SAFETY DATA SHEET

KL-6 KIT
Enzyme antibody conjugate concentrate

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: KL-6 KIT (Enzyme antibody conjugate concentrate)

* KL-6 KIT (1 box) consists of 9 reagents (Standard antigen 6 concentrations ×1 vial, Sample diluent concentrate ×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 (Standard antigen, Sample diluent concentrate, Antibody coated cup, Reaction solution, Enzyme substrate, Chromogen, Stop reaction solution, Wash solution concentrate) (No.S515828A, S515828B, S515828C, S515828D, S515828F, S515828G, S515828H, S515828I).

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
and restrictions on use
Reference number: S515828E

2. HAZARDS IDENTIFICATION

GHS classification: No classification.
Other hazards: The product contains normal rabbit serum, 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>Methyl 4-hydroxybenzoate (Methyl p-hydroxybenzoate)</td>
<td>99-76-3</td>
<td>0.075</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.

Skin contact: Immediately take off contaminated clothing. Wash the contaminated skin with running water.
SAFETY DATA SHEET
KL-6 KIT
Enzyme antibody conjugate concentrate

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.
9. PHYSICAL AND CHEMICAL PROPERTIES

The product is a mixture.

**Appearance** : light yellow to yellowish brown liquid
**Odor** : No data available
**pH** : 5.2-5.8 (25°C)
**Boiling point, initial boiling point and boiling range** : No data available
**Flash point** : No data available
**Upper/lower flammability or explosive limits** : No data available
**Vapour pressure** : No data available
**Specific Gravity** : No data available
**Auto-ignition temperature** : No data available

10. STABILITY AND REACTIVITY

The product is a mixture.

**Reactivity** : No autoreactivity
**Chemical stability** : Stable under normal conditions
**Hazardous reactions** : None under normal conditions
**Conditions to avoid** : No information available
**Incompatible materials** : No information available
**Hazardous decomposition products** : No information available

11. TOXICOLOGICAL INFORMATION

Acute toxicity

**Product**

No information available

**Ingredient**

- Methyl 4-hydroxybenzoate

**Oral LD₅₀**: 8000 mg/kg (rat)
**Dermal LD₅₀**: No information available
**Inhalation LC₅₀**: No information available

<table>
<thead>
<tr>
<th>Acute toxicity (oral)</th>
<th>Acute toxicity (dermal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not classified based on the LD50 of 8,000 mg/kg in an oral treatment study in rats (JECFA (1966)). Additionally, it is described in JECFA (1966) that “mouse LD50 is 8,000 mg/kg,” while the section of acute toxicity of Food Chem. Toxicol. 40 (2002) that is used as a reference for reproductive toxicity cites the same literature (Drug Stand. 20 (1952)) as data in rats, the data is judged to be rat data and is used as such.</td>
<td>Classification not possible because there is no data available. Additionally, it is described that “a dermal treatment test was performed with an eye makeup cosmetic containing % of the substance, and it resulted in the LD50 &gt;2,000 mg/kg” in the section of acute toxicity of Food Chem. Toxicol. 40 (2002) that is used as a reference for reproductive toxicity for reproductive toxicity.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
KL-6 KIT
Enzyme antibody conjugate concentrate

<table>
<thead>
<tr>
<th>Acute toxicity</th>
<th></th>
<th>Acute toxicity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Inhalation: gas)</td>
<td>Not applicable because the substance is solid according to the GHS definition and the inhalation of gas is not expected.</td>
<td>Classification not possible because there is no data available.</td>
<td>Classification not possible because there is no data available.</td>
</tr>
</tbody>
</table>

Skin irritation/corrosion

Product
No information available

Ingredient
• Methyl 4-hydroxybenzoate

Skin irritation/corrosion

In humans, there are the descriptions that “non-irritating to the normal human skin” while “the maximum concentration of the substance was 5% when no irritation was observed after applying a dilution on the back of 50 subjects daily for 5 days” (HSDB (2007)). In animals, it is described that “evaluated as mild skin irritation based on PII = 0.67 (maximum 4.0) with undiluted liquid” in a 24-hour Draize test in rabbits (HSDB (2007)). Based on the above, the substance is considered to fall under UN GHS skin irritation category 3, but the category is not employed in Japan, and thus it is classified as Not classified.

Serious eye damage/ irritation

Product
No information available

Ingredient
• Methyl 4-hydroxybenzoate

Serious eye damage/ irritation

While it is described that “saturated solution is moderately irritating to eye” (HSDB (2007)), it is described in an eye irritation study in rabbits that “at 100% concentration, the eye irritation score on Day 1 was 1 (maximum 110), and thus transiently and slightly irritating to eye” (HSDB (2007)). Classification not possible due to insufficient data.

Respiratory or skin sensitization

Product
No information available

Ingredient
• Methyl 4-hydroxybenzoate

Respiratory sensitization

Classification not possible because there is no data available.

Skin sensitization

In humans, it is described as “No sensitization” in a RIPT (HSDB (2007)) RIPT (repeat insult patch test) in 25 males and females each. In animals, it is described as “no reactions” in a contact sensitization test in 5 male and female guinea pigs each (HSDB (2007)). Both are the data of List2 information source, and there is no clear negative data other than these, and
SAFETY DATA SHEET
KL-6 KIT
Enzyme antibody conjugate concentrate

therefore classification not possible. Additionally, in the section of human cases of Food Chem. Toxicol. 40 (2002) that is used as a reference for reproductive toxicity, it is described as “positive” as a result of a quantitative patch test with a 100,000-fold dilution in a 6-year-old female with chronic recurrent dermatitis.

Reproductive cell mutagenicity

Product
No information available

Ingredient
• Methyl 4-hydroxybenzoate

<table>
<thead>
<tr>
<th>Reproductive cell mutagenicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not classified because there are the descriptions in an in vivo heritable mutagenicity test in germ cells (dominant lethal test in rats) that “no dose dependency or temporal trend that suggested the dominant lethal effect was observed” (HSDB (2007)), and in an in vivo mutagenicity test in somatic cells (chromosomal aberration test in rat bone marrow) that “no chromosomal aberration was observed” (HSDB (2007)). Additionally, there is the description in an in vitro mutagenicity test (chromosomal aberration test in CHL cell culture) that “it was negative under non-metabolic-activation conditions, while a significant increase in chromosomal aberration was observed under metabolic activation conditions.” (HSDB (2007))</td>
</tr>
</tbody>
</table>

Carcinogenicity

Product
No information available

Ingredient
• Methyl 4-hydroxybenzoate

<table>
<thead>
<tr>
<th>Carcinogenicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification not possible because the substance has not been evaluated by major international evaluation organizations. Additionally, it has been described in a 96-week dietary administration study in rats that “no effect of treatment was observed.” (HSDB (2007))</td>
</tr>
</tbody>
</table>

Reproductive toxicity

Product
No information available

Ingredient
• Methyl 4-hydroxybenzoate

<table>
<thead>
<tr>
<th>Reproductive toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>While it is described in an oral treatment study in female rats and female mice in Day 6-15 of gestation that “no effect was observed on implantation or the survival of fetuses at doses in which no effect was observed on the survival of dams, and no significant difference was observed between the frequencies of visceral anomalies, skeletal anomalies and external anomalies” (HSDB (2007)), the dosage was up to 500 mg/kg. This agrees with the content of Food Chem. Toxicol. 40 (2002) used as a reference in the description of human health effects in HSDB (2007) that “there is no teratogenicity or fetal toxicity, and it is negative in an uterotrophic assay.” Moreover, the effect at a higher dose is not known, and there is no data on male reproductive function, and therefore it is classified as Classification not possible.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
KL-6 KIT
Enzyme antibody conjugate concentrate

STOT-single exposure

Product
No information available

Ingredient
• Methyl 4-hydroxybenzoate

<table>
<thead>
<tr>
<th>STOT - single exposure</th>
</tr>
</thead>
</table>
| It is described in a study to obtain the lethal concentration by oral administration to rats that “no toxicity, abnormal behavior, or visual histopathological observation was found in survived animals” (HSDB (2007)), and the doses were out of the range of the guidance value of Category 2. However, there is the description of the case of “a 17-year old patient with psychosis who showed delayed hypersensitivity reaction by oral treatment with the substance” in the section of human cases Food Chem. Toxicol. 40 (2002) which was used as a reference for reproductive toxicity. The substance is therefore classified as Classification not possible.

STOT-repeated exposure

Product
No information available

Ingredient
• Methyl 4-hydroxybenzoate

<table>
<thead>
<tr>
<th>STOT-repeated exposure</th>
</tr>
</thead>
</table>
| It is described in an 18-week oral treatment study in rats with feed mixed with propyl ester that “growth suppression to some extent was observed, while there was no pathological change” (JECFA (1966)), but the dose was within the range of the guidance value of Category 1. The effect at a higher dose is not known, and thus it is classified as Classification not possible.

Aspiration hazard

Product
No information available

Ingredient
• Methyl 4-hydroxybenzoate

<table>
<thead>
<tr>
<th>Aspiration hazard</th>
</tr>
</thead>
</table>
| Classification not possible because there is no data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Product
No information available

Ingredient
• Methyl 4-hydroxybenzoate

<table>
<thead>
<tr>
<th>Aquatic toxicity (acute)</th>
<th>Aquatic toxicity (chronic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Justification: Classified as Category 3 based on crustacean (Daphnia magna) 48-hour</td>
<td></td>
</tr>
<tr>
<td>Justification: Classified as Category 3 because it is in acute toxicity category 3 and there is no</td>
<td></td>
</tr>
</tbody>
</table>

SEKISUI MEDICAL CO., LTD.
SAFETY DATA SHEET
KL-6 KIT
Enzyme antibody conjugate concentrate

EC50 = 36mg/L (Eco-toxicity tests of chemicals conducted by Ministry of the Environment, 1999).

<table>
<thead>
<tr>
<th>Persistence and degradability</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioaccumulative potential</td>
<td>No data available</td>
</tr>
<tr>
<td>Mobility in soil</td>
<td>No data available</td>
</tr>
<tr>
<td>Hazard to the ozone layer</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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: Methyl 4-hydroxybenzoate Class 1 specified chemicals (Law Art.1, Para.(2), and Enforcement Order Art.1, Appended Table 1)

Industrial Safety and Health Act: Not applicable

Poisonous and Deleterious Substances Control Act: Not applicable

SEKISUI MEDICAL CO., LTD.
16. OTHER INFORMATION

Literature and references: GHS Classification Result “Methyl 4-hydroxybenzoate” (2008, METI, 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.