SAFETY DATA SHEET

KL-6 KIT
Enzyme substrate

SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: KL-6 KIT [Enzyme substrate]
* 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, Chromogen, Stop reaction solution, Wash solution concentrate) (No.S515828A, S515828B, S515828C, S515828D, S515828E, 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: S515828F

2. HAZARDS IDENTIFICATION

GHS classification
Skin corrosion/irritation: Category 2
Serious eye damage/eye irritation: Category 1
Carcinogenicity: Category 2
Specific target organ toxicity (single exposure): Category 2
Respiratory system
Specific target organ toxicity (repeated exposure): Lung Category 2

Environmental hazards
Aquatic environment (acute hazard): Category 2

GHS label elements
Pictograms or symbols:

Signal word: Danger
Hazard statements:
H315 Causes skin irritation
H318 Causes serious eye damage
H351 Suspected of causing cancer

SEKISUI MEDICAL CO., LTD.
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H371 May cause damage to respiratory organs
H373 May cause damage to respiratory organs through prolonged or repeated exposure
H401 Toxic to aquatic life

Precautionary statements
P264 Wash exposed hands and skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response: P302+P352 If on skin: Wash with plenty of water and soap.
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Next, remove contact lenses if present and easy to do – continue rinsing.
P310 Immediately call a doctor.
P308+P311 IF exposed or concerned: Call a doctor.
P314 Get Medical advice/attention if you feel unwell.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

Storage: Not applicable
Disposal: P501 Dispose of contents/container to an industrial waste disposal contractor.

Other hazards: The product is both oxidizing and reducing.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Single substance or mixture</th>
<th>Chemical (substance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Hydrogen peroxide</td>
</tr>
<tr>
<td>Other names</td>
<td>Oxydol</td>
</tr>
<tr>
<td>Chemical properties (formula)</td>
<td>H₂O₂</td>
</tr>
<tr>
<td>CAS registry number</td>
<td>7722-84-1</td>
</tr>
<tr>
<td>Ingredient and concentration</td>
<td>2.5-3.5 w/v% Hydrogen peroxide solution in water</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. Make sure to get medical attention even if there are no immediate symptoms.

Skin contact: If skin irritation occurs, get medical advice/attention. If the product is on skin, it is required to start rinsing as soon as possible, and wash off the adhered product completely. Delayed or insufficient washing may cause skin disorder.

Eye contact: If the product is in eyes, it is required to start rinsing as soon as possible, and wash off the product completely. Delayed or insufficient washing may cause irreversible eye disorder. Make sure to get medical attention even if there is no immediate pain or influence on eyesight because disorder may occur later. Remove contact lenses if present as long as they are not stuck, and continue rinsing.

Ingestion: Rinse mouth with water. Immediately call a doctor.
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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: Heat, light and alkaline substances

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: Desirable to wear impermeable protective gloves.

Eye protection: Desirable to wear protective goggles.

Skin and body protection: Desirable to wear proper protective clothing (long-sleeved working clothes).

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear and colorless liquid

Odor: Odorless or an ozone-like odor

pH: 3.0-5.0 (20°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

vapor pressure: No data available
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Specific Gravity : About 1.01 g/L (20°C)
Octanol-water partition coefficient : No data available
Spontaneous ignition temperature : No data available
Auto-ignition temperature : No data available

10. STABILITY AND REACTIVITY
Reactivity : No autoreactivity
Chemical stability : Stable under normal conditions
Hazardous reactions
- The product degrades slowly when left at rest or shaken vigorously.
- The product degrades rapidly when contacted with an oxidizing agent or a reducing agent.
- The product degrades while bubbling violently when contacted with the alkaline pH.
- The product changes with light.

Conditions to avoid : Heat and light
Incompatible materials : Heavy metals and alkaline substances
Hazardous decomposition products : Oxygen (combustion-supporting gas)

11. TOXICOLOGICAL INFORMATION
Acute toxicity
- Hydrogen peroxide
  Oral LD$_{50}$: 805 mg/kg (rat)
  Dermal LD$_{50}$: 690 mg/kg (rabbit)
  Inhalation (vapour) LC$_{50}$: 2000 mg/m$^3$ (4 hours, rat)
  Inhalation (dust/mist) LC$_{50}$: 0.55 mg/L (4 hours, mouse)

<table>
<thead>
<tr>
<th>Acute toxicity (oral)</th>
<th>Acute toxicity (dermal)</th>
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<tbody>
<tr>
<td>There have been 2 reports of rat LD$_{50}$ using 70% solution of the substance. 75 mg/kg (EU-RAR (2003), ECETOC Special Report (1996)) falls under Category 3, while 805 mg/kg (EU-RAR (2003), DFGOT vol.26 (2011), ECETOC Special Report (1996)) falls under Category 4, and there is a large gap between the two. However, in EU-RAR (2003), the observation of 75 mg/kg is described in Appendix and is not cited in the text. Therefore, it is not judged that the observation of 75 mg/kg is very weighted, and Category 4 of less hazard is employed. Additionally, data described in DFGOT vol.26 (2011) obtained in this survey was added, and classification was carried out using the data of 70% solution of the substance.</td>
<td>There have been 2 reports of LD$<em>{50}$ using 90% solution of the substance. The rat LD$</em>{50}$ is about 3.5 mL/kg (= about 5,000 mg/kg) (EU-RAR (2003)), and falls under Not classified (Category 5 of UN classification). The rabbit LD$<em>{50}$ is 690 mg/kg (EU-RAR (2003), DFGOT vol.26 (2011), ECETOC Special Report (1996)) and falls under Category 3. Because there were the same numbers of Category 3 and Not classified, Category 3 of higher hazard is employed. Additionally, the rat LD$</em>{50}$ of 4,060 mg/kg (EU-RAR (2003)) that was the basis of the previous classification was not employed because the test substance concentration was not specified, and data described in DFGOT vol.26 (2011) obtained in this survey was added, and classification was carried out using the data of 90% solution of the substance.</td>
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Acute toxicity (Inhalation: gas) | Acute toxicity (Inhalation: vapour)
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The product is liquid according to the GHS definition.

The rat LC50 (4 hours) 2,000 mg/m3 (= 1,438 ppmV) (EU-RAR (2003), DFGOT vol.26 (2011), ECETOC Special Report (1996)) using the vapour of the substance falls under Category 3. Data described in DFGOT vol.26 (2011) obtained in this survey was added, and classification was carried out using the standard value in ppmV considering that mist was not contained based on the description that the study was carried out using the vapour of the substance.

Acute toxicity
(Inhalation: dust/mist)

There is a report that mice were exposed to the aerosol of 90% solution of the substance at 13,200 mg/m3 for 10 minutes (conversion into 4 hours: 0.55 mg/L) and at 11,800 mg/m3 for 15 minutes (conversion into 4 hours: 0.74 mg/L), and it resulted in the death of 5 of 10 animals in both (EU-RAR (2003), ECETOC Special Report 10 (1996)). Moreover, based on this report, it is reported that the LC50 in mice exposed for 2 hours to the aerosol of 90% solution of the substance is 920-2,000 mg/m3 (conversion into 4 hours: 0.46-1.00 mg/L) (DFGOT vol.26 (2011)). Because the same numbers of these LC50 values fall under Category 2 and Category 3, Category 2 with the minimum LC50 was employed. Data described in DFGOT vol.26 (2011) obtained in this survey was added, and classification was carried out using the data of 90% solution of the substance. Additionally, though the LC50 converted into 4 hours is smaller than the saturated vapor pressure concentration of 3.605 mg/L, the standard value in mg/L was applied based on the description that the study was performed using aerosol.

Skin irritation/corrosion

- Hydrogen peroxide

Skin irritation/corrosion

The application of the substance in rabbit skin for 3 minutes, 1 hour or 4 hours is described as necrosis ranging all the skin layers or corrosion (EU-RAR (2003), ECETOC Special Report 10 (1996)). Moreover, the substance is a skin corrosive substance, and classified by EU DSD classification as “C; R35” and by EU CLP classification as “Skin Corr. 1A H314.” Based on the information above, it is classified as Category 1. EU DSD classification and EU CLP classification obtained in this survey were added.

Serious eye damage/ irritation

- Hydrogen peroxide

Serious eye damage/ irritation

The substance is a skin corrosive substance. There is the description that it is seriously irritative in animals and is a corrosive substance (ECETOC JACC (1993), EU-RAR (2003)). Based on the information above, it is classified as Category 1.

Respiratory or skin sensitization

- Hydrogen peroxide

Respiratory sensitization

Classification not possible due to insufficient data.

Skin sensitization
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There have been negative results in 2 studies in guinea pigs (EU-RAR (2003), ECETOC JACC (1993)), and it is described that many subjects were negative in a patch test in humans (EU-RAR (2003)). In EU-RAR (2003), it is described that “there are 2 cases reported as positive in the hydrogen peroxide patch test, and there is uncertainty in old animal studies (results were negative), and there are observations of extensive professional and consumer use over several decades, and it is clear that the capacity of hydrogen peroxide to induce skin sensitization is extremely low and that the classification is not applicable.” However, ACGIH (7th, 2001) concludes in summary that there is no available data sufficient to recommend that the substance is a sensitizer; it is different from the conclusion in EU-RAR (2003), and it is judged that there is no sufficient evidence as a whole, and ACGIH (7th, 2001) is employed and it is classified as Classification not possible.

Reproductive cell mutagenicity

- Hydrogen peroxide

Reproductive cell mutagenicity

Classified as “Classification not possible” because “Not classified” cannot be selected due to the revision of the classification guidance. That is, it is negative in vivo in the micronucleus assay in mouse bone marrow cells (EU-RAR (2003), ECETOC-JACC (1993)) and in the chromosomal aberration assay in rat bone marrow cells (IARC 71 (1999), ECETOC-JACC (1993)). There are more than one positive results in vitro in the bacterial reverse mutation assay, gene mutation assay and chromosomal aberration assay in mammalian cell culture (IARC 71 (1999)). While the substance is considered as an in vitro mutagen, it is concluded that the substance is not classified as a mutagen in vivo (SIDS (1999), EU-RAR (2003)).

Carcinogenicity

- Hydrogen peroxide

Carcinogenicity

Classified as Group 3 by IARC (1999) and A3 by ACGIH (7th, 2001). ACGIH (7th, 2001) classifies as A3 because there are limited evidences in the carcinogenicity of the substance in the carcinogenicity data reviewed by IARC (1999). Therefore it is classified as Category 2 employing the new ACGIH classification. The category is changed due to the revision of the classification guidance.

Reproductive toxicity

- Hydrogen peroxide

Reproductive toxicity

Classification not possible due to insufficient data. Additionally, the report that effects on sperm motility and on the estrous cycle in females, a decrease in the number of dams that gave birth, and weight loss of offspring were observed in the study in rats with the oral (drinking water) route in ECETOC JACC (1993) cannot be evaluated due to insufficient descriptions. In addition, for the study that investigated the effect on the sperm of male mice and male rabbits as well as the reproductive potential with the oral (drinking water) route, conclusion cannot be confirmed because the study was limited without using a control group. It is therefore classified as Classification not possible. Additionally, in the latest evaluation document EU-RAR (2003), the substance is judged not to have reproductive toxicity because no serious disorder in the reproductive function is shown in the results of limited reproductive toxicity studies, and because no harmful effects were observed in a 90-day repeated toxicity study in mice and in a carcinogenicity study in mice and rats.
STOT-single exposure

- Hydrogen peroxide

<table>
<thead>
<tr>
<th>STOT - single exposure</th>
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<tbody>
<tr>
<td>Irritation in the nose, throat and trachea is reported for inhalation exposure in animals (rats and mice) (EU-RAR (2003)) and humans (ACGIH (7th, 2001)). For animals (rats and mice), congestion of the lung and trachea, pulmonary edema, emphysema and pulmonary congestion are described at doses all within the range of the guidance value of Category 1 (0.34-0.43 mg/L) (EU-RAR (2003), ECETOC Special Report 10 (1996)). It is classified as Category 1 (respiratory) based on these. Headache, dizziness, tremor, convulsion, loss of consciousness, syncope, and cerebral infarction are described in humans (ACGIH (7th, 2001), EU-RAR (2003)), but there is no detailed information on these observations, and these are judged as secondary or nonspecific symptoms due to the inhalation of a corrosive substance, and are not employed.</td>
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</table>

STOT-repeated exposure

- Hydrogen peroxide

<table>
<thead>
<tr>
<th>STOT-repeated exposure</th>
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<tbody>
<tr>
<td>In an inhalation study with the vapour of the substance in dogs and rats, it is described that fibrotic lesions were observed occasionally in the lung, and mixed regions of atelectasis and emphysema (dogs), and necrosis and inflammation in the epithelium of the nasal cavity and cell infiltration in the larynx (rats) were observed at concentrations within the range of the guidance value of Category 1 (0.005-0.01 mg/L) (EU-RAR (2003)), and it is also described that irritation in the nose and throat are observed and there is the risk of pulmonary edema in the worst case in humans (ECETOC JACC (1993)), and therefore it is classified as Category 1 (respiratory). Additionally, it was classified as Category 2 (blood) in the old classification based on the results of a 100-day oral treatment study in rats, blood observations in the dose range of Category 2 were only decreased hematocrit and plasma protein and decreased plasma catalase activity, and there was no description of “hemolysis” (EU-RAR (2003)), and thus it is judged that there are no observations sufficient to support classification as Category 2 (blood), and it is deleted in the present classification.</td>
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</table>

Aspiration hazard

- Hydrogen peroxide

<table>
<thead>
<tr>
<th>Aspiration hazard</th>
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<tbody>
<tr>
<td>Classification not possible due to insufficient data.</td>
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</table>

12. ECOLOGICAL INFORMATION

Ecotoxicity

- Hydrogen peroxide

<table>
<thead>
<tr>
<th>Aquatic toxicity (acute)</th>
<th>Aquatic toxicity (chronic)</th>
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<tbody>
<tr>
<td>Classified as Category 1 based on 72-hour EC50 = 0.85 mg/L in algae (Nitzschia) (EU-RAR, 2003).</td>
<td>When chronic toxicity data is used, the substance has rapid degradability (“ready biodegradability” that meets the 10 day window standard (EU-RAR, 2003)), and 72-hour NOEC is 0.1 mg/L in algae (Chlorella) (EU-RAR, 2003), and therefore is classified as Category 2. When acute toxicity data is used for the</td>
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</table>
trophic level where chronic toxicity data has not been obtained, crustacean (Daphnia magna) 24-hour EC50 is 2.3 mg/L (EU-RAR, 2003), the substance has rapid degradability (“ready biodegradability” that meets the 10 day window standard (EU-RAR, 2003)), and estimated that its bioaccumulativity is low (log Kow = -1.36 (ICSC, 2000)), and therefore is classified as Not classified. Based on the comparison of the results shown above, it is classified as Category 2, and it is suggested that chronic toxicity is concerned when there is continuous release of the substance to the environment because a chronic toxicity value is obtained; however, it is known that the substance is rapidly degraded in the actual environment, and therefore it is classified as Not classified based on the judgment of experts.

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

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

15. REGULATORY INFORMATION

Japanese regulations

Pollutant Release and Transfer Register Law: Not applicable
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Industrial Safety and Health Act
- Harmful Substances Whose Names Are to be Indicated on the Label (Law Art.57, Para.1, Enforcement Order Art.18)
- 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, Appendix Table 9)
  * Not applicable because the product is an in vitro diagnostic.

Poisonous and Deleterious Substances Control Act
- Hydrogen peroxide
  Deleterious Substances (Cabinet Order for the Designation of the Poisonous and Deleterious Substances, Art.2)
  * Not applicable because the product is an in vitro diagnostic.

16. OTHER INFORMATION

Literature and references: GHS Classification Result “Hydrogen peroxide”
(2013, MHLW, MOE)
Japanese Pharmacopoeia 17th Edition
(March 7, 2016, the MHLW Ministerial Notification No.64)

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.