Date of issue: 02. Aug. 2016

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: Uricase (U-TE)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses: Production and research use only

1.3. Details of the supplier of the safety data sheet

Name of manufacturer in Japan: Kikkoman Biochemifa Company

Address 2-1-1, Nishi-Shinbashi, Minato-ku, Tokyo 105-0003, Japan

Telephone number +81-3-5521-5493 **Fax number** +81-3-5521-5498

e-mail address biochemifa@mail.kikkoman.co.jp

1.4. Emergency telephone number +81-3-5521-5493

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification in accordance with EC No 1272/2008:

Health hazards Resp. Sens. Cat.1

Repr. Cat.1B STOT-SE Cat.2

2.2. Label elements

In accordance with EC No 1272/2008:

Pictogram



Signal word Danger

Hazard Statements May cause allergy or asthma symptoms or breathing difficulties if

inhaled.

May damage fertility or the unborn child.

May cause damage to digestive system and nervous system.

Precautionary Statements

Prevention Do not handle until SDS have been read and understood.

Do not breathe dust/fume/gas/mist/vapours/spray.

Wash hands thoroughly after handling.

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

Wear protective gloves / protective clothing / eye protection / face

protection.

[In case of inadequate ventilation] wear respiratory protection.

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Emergency response IF INHALED: Remove person to fresh air and keep comfortable for

breathing.

If experiencing respiratory symptoms: Call a doctor. If exposed or concerned: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of container/its content to in accordance with local and

applicable regulations.

2.3. Other hazards

The product does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

SECTION 3: Composition/information on ingredients

3.1. Substances Not applicable

3.2. Mixtures

Product Name: Uricase (U-TE)

Information on ingredients:

Comp.	Chemical name	CAS No.	EC No.	Index No.	REACH Registration No.*	Concentration (wt %)
1.	Uricase	9002-12-4	232-655-5	-	-	50-60
2.	Sucrose	57-50-1	200-334-9	-	-	20-30
3.	Trisodium citrate dihydrate	6132-04-3	-	-	-	10-20
4.	EDTA · 2Na	6381-92-6	-	-	-	1-10
5.	Boric acid	10043-35-3	233-139-2	-	-	1-5

^{*} Registration numbers of ingredients which shall be in compliance with Regulation (EC) No 1907/2006 will be filled in later.

SECTION 4: First aid measures

4.1. Description of first aid measures

IF INHALED Remove victim to fresh air and keep at rest in a position

comfortable to breathing. Call a doctor as needed.

IF ON SKIN Gently wash skin with plenty of water and soap. If a symptom

occurs, see a doctor.

IF IN EYES Rinse eyes with plenty of water for a few minutes. If eye irritation

persists, call a doctor.

IF SWALLOWED Rinse mouth and throat thoroughly with water. Do not induce

vomiting. Call a doctor as needed.

4.2. Most important symptoms and effects, both acute and delayed

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May damage fertility or the unborn child.

May cause damage to digestive system and nervous system.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Water spray, foam, dry chemical powder, carbon dioxide, dry sand.

Unsuitable extinguishing media

Applying direct water may be dangerous because fire may expand to surroundings.

5.2. Special hazards arising from the substance or mixture

Toxic, irritating dust or smoke may be emitted.

A container might explode by heating.

5.3. Advice for firefighters

Wear normal protective equipment and self-contained breathing apparatus if necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

Remove spilled substances and ignition sources, and ventilate the area.

Avoid formation of dust, and avoid contact with skin and eyes.

For emergency responders:

Keep out except responsible personnel.

Wear suitable protective equipment described in "Section 8: Exposure controls/ personal protection".

6.2. Environmental precautions

Protect spills from entering drains.

Do not allow to enter public sewers and watercourses.

Avoid releasing to the environment.

6.3. Methods and material for containment and cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4. Reference to other sections

Refer to SECTION 7 for storage and SECTION 13: Disposal considerations as appropriate.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures:

See SECTION 8: Exposure controls/personal protection.

Ensure good ventilation of the room when handling this substance.

Avoid contact with eyes, skin and clothing. Avoid prolonged and repeated exposure.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures:

Install appropriate equipment and wear suitable protective apparatus described in "SECTION 8: Exposure controls/ personal protection".

Conditions for safe storage:

Store desiccated below -20°C.

Keep container tightly closed in a dry and well-ventilated place.

Packing material:

Use a sealed container without damage or leakage.

7.3. Specific end use(s)

Production and research use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Acceptable concentration (exposure limit, biological exposure index)

Not regulated

8.2. Exposure controls

Appropriate engineering controls:

Use exhaust ventilation to keep airborne concentrations below exposure limits. Use only with adequate ventilation.

Personal protective equipment:

Respiratory protection Use a NIOSH/MSHA or European Standard EN149

approved respirator if the vapour concentrations exceed

regulatory guidelines.

Hand protection Impermeable gloves.

Eye protection Safety glasses (goggles).

Skin and body protection Protective clothing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance Light brownish lyophilizate

(physical state, form and colour)

Odour No information pH No information Initial boiling point and boiling range No information Flash point No information No information Vapour pressure No information Relative density No information Solubility (ies) Soluble in water

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Auto-ignition temperature No information

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under recommended storage conditions.

10.2. Chemical stability

Stable under normal handling condition.

10.3. Possibility of hazardous reactions

No hazardous reactions expected under normal handling.

10.4. Conditions to avoid

Sunlight, heat.

10.5. Incompatible materials

A strong oxidizing agent, a strong base, copper and copper alloy, nickel.

10.6. Hazardous decomposition products

Nitrogen oxide, boron oxide, carbon monoxide, carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Information on product:

Respiratory sensitization: Comp.1 (Uricase)

May cause allergic respiratory reaction.

Reproductive cell mutagenicity: Comp.5 (Boric acid)

Based on the NITE GHS classification results.

Specific target organ toxicity Comp.5 (Boric acid)

(single exposure): Based on the NITE GHS classification results.

SECTION 12: Ecological information

Information on product: No information Information on ingredients: No information

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Any disposal practice must be in compliance with country, local, state, and federal laws and regulations (contact country, local or state environmental agency for specific rules). After contents are completely removed, dispose of its container in accordance with local/regional/national/international regulation.

SECTION 14: Transport information

14.1. UN number Not applicable

14.2. UN proper shipping name Not applicable

14.3. Transport hazard class(es) Not applicable

14.4. Packing group Not applicable

14.5. Environmental hazards Not applicable

14.6. Special precautions for user

When transporting, avoid direct sunlight. Confirm no leakage to containers. When loading, prevent containers from falling, dropping off or damaging. Take preventive measures of collapse.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and IBC code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/ legislation specific for the substance or mixture

SVHC Listed

Comp.5 (Boric acid)

POPs Not Listed

Japanese Regulations

PRTR Listed

Comp.5 (Boric acid)

15.2. Chemical safety assessment

Not conducted

SECTION 16: Other information

Update history:

Date of issue: 2nd August 2016

References:

1) NITE CHRIP

2) JIS Z 7252 : 2014 3) JIS Z 7253 : 2012

4) Globally Harmonized System of classification and labeling of chemicals, (6th ed., 2015), UN

Abbreviations

PBT: Persistent, Bioaccumulative and Toxic substance

POPs: Persistent Organic Pollutants STOT: Specific Target Organ Toxicity SVHC: Substances of Very High Concern

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vPvB: Very Persistent and Very Bioaccumulative

PRTR: Law concerning Pollutant Release and Transfer Register

[Disclaimer]

This SDS has been prepared based on the best available information however, it may not be sufficient in some cases. It is user's responsibility to modify or update any contents in this SDS regarding information on hazardous properties and/or instruction for safe handling of the product when they become available. Precautionary measures in this SDS are only applicable for normal handling conditions and it is necessary to take appropriate additional measures to ensure safe handling which depend on your specific use conditions or situations.