

Safety Data Sheet

1 Chemical Product and Company Identification

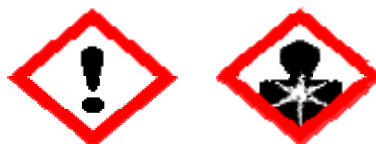
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|---|---|
| Identification of the product | Cholesterol esterase |
| Product Code | COE-311 |
| Supplier | |
| Name | TOYOBO CO.,LTD. |
| Address | Osaka Umeda Twin Towers South, 1-13-1 Umeda Kita-ku, Osaka 530-0001, Japan |
| Department | Biotechnology Overseas Sales and Marketing Department |
| Phone | +81-6-6348-3846 |
| Fax | +81-6-6348-3833 |
| Recommended use and restrictions on use | diagnostic product |

2 Hazard Identification

| | |
|---|--|
| Most Important Hazards and Effects | Harmful if Boric acid is swallowed. |
| Hazards and Effect for human health | Lethal dose (Boric acid) : Adult 10g, Child 5g |
| GHS classification | |
| Physical hazards | - |
| Health hazards | |
| Acute toxicity : Oral | Category 5 |
| Acute toxicity : Dermal | - |
| Acute toxicity : Inhalation | Not applicable |
| Acute toxicity : Inhalation | - |
| Skin corrosion/irritation | Category 2 |
| Serious eye damage/Eye irritation | Category 2 |
| Sensitization : Respiratory | - |
| Sensitization : Skin | - |
| Germ cell mutagenicity | - |
| Carcinogenicity | - |
| Toxic to reproduction | Category 1B |
| Specific target organ toxicity (Single) | Category 1(nervous system,digestive trace) |
| Specific target organ toxicity | Category 3(respiratory tract) |
| Aspiration hazard | - |
| Environmental hazards | |
| Acute hazards to the aquatic | Category 3 |
| Long-term hazards to the aquatic | Category 3 |
| Hazard to the ozone layer | - |
| | -:Classification not possible |

GHS Label Elements

Symbol/Pictograms



Signal word

Danger

Hazard statements

Harmful if swallowed.
Cause skin irritation.
Causes serious eye irritation.
Damage fertility or the unborn child
Causes damage to organs (Nervous system, digestive organ, respiratory organ).
May cause respiratory irritation.

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Harmful to aquatic life with long lasting effects.

Instructions

Precaution Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Use only outdoors or in a well-ventilated area.

Wear protective gloves/protective clothing/eye protection/face protection.

Do not breathe dust/fume.

Do not eat, drink or smoke when using this product.

Wash hands thoroughly after handling.

Avoid release to the environment.

First-aid measures IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Take off immediately all contaminated clothing. Rinse skin with water /shower.

If skin irritation occurs: Get medical

If in eye: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice

IF exposed or concerned: Get medical attention/advice.

Get medical advice/attentions if you feel unwell.

Storage Store locked up.

Store in a well-ventilated place. Keep container tightly closed.

Disposal Dispose of contents/container in accordance with local/regional/national/international/regulation.

Important symptoms (Boric acid)

Symptoms of vomit, diarrhea, collapse, erythema may appear after 2-3 hours later.

3 Composition/Information on Ingredients

Substance/Mixture

Mixture

Chemical Nature

Cholesterol esterase

Chemical specificity

Freeze and drying powder including enzyme

Amounts contained

Approximate 50% (W/W)

CAS#

Cholesterol esterase

9026-00-0

Boric acid

10043-35-3

Ingredients Contributing to the Hazard

Common Chemical name

Boric acid

Amounts contained

ca 10% (W/W)

Chemical formula

H₃BO₃

CAS#

10043-35-3

Common Chemical name

Polyethylene Glycol-p-octylphenyl Ether

TritonX-100

Concentration or concentration range

ca 6% (W/W)

Chemical formula

C₈H₁₇-C₆H₄O(C₂H₄O)_nH

CAS#

9002-93-1

4 First Aid Measures

Inhalation

Remove to fresh air. Consult a physician when unpleasantness occurs.

Skin Contact

Wash off with plenty of water.

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| Eye Contact | Rinse off with running water for several minutes. Consult a physician afterwards. |
| Ingestion | Rinse mouth. Swill plentiful amount of water or milk for immediate vomiting. Consult a physician. |
| Most important symptoms/effects, acute and delayed. | Inhalation: Cough, Sore throat Skin: Redness Eyes: Redness, Pain Ingestion: Abdominal pain. Convulsions. Diarrhoea. Nausea. Vomiting. Skin rash. |

5 Fire Fighting Measures

| | |
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| Extinguishing Media | Water spray, dry chemical powder, or carbon dioxide etc. |
| Particular hazardous | Firefighter should work from the windward side. |

6 Accidental Release Measures

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| Personal Precautions, protective equipment, and emergency procedure | Wear proper protective gear to avoid eye/skin contact and inhalation. Work from the windward side. |
| Environmental Precautions | Do not wash away into sewer, watercourse or river. |
| Methods and materials for containment and cleaning up | Take up under vacuum using dust collecting filter, wash residual spill with copious amounts of water. Use cloth, paper or anything similar to soak up the solution leaking out of the container. (Waste water should be treated with activated sludge or adsorbed with activated carbon etc.) |

7 Handling and Storage

| | |
|--------------------------------------|---|
| Handling | |
| Technical Measures | Wear protective gear to avoid eye/skin contact and inhalation. |
| Precautions | Do not drop the container to prevent the content popping out. |
| Storage | |
| Technical Measures | Keep sealed container in freezer. |
| Incompatible substances and mixtures | None specified. |
| Storage Conditions | Store under -20°C to avoid deactivating. |
| Packaging Materials | Use the initial container of the product. |

8 Exposure Controls/Personal Protection

| | |
|--|--|
| Engineering controls | Provide shower and eye washing apparatus nearby. |
| Occupational exposure limit, biological limit | (Boric acid) TLV: TWA 2mg/m ³ , STEL 6mg/m ³ |
| Personal Protective Equipment | |
| Respiratory Protection | Protecting mask |
| Hand Protection | Protecting gloves |
| Eye Protection | Safety goggles |
| Skin and Body Protection | Long sleeve working wear |

9 Physical and Chemical Properties

| | |
|---------------------------------|----------------------------|
| Physical State, form and colour | Powder / Light brown |
| Odour | No odour |
| pH | Approximate pH7.5 (1% W/V) |
| Flash Point | No information available. |
| Explosiveness | No information available. |
| Density | No information available. |

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Solubility

Freely soluble in water.

10 Stability and Reactivity

Stability

Possible hazard

reactions at specific condition

Conditions to avoid

Materials to avoid

Hazardous Decomposition Products

Stable at temperatures below -20°C. When left for long at room temperature, proteins might be degraded, which does not cause any hazardous reaction.

Prolonged storage under higher temperature than room temperature and high humidity.

Oxidizing agent

No information available.

11 Toxicological Information

No information available on the product in toxicity, however, the information on the boric acid and triton X-100 is shown below.

Acute Toxicity (Oral)

Boric acid

LD₅₀ 2660mg/kg (Rat)

Skin corrosion/irritation

Guinea pig skin irritation tests (exposure duration unknown) : At 24 and 72 hours, moderate irritation

Serious eye damage/irritation

Irritates the human eye (though the severity of the effects and recovery period are not presented).

Germ cell mutagenicity

in vivo: Mouse bone marrow cell mutagenicity tests (micronucleus tests): Negative

in vitro: Reverse mutation test using bacteria, gene mutation test and chromosome aberration test using mammalian cultured cells: Negative

Carcinogenicity

ACGIH classified as Category A4 (as inorganic borate compounds)

Toxic to reproduction

Mouse: Reproductive Assessment by Continuous Breeding, Rat: 3 generation reproductive toxicity study: Adverse effects on reproduction

Rat: Developmental toxicity: Teratogenicity is observed.

Specific target organ systemic toxicity (Single exposure)

Human: Nausea, vomiting, abdominal pain and diarrhea, central nervous system depression, convulsion and respiratory irritation.

Animal studies: Slight respiratory irritation was observed.

Specific target organ systemic toxicity (Repeated exposure)

Human: No information available. Animal studies: Oral administration, adverse effects were observed at over the guidance dose for category 2.

Though this corresponds to "not classified" in oral route, no information of the effects via the other routes of administration.

Eye damage/irritation

TritonX-100

Rabbit eye irritation was observed, and the symptoms had been healed within 21 days (ECETOC TR 48 (2))

12 Ecological Information

No information available on the product in toxicity, however, the information on the boric acid and triton X-100 is shown below.

Boric acid

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Ecotoxicity

Algae (*Pseudokirchneriella subcapitata*) 72hr ErC50 = 290 mg/L

Crustacea (*Daphnia magna*) 48hr LC50 = 133 mg/L (as boron)

Fish (Coho salmon) 96hr LC50 = 447 mg/L

Not bioaccumulative

Considered not bioaccumulative

Triton X-100

LC50/96hr = 3mg/L (bluegill)

Bioaccumulative potential

Ecotoxicity

Persistence /Degradability

Persistent substance: 22% by BOD (National Institute of Technology and Evaluation, Japan)

Enzyme and other organic ingredients are biodegradable and does not remain on the environment for long.

13 Disposal Considerations

Residues

Dispose of in accordance with all applicable local and national laws and regulations.

A pollution container and packing

Wash with copious amounts of water and waste conforming to local regulations depending on the type of the material.

14 Transport Information

International regulations

Not applicable

Domestic regulations

Not applicable

Specific precautions transport measures and conditions

Avoid direct sunshine and check the container and loading to prevent leakage or turnover, fall and damage. Do not load with foods and feed. Keep at temperatures below -20°C.

15 Regulatory Information

Registration, Evaluation, Authorization and Restriction of Chemicals (EU)

The following ingredient is included in SVHC (Candidate list of authorization).

Common Chemical name

Boric acid

Common Chemical name

Polyethylene Glycol-p-octylphenyl Ether (Triton X-100)

Regulations

Follow all of laws and regulations in your country.

16 Other Information

Notice

The information shall not be taken as being all inclusive and is to be used only a guide. All materials and mixtures may be present unknown hazards and should be used with caution. The SDS is subject to revision as new information becomes available. The information in this SDS, to the best of our knowledge, is accurate and correct. However, TOYOBO makes no warranty and assumes no liability whatsoever in connection with any use of this information.