : No information available
Storage Safe storage conditions : Store at 2-10°C.
Safe packaging material : No information available

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protective equipment Respiratory protection : Dust respirator or simplified dust respirator as appropriate.
Hand protection : Impermeable protective gloves as appropriate.
Eye protection : Protective goggles as appropriate.
Skin and body protection : Proper protective clothing (long-sleeved working clothes) as appropriate.
SAFETY DATA SHEET
KL-6 KIT
Standard antigen

9. PHYSICAL AND CHEMICAL PROPERTIES
The product is a mixture.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Blue to bluish purple and clear liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY
The product is a mixture.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No autoreactivity</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions</td>
</tr>
<tr>
<td>Hazardous reactions</td>
<td>None under normal conditions</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>No information available</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>No information available</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>Sodium azide contained in the product may react with lead or copper piping to form highly explosive metal azides.</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product
No information available

Ingredient
• Sodium azide
  Oral LD₅₀: 45 mg/kg (rat)
  Dermal LD₅₀: 20 mg/kg (Rabbit)
  Inhalation LC₅₀: No information available

<table>
<thead>
<tr>
<th>Acute toxicity (oral)</th>
<th>Acute toxicity (dermal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classified as Category 2 based on Rat LD₅₀ = 45 mg/kg (DFGOT vol.20 (2003)).</td>
<td>Classified as Category 1 based on Rabbit LD₅₀ = 20 mg/kg (ACGIH (2001)).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute toxicity (Inhalation: gas)</th>
<th>Acute toxicity (Inhalation: vapour)</th>
<th>Acute toxicity (Inhalation: dust/mist)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The product is solid according to the GHS definition.</td>
<td>No data available.</td>
<td>Cannot be classified due to insufficient data. There is a report that Rat LC₅₀ = 37 mg/m³ (RTECS (2008)), with exposure duration unspecified.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
KL-6 KIT
Standard antigen

Skin irritation/corrosion

Product
No information available

Ingredient
- Sodium azide

<table>
<thead>
<tr>
<th>Skin irritation/corrosion</th>
</tr>
</thead>
</table>
| Classified as Category 1 based on a report (DFGOT vol.20 (2003)) that corrosion was observed 4 hours after application and 3 of 6 animals died as a result of a rabbit skin application test.

Serious eye damage/ irritation

Product
No information available

Ingredient
- Sodium azide

<table>
<thead>
<tr>
<th>Serious eye damage/ irritation</th>
</tr>
</thead>
</table>
| Classified as Category 1 based on skin corrosion classified as Category 1.

Respiratory or skin sensitization

Product
No information available

Ingredient
- Sodium azide

<table>
<thead>
<tr>
<th>Respiratory sensitization</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Skin sensitization</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available.</td>
</tr>
</tbody>
</table>

Reproductive cell mutagenicity

Product
No information available

Ingredient
- Sodium azide

<table>
<thead>
<tr>
<th>Reproductive cell mutagenicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification not possible due to lack of in vivo study data. In vitro mutagenicity showed a positive result in a microbial reverse mutation assay (ACGIH (2001)), and negative results in chromosomal aberration assay in human lymphocytes or Chinese hamster ovary cells and gene mutation assay in mouse lymphoma cells (DFGOT vol.20, (2003)). Strong mutagenicity is considered to be specific to microbes (DFGOT vol.20 (2003)).</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
KL-6 KIT
Standard antigen

Carcinogenicity

Product
No information available

Ingredient
• Sodium azide

<table>
<thead>
<tr>
<th>Carcinogenicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classified as &quot;Not classified&quot; because it is classified as A4 in ACGIH (ACGIH-TLV (2005)). In a 2-year oral treatment study in rats, a decreased survival rate in a high-dose group and dose-dependent weight gain inhibition were observed, while no evidence of carcinogenicity was found (NTP TR389 (1991)).</td>
</tr>
</tbody>
</table>

Reproductive toxicity

Product
No information available

Ingredient
• Sodium azide

<table>
<thead>
<tr>
<th>Reproductive toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classified as &quot;Classification not possible&quot; because: Exposure during Day 7-9 of gestation via an osmotic minipump implanted subcutaneously in hamsters resulted in death in 2/15 animals, an significant increase in early resorption, and the occurrence of brain herniation (DFGOT vol.20 (2003)), but at the same time it is described that it cannot be used for prenatal toxicity evaluation because it is insufficient as a documentary evidence (DFGOT vol.20 (2003)). In addition, the method of administration also is special.</td>
</tr>
</tbody>
</table>

STOT - single exposure

Product
No information available

Ingredient
• Sodium azide

<table>
<thead>
<tr>
<th>STOT - single exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classified as Category 1 (cardiovascular) because: While there are case reports including the case of 5 technicians who showed strong heartbeats, faint and cardiac ischemia in an oral poisoning accident (NTP TR.389 (1991)), the lethal case of a chemist after ingestion of 10-20 g causing a change in mental state, significant acidosis, cardiac dysrhythmia, decreased heart rate and hypotension (NTP TR.389 (1991)), and the case of a technician who showed tachycardia, hyperventilation and hypotension after ingestion of an extremely small amount (HSDB (2009)), it is described that the target organ of the substance is the cardiovascular system, causing peripheral vessel dilation, leading to hypotension (DFGOT vol.20 (2003)). In addition, it is classified as Category 1 (lung, central nervous system, systemic toxicity) because the human cases described above also showed symptoms of dizziness, faint, a change in mental state, extracardiac pulmonary edema and metabolic acidosis, and there is the description that pulmonary edema and cerebral edema were observed in a suicidal case of ingestion of several grams of the substance. . In animal studies, decreased heart rate and generalized convulsion in rats (DFGOT vol.20 (2003)) and hypotension and cardiac disorder in rabbits (PATTY (5th.2001)) by oral administration were recorded.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET  
KL-6 KIT  
Standard antigen

STOT-repeated exposure

Product
No information available

Ingredient
• Sodium azide

<table>
<thead>
<tr>
<th>STOT - repeated exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>In a 13-week repeated oral exposure study in rats, clinical symptoms of lethargy, labored breathing and death, and histological lesions of necrosis in the cerebrum and the thalamus were observed at the highest dose (20 mg/kg/day) (NTP TR389 (1991)). In a 2-year repeated oral exposure study, a decrease in the survival rate was observed at the highest dose (10 mg/kg/day), and it is described that this decrease is caused by brain necrosis and cardiovascular collapse due to exposure to the test substance (NTP TR389 (1991)), and therefore it is classified as Category 1 (central nervous system, cardiovascular system). In the 13-week repeated oral exposure study in rats described above, pulmonary congestion, hemorrhage and edema were also observed at 20 mg/kg/day, and therefore it was classified as Category 2 (lung). In a repeated oral exposure study in dogs (1-10 mg/kg/day), ataxia was also observed, and a histomorphological change in the cerebrum is reported (HSDB (2009)), while no report in particular is found that reports the occurrence of serious adverse effects of human exposure.</td>
</tr>
</tbody>
</table>

Aspiration hazard

Product
No information available

Ingredient
• Sodium azide

<table>
<thead>
<tr>
<th>Aspiration hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available.</td>
</tr>
</tbody>
</table>

12. ECOLOGICAL INFORMATION

Ecotoxicity

Product
No information available

Ingredient
• Sodium azide

<table>
<thead>
<tr>
<th>Aquatic toxicity (acute)</th>
<th>Aquatic toxicity (chronic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classified as Category 1 based on 96-hour ErC50 = 348μg/L in algae (Pseudokirchneriella subcapitata) (AQUIRE, 2010).</td>
<td>Classified as Category 1 based on that it is Acute toxicity category 1 and it has no rapid degradability (Degradability by direct measurement (HPLC): 1% (existing substance inspection, 2000)).</td>
</tr>
</tbody>
</table>

Persistence and degradability : No data available
Bioaccumulative potential : No data available
Mobility in soil : No data available
Hazard to the ozone layer : No data available

SEKISUI MEDICAL CO., LTD.
SAFETY DATA SHEET
KL-6 KIT
Standard antigen

13. DISPOSAL CONSIDERATIONS

Waste from residues : Dispose to a licensed industrial waste disposal contractor. It should be noted during the disposal of the product that it is potentially infectious. (Disposal should be in accordance with applicable regional, national and local laws and regulations.)

Contaminated container and packaging : Dispose to a licensed industrial waste disposal contractor. It should be noted during the disposal of the product that it is potentially infectious. (Disposal should be in accordance with applicable regional, national and local laws and regulations.)

14. TRANSPORT INFORMATION

Japanese regulations

Land transport : According to transport methods specified in the Fire Services Act and the Industrial Safety and Health Act, etc.


Air transport : According to transport methods specified in the Civil Aeronautics Law.

15. REGULATORY INFORMATION

Japanese regulations

Pollutant Release and Transfer Register Law

- Sodium azide
  Class 1 specified chemicals (Law Art.1, Para.(2), and Enforcement Order Art.1, Appended Table 1)
  * Not applicable because the content in the product is less than 1 mass%.

Industrial Safety and Health Act

- Sodium azide
  - Harmful Substances whose names, etc., are to be indicated on the label of the container or package (Law Art.57-1 and Enforcement Order Art.18-1, 2, Appended Table 9)
  * Not applicable because the product is an in vitro diagnostic.

- Notifiable substances for which delivering SDS is required (Law Art.57-2 and Enforcement Order Art.18-2-1, 2, Appended Table 9)
  * Not applicable because the product is an in vitro diagnostic.

Poisonous and Deleterious Substances Control Act

- Sodium azide
  - Poisonous Substances (Cabinet Order for the Designation of the Poisonous and Deleterious Substances, Art.1)
  * Not applicable because the product is an in vitro diagnostic.
16. OTHER INFORMATION

Literature and references:

: GHS Classification Result  “Sodium azide”
(2009, MHLW, MOE)

Disclaimer
This SDS is in accordance with JIS Z 7253:2012.
The hazard assessment of the product is not entirely complete and the product should be handled with care. This SDS is prepared based on documents, information and data currently available, and does not certify the contents including the content, physical and chemical properties, and hazards. The precautions are intended for normal handling in laboratories. Take safety measures suitable for application and usage. The contents of the SDS may be revised due to amendments of laws and regulations and new findings.