

SAFETY DATA SHEET



Cefalexin Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11474863-00002

Date of last issue: 2024/11/26
Date of first issue: 2024/11/26

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Cefalexin Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

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

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Respiratory sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - single exposure : Category 3

Specific target organ toxicity - repeated exposure : Category 2 (Kidney, Adrenal gland, Blood, Gastrointestinal tract)

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.
H361f Suspected of damaging fertility.
H373 May cause damage to organs (Kidney, Adrenal gland, Blood, Gastrointestinal tract) through prolonged or repeated exposure.

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Precautionary statements

: **Prevention:**

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P284 Wear respiratory protection.

: **Response:**

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

: **Storage:**

P405 Store locked up.

: **Disposal:**

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

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 21 %

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|---------------|------------|-----------------------|----------|
| Cefalexin | 15686-71-2 | >= 20 - < 30 | - |

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.
If not breathing, give artificial respiration.

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| | |
|---|--|
| In case of skin contact | <p>If breathing is difficult, give oxygen. Get medical attention.</p> <p>: 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.</p> |
| In case of eye contact | <p>: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.</p> |
| If swallowed | <p>: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.</p> |
| Most important symptoms and effects, both acute and delayed | <p>: Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation. Suspected of damaging fertility. May cause damage to organs through prolonged or repeated exposure.</p> |
| Protection of first-aiders | <p>: 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).</p> |
| Notes to physician | <p>: Treat symptomatically and supportively.</p> |

5. FIREFIGHTING MEASURES

| | |
|---|---|
| Suitable extinguishing media | <p>: Water spray Alcohol-resistant foam Carbon dioxide (CO₂) Dry chemical</p> |
| Unsuitable extinguishing media | <p>: None known.</p> |
| Specific hazards during fire-fighting | <p>: Exposure to combustion products may be a hazard to health.</p> |
| Hazardous combustion products | <p>: Carbon oxides Nitrogen oxides (NO_x) Sulphur oxides</p> |
| Specific extinguishing methods | <p>: 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.</p> |
| Special protective equipment for firefighters | <p>: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.</p> |

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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. Prevent spreading over a wide area (e.g. by containment or oil barriers). 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 : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. 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 determine 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 : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not breathe mist or vapours. 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. Keep container tightly closed. Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers. Take care to prevent spills, waste and minimize release to the environment.

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Avoidance of contact
Hygiene measures :
Oxidizing agents
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.
Keep tightly closed.
Keep in a cool, well-ventilated place.
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

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Concentration standard / Permissible concentration | Basis |
|---------------------------|------------|-------------------------------|---|----------|
| Cefalexin | 15686-71-2 | TWA | 550 µg/m ³ (OEB 2) | Internal |
| Further information: RSEN | | | | |

Engineering measures

: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

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 : Combined particulates and organic vapour type

Hand protection : Chemical-resistant gloves

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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

Physical state : liquid

Colour : clear

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Up- : No data available
per flammability limit

Lower explosion limit / : No data available
Lower flammability limit

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

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| | | |
|-----------------------------------|---|--|
| Vapour pressure | : | No data available |
| Density and / or relative density | | |
| Relative density | : | No data available |
| Density | : | No data available |
| Relative vapour density | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle characteristics | | |
| Particle size | : | Not applicable |

10. STABILITY AND REACTIVITY

| | |
|------------------------------------|--|
| Reactivity | : Not classified as a reactivity hazard. |
| Chemical stability | : Stable under normal conditions. |
| Possibility of hazardous reactions | : Can react with strong oxidizing agents. |
| Conditions to avoid | : None known. |
| 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.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:

Cefalexin:

Acute oral toxicity : LD50 (Mouse): 1,600 - 6,200 mg/kg

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| | |
|---|--|
| | LD50 (Dog): > 2,000 mg/kg Symptoms: Vomiting |
| | LD50 (Monkey): > 1,000 mg/kg Symptoms: Vomiting |
| | LD50 (Rat): > 20,000 mg/kg |
| Acute toxicity (other routes of administration) | LD50 (Dog): > 1 g/kg Application Route: Intraperitoneal |
| | LD50 (Dog): > 0.1 g/kg Application Route: Intravenous |

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

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

Components:

Cefalexin:

| | |
|------------|--|
| Assessment | : Probability or evidence of high respiratory sensitisation rate in humans |
| Remarks | : Based on data from similar materials May cause sensitisation by inhalation. |
| Result | : Sensitiser |
| Remarks | : Based on data from similar materials May cause sensitisation by inhalation. |

Germ cell mutagenicity

Not classified based on available information.

Components:

Cefalexin:

| | |
|-----------------------|---|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| | Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative |

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Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Suspected of damaging fertility.

Components:

Cefalexin:

Effects on fertility : Test Type: Two-generation study
Species: Rat
Application Route: Oral
Fertility: NOAEL: 250 mg/kg body weight
Result: May cause adverse reproductive effects., Reduced fertility of F1 generation

Effects on foetal development : Test Type: Development
Species: Mouse
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 400 mg/kg body weight
Remarks: No significant adverse effects were reported
Maternal toxicity observed.

Test Type: Development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 1,200 mg/kg body weight
Remarks: No significant adverse effects were reported
Maternal toxicity observed.

Reproductive toxicity - Assessment : Suspected of damaging fertility.

STOT - single exposure

May cause respiratory irritation.

Components:

Cefalexin:

Exposure routes : Inhalation
Assessment : May cause respiratory irritation.

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STOT - repeated exposure

May cause damage to organs (Kidney, Adrenal gland, Blood, Gastrointestinal tract) through prolonged or repeated exposure.

Components:**Cefalexin:**

| | | |
|-----------------------------|---|--|
| Target Organs Assessment | : | Kidney, Adrenal gland, Blood, Gastrointestinal tract |
| | : | May cause damage to organs through prolonged or repeated exposure. |

Repeated dose toxicity**Components:****Cefalexin:**

| | | |
|-------------------|---|--|
| Species | : | Rat |
| NOAEL | : | < 160 mg/kg |
| Application Route | : | Oral |
| Target Organs | : | Kidney, Adrenal gland, Blood |
| Symptoms | : | Vomiting, Diarrhoea, Kidney disorders, Blood disorders |

| | | |
|-------------------|---|--|
| Species | : | Dog |
| NOAEL | : | < 160 mg/kg |
| Application Route | : | Oral |
| Target Organs | : | Kidney, Adrenal gland, Blood |
| Symptoms | : | Vomiting, Diarrhoea, Blood disorders, Kidney disorders |

| | | |
|-------------------|---|--|
| Species | : | Monkey |
| NOAEL | : | < 160 mg/kg |
| Application Route | : | Oral |
| Target Organs | : | Kidney, Adrenal gland, Blood |
| Symptoms | : | Vomiting, Diarrhoea, Blood disorders, Kidney disorders |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Cefalexin:**

| | | |
|------------|---|---|
| Inhalation | : | Target Organs: Respiratory Tract Remarks: May cause irritation of respiratory tract. May cause sensitisation by inhalation. |
| Ingestion | : | Target Organs: Gastrointestinal tract Symptoms: The most common side effects are:, Nausea, Vomiting, Abdominal pain, Diarrhoea, liver function change, blood effects |

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12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cefalexin:

Ecotoxicology Assessment

| | | |
|--------------------------|---|----------------------------------|
| Acute aquatic toxicity | : | Toxic effects cannot be excluded |
| Chronic aquatic toxicity | : | Toxic effects cannot be excluded |

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

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. Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

| | | |
|---------------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Environmentally hazardous | : | no |

IATA-DGR

| | | |
|-----------|---|---------|
| UN/ID No. | : | UN 3334 |
|-----------|---|---------|

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| | | |
|--|---|--|
| Proper shipping name | : | Aviation regulated liquid, n.o.s. (Cefalexin) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | Miscellaneous |
| Packing instruction (cargo aircraft) | : | 964 |
| Packing instruction (passenger aircraft) | : | 964 |

IMDG-Code

| | | |
|----------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| EmS Code | : | Not applicable |
| Marine pollutant | : | Not applicable |

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

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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

Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

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

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

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Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

The components of this product are reported in the following inventories:

DSL : not determined
AICS : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

Full text of other abbreviations

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 - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median

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Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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