SAFETY DATA SHEET

KL-6 KIT
Wash solution concentrate

SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: KL-6 KIT [Wash solution concentrate]

* 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 (Standard antigen, Sample diluent concentrate, Antibody coated cup, Reaction solution, Enzyme antibody conjugate concentrate, Enzyme substrate, Chromogen, Stop reaction solution) (No. S515828A, S515828B, S515828C, S515828D, S515828E, S515828F, S515828G, S515828H).

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+81-29-889-2242

Recommended uses: Research use only

and restrictions on use

Reference number: S515828I

2. HAZARDS IDENTIFICATION

GHS classification: No classification.

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>2-Chloroacetamide (Monochloroacetamide)</td>
<td>79-07-2</td>
<td>0.50</td>
</tr>
<tr>
<td>Methyl 4-hydroxybenzoate (Methyl p-hydroxybenzoate)</td>
<td>99-76-3</td>
<td>0.15</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.

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**

: No information available

**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.
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<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Colorless and clear liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>7.2-7.8 (20°C)</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.

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

• 2-Chloroacetamide
Oral LD₅₀: 138 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>Classified as Category 3 based on the rat LD₅₀ of 138 mg/kg (BUA Report 225 (2000)).</td>
<td>No data available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute toxicity (Inhalation: gas)</th>
<th>Acute toxicity (Inhalation: vapor)</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>No data available.</td>
</tr>
</tbody>
</table>

• 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</td>
<td>Classification not possible because there is no data available. Additionally, it is described that &quot;a dermal treatment test was performed with an</td>
</tr>
</tbody>
</table>
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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.

<table>
<thead>
<tr>
<th>Acute toxicity (Inhalation: gas)</th>
<th>Acute toxicity (Inhalation: vapor)</th>
<th>Acute toxicity (Inhalation: dust/mist)</th>
</tr>
</thead>
<tbody>
<tr>
<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 due to insufficient data.</td>
</tr>
</tbody>
</table>

eye makeup cosmetic containing % of the substance, and it resulted in the LD50 >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.

Skin irritation/corrosion

Product
No information available

Ingredient
• 2-Chloroacetamide

Skin irritation/corrosion
In a test in which 500 mg of the test substance made into a paste with saline was applied to 3 rabbits for 4 hours (OECD TG 404), 1 animal showed mild erythema and edema, 1 animal showed moderate erythema and edema, and the other 1 animal showed serious erythema and moderate edema 1 hour to 3 days after removing the patch; the animals recovered from all the irritation symptom 7 days after removing the patch, and the substance was evaluated as slightly irritating (BUA Report 225 (2000)), and classified as Category 2 because moderate or severer erythema was observed 1 hour to 3 days after removing the patch in 2 of 3 animals.

• 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
• 2-Chloroacetamide

Serious eye damage/ irritation
In an eye irritation test in which 100 mg of the test substance was applied to the conjunctival sac in rabbits (GECD TG 405.), serious reddening and edema in the conjunctiva in addition to
corneal opacity were observed 1-7 hours after application. The symptoms disappeared very slowly, and the animals recovered after 21 days. The substance is classified as Category 2A based on the evaluation as irritating to eye (BUA Report 225 (2000)).

• 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**

• 2-Chloroacetamide
  
  **Respiratory sensitization**
No data available.

  **Skin sensitization**

  There are many case reports as well as positive reports of patch tests in patients and normal subjects on the induction of allergic contact dermatitis with the substance in humans (BUA Report 225 (2000) and HSDB (2006)). In a maximization test in guinea pigs, high percentage of sensitization was observed in animals with the positive rate of 60-80% in the first induction and 80% in the second induction, and it was concluded that the substance is a strong sensitizer (BUA Report 225 (2000)). Moreover, the substance is used as an antiseptic in cutting fluid, paint and adhesives, etc., as well as in leather, and may cause contact dermatitis in barbers and shoemakers, and is listed as a skin sensitizer (Contact Dermatitis (Frosch) (4th, 2006)). It is classified as Category 1 based on the observations and information shown above.

• 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 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.

**Carcinogenicity**

**Product**
No information available
Ingredient

• 2-Chloroacetamide

Reproductive cell mutagenicity

Not classified based on that negative results have been reported in all of a dominant lethal test in mice by intraperitoneal administration (in vivo heritable mutagenicity test in germ cells), a chromosomal aberration test in spermatogonia and bone marrow in Chinese hamsters by oral administration (in vivo mutagenicity test in germ cells and somatic cells), and a micronucleus test in bone marrow in mice by oral administration (in vivo mutagenicity test in somatic cells) (BUA Report 225 (2000)). Additionally, as for in vitro tests, it has been reported as negative in an Ames assay (BUA Report 225 (2000)).

• Methyl 4-hydroxybenzoate

Reproductive cell mutagenicity

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))

Reproductive toxicity

Product

No information available

Ingredient

• 2-Chloroacetamide

Carcinogenicity

No data available.

• Methyl 4-hydroxybenzoate

Carcinogenicity

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))

Reproductive toxicity

Product

No information available

Ingredient

• 2-Chloroacetamide

Reproductive toxicity

 Classified as Category 2, because it has been reported that no effect on prenatal development was observed but about half of offspring after birth died in both strains in a study in which 50 mg/kg was administered subcutaneously on Day 12 and 14 of gestation in 2 strains (CD and BDIX) of rats (BUA Report 225 (2000)), in addition that it is classified in EU as GHS Repro cat. 2. Additionally, it has also been reported that no effect on offspring was observed in a study in which
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20 mg/kg was administered intraperitoneally on Day 7, 11 and 12 of gestation in rats (BUA Report 225 (2000)). In addition, the use of the substance has been prohibited since 2009 in Canada, and evaluation is required for market release again.

• Methyl 4-hydroxybenzoate
  Reproductive toxicity
  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.

STOT-single exposure

Product
No information available

Ingredient
• 2-Chloroacetamide
  STOT - single exposure
  No data available.

• Methyl 4-hydroxybenzoate
  STOT - single exposure
  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
• 2-Chloroacetamide
  STOT - repeated exposure
  A significant decrease in testis weight and disorder in the spermatogenic capacity are reported at the maximum dose of 50 mg/kg/day or higher in both of 2 studies of 3-month dietary treatment in rats (BUA Report 225 (2000)), and these are classified as toxicity separately in the section of reproductive toxicity, and therefore these are not classified in this section. As for the other effects, there is no report of harmful effects, and the effect is not known at a dose of the upper limit of the range of the guidance value (100 mg/kg/day) or higher. In addition, in a 30-day dermal treatment study in rabbits, fatty infiltration in the liver and the heart and hemosiderosis in the spleen are
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reported at 100 mg/kg/day (conversion into 90 days: 33.3 mg/kg/day) or higher (BUA Report 225 (2000)), while no effect was observed in blood tests, etc., and the level or significance of pathological changes are not known, and therefore it is classified as “Classification not possible”.

- Methyl 4-hydroxybenzoate
  STOT - repeated exposure
  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
- 2-Chloroacetamide
  Aspiration hazard
  No data available.

- Methyl 4-hydroxybenzoate
  Aspiration hazard
  Classification not possible because there is no data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Product
No information available

Ingredient
- 2-Chloroacetamide
  Aquatic toxicity (acute)
  Classified as Category 3 based on crustacean (Daphnia magna) 48-hour EC50 = 14 mg/L (BUA 225, 2000).
  Aquatic toxicity (chronic)
  Not classified, because although it is in acute toxicity category 3 it is rapidly degradable (BIOWIN) and is estimated to have low bioaccumulativity (Log Kow = -0.53 (PHYSPROP Database, 2011)).

- Methyl 4-hydroxybenzoate
  Aquatic toxicity (acute)
  Justification: Classified as Category 3 based on crustacean (Daphnia magna) 48-hour EC50 = 36mg/L (Eco-toxicity tests of chemicals conducted by Ministry of the Environment, 1999).
  Aquatic toxicity (chronic)
  Justification: Classified as Category 3 because it is in acute toxicity category 3 and there is no data on rapid degradability.

Persistence and degradability: No data available
Bioaccumulative potential: No data available
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13. DISPOSAL CONSIDERATIONS

| Waste from residues | : Dispose to a licensed industrial waste disposal contractor. (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. (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.
- **Marine transport**: According to transport methods specified in the Ship Safety Act.
- **Air transport**: According to transport methods specified in the Civil Aeronautics Law.

15. REGULATORY INFORMATION

**Japanese regulations**

- **Pollutant Release and Transfer Register Law**: 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

16. OTHER INFORMATION

**Literature and references**

- GHS Classification Result “2-Chloroacetamide” (2010, MHLW, MOE)
- 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.