SAFETY DATA SHEET

Fenbendazole (4%) Solid Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

   Chemical product name : Fenbendazole (4%) Solid Formulation

   Supplier's company name, address and phone number
   Company name of supplier : MSD
   Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
   Menuma factory
   Telephone : 048-588-8411
   E-mail address : EHSDATASTEWARD@msd.com
   Emergency telephone number : +1-908-423-6000

   Recommended use of the chemical and restrictions on use
   Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

   GHS classification of chemical product
   Reproductive toxicity : Category 2
   Short-term (acute) aquatic hazard : Category 1
   Long-term (chronic) aquatic hazard : Category 1

   GHS label elements
   Hazard pictograms : 
   
   Signal word : Warning
   Hazard statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child. H410 Very toxic to aquatic life with long lasting effects.
   Precautionary statements : Prevention:
   P201 Obtain special instructions before use.
   P202 Do not handle until all safety precautions have been read and understood.
   P273 Avoid release to the environment.
   P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
   Response:
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Date of first issue: 2018/04/20

P308 + P313 IF exposed or concerned: Get medical advice/attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed:

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>&gt;= 30 - &lt; 40</td>
<td>1-122</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 30 - &lt; 40</td>
<td>8-98</td>
</tr>
<tr>
<td>fenbendazole</td>
<td>43210-67-9</td>
<td>&gt;= 3 - &lt; 10</td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: Suspected of damaging fertility. Suspected of damaging the unborn child.
Contact with dust can cause mechanical irritation or drying of
Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

| Unsuitable extinguishing media | None known. |

| Specific hazards during firefighting | Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health. |

<table>
<thead>
<tr>
<th>Hazardous combustion products</th>
<th>Carbon oxides</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Metal oxides</td>
</tr>
<tr>
<td></td>
<td>Silicon oxides</td>
</tr>
</tbody>
</table>

| Specific extinguishing methods | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. |

| Special protective equipment for firefighters | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

### 6. ACCIDENTAL RELEASE MEASURES

| Personal precautions, protective equipment and emergency procedures | Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |

| Environmental precautions | Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. |

| Methods and materials for containment and cleaning up | Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- |
mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling
Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Storage
Conditions for safe storage: Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
</table>
Calcium carbonate | 471-34-1 | OEL-M (Respirable dust) | 2 mg/m³ | JP OEL JSOH
--- | --- | --- | --- | ---
Further information: Class 3 Dust
---
Starch | 9005-25-8 | TWA | 10 mg/m³ | ACGIH
fenbendazole | 43210-67-9 | TWA | 100 µg/m³ (OEB 2) | Internal

**Engineering measures**

Use feasible engineering controls to minimize exposure to compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

**Personal protective equipment**

Respiratory protection:

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

- **Filter type**: Particulates type
- **Hand protection**:
  - **Material**: Chemical-resistant gloves

Eye protection:

Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**:

Work uniform or laboratory coat.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Lower explosion limit and upper explosion limit / flammability limit</td>
<td></td>
</tr>
<tr>
<td>Upper explosion limit / Upper</td>
<td>No data available</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>2020/10/10</td>
<td>2726691-00006</td>
<td>2020/03/23</td>
<td>2018/04/20</td>
</tr>
</tbody>
</table>

- **Conditions to avoid**: Heat, flames and sparks. Avoid dust formation.
- **Incompatible materials**: Oxidizing agents
- **Hazardous decomposition products**: No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

#### Acute toxicity
Not classified based on available information.

**Components**:

**Calcium carbonate**:
- **Acute oral toxicity**: LD50 (Rat): > 2,000 mg/kg
  - Method: OECD Test Guideline 420
  - Assessment: The substance or mixture has no acute oral toxicity
- **Acute inhalation toxicity**: LC50 (Rat): > 3 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: OECD Test Guideline 403
  - Assessment: The substance or mixture has no acute inhalation toxicity
- **Acute dermal toxicity**: LD50 (Rat): > 2,000 mg/kg
  - Method: OECD Test Guideline 402
  - Assessment: The substance or mixture has no acute dermal toxicity

**Starch**:
- **Acute oral toxicity**: LD50 (Rat): > 5,000 mg/kg
- **Acute dermal toxicity**: LD50 (Rabbit): > 2,000 mg/kg

**fenbendazole**:
- **Acute oral toxicity**: LD50 (Rat): > 10,000 mg/kg
  - LD50 (Mouse): > 10,000 mg/kg

**Skin corrosion/irritation**
Not classified based on available information.

**Components**:

**Calcium carbonate**:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

**fenbendazole:**
Species : Rabbit
Result : No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Calcium carbonate:**
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

**Starch:**
Species : Rabbit
Result : No eye irritation

**fenbendazole:**
Species : Rabbit
Result : No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Calcium carbonate:**
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative

**Starch:**
Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

**Germ cell mutagenicity**
Not classified based on available information.
Components:

Calcium carbonate:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative

  Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: negative

  Test Type: In vitro mammalian cell gene mutation test
  Method: OECD Test Guideline 476
  Result: negative

Starch:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

fenbendazole:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

  Test Type: DNA Repair
  Result: negative

  Test Type: Chromosomal aberration
  Result: negative

  Test Type: in vitro assay
  Test system: mouse lymphoma cells
  Metabolic activation: Metabolic activation
  Result: equivocal

Carcinogenicity
Not classified based on available information.

Components:

fenbendazole:
Species: Mouse
Application Route: oral (feed)
Exposure time: 2 Years
NOAEL: 405 mg/kg body weight
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 2 Years
NOAEL: 5 mg/kg body weight
Result: negative
Target Organs: Lymph nodes, Liver
Reproductive toxicity
Suspected of damaging fertility. Suspected of damaging the unborn child.

**Components:**

**Calcium carbonate:**
- Effects on fertility:
  - Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
  - Species: Rat
  - Application Route: Ingestion
  - Method: OECD Test Guideline 422
  - Result: negative

- Effects on foetal development:
  - Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Ingestion
  - Method: OECD Test Guideline 414
  - Result: negative

**fenbendazole:**
- Effects on fertility:
  - Test Type: Three-generation reproduction toxicity study
  - Species: Rat
  - Application Route: oral (feed)
  - General Toxicity - Parent: NOAEL: 15 mg/kg body weight
  - Fertility: LOAEL: 45 mg/kg body weight
  - Result: Effects on fertility

- Effects on foetal development:
  - Test Type: Development
  - Species: Dog, female
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 100 mg/kg body weight
  - Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects

  Test Type: Embryo-foetal development
  - Species: Rabbit
  - Application Route: Oral
  - Developmental Toxicity: NOAEL: 25 mg/kg body weight
  - Result: Fetotoxicity

  Test Type: Embryo-foetal development
  - Species: Rabbit
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 63 mg/kg body weight

  Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: NOAEL: 120 mg/kg body weight
  - Result: No effects on foetal development

**Reproductive toxicity - Assessment:**
- Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:
fenbendazole:
Exposure routes : Ingestion
Target Organs : Liver, Lymph nodes, Stomach, Nervous system
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:
Calcium carbonate:
Species : Rat
NOAEL : > 1,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days
Method : OECD Test Guideline 422

Starch:
Species : Rat
NOAEL : >= 2,000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days
Method : OECD Test Guideline 410

fenbendazole:
Species : Rat
LOAEL : 500 mg/kg
Application Route : Oral
Exposure time : 2 Weeks
Target Organs : Kidney, Liver

Species : Rat
NOAEL : > 2,500 mg/kg
Application Route : Oral
Exposure time : 30 Days
Remarks : No significant adverse effects were reported

Species : Rat
LOAEL : 1,600 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Central nervous system
Symptoms : Tremors
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Species: Dog
NOAEL: 4 mg/kg
LOAEL: 8 mg/kg
Exposure time: 6 Months
Target Organs: Stomach, Lymph nodes, Nervous system

Aspiration toxicity
Not classified based on available information.

Components:
fenbendazole:
No aspiration toxicity classification

Experience with human exposure

Components:
fenbendazole:
Ingestion:
Symptoms: Rapid respiration, Salivation, anorexia, Diarrhoea

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
Calcium carbonate:
Toxicity to fish:
LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:
EL50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
NOELR (Pseudokirchneriella subcapitata (green algae)): 50 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201

EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201

Toxicity to microorganisms:
NOEC: 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
fenbendazole:
Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 7.5 mg/l
Exposure time: 96 h
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.008 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

M-Factor (Acute aquatic toxicity) : 100
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0015 mg/l
Exposure time: 21 Days
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

Persistence and degradability
No data available

Bioaccumulative potential

Components:
fenbendazole:
Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 240
Partition coefficient: n-octanol/water : log Pow: 2.3

Mobility in soil

Components:
fenbendazole:
Distribution among environmental compartments : log Koc: 4.37

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste han-
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14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (fenbendazole)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (fenbendazole)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (fenbendazole)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable
### 16. OTHER INFORMATION

**Further information**

Date format: yyyy/mm/dd

**Full text of other abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>JP OEL JSOH / OEL-M</td>
<td>Occupational Exposure Limit-Mean</td>
</tr>
</tbody>
</table>

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -
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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

JP / EN