

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Ampicillin Formulation

Version  
3.0

Revision Date:  
2025/04/14

SDS Number:  
10082467-00009

Date of last issue: 2024/09/28  
Date of first issue: 2021/10/27

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ampicillin Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road  
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

**Appearance** : suspension  
**Colour** : white to off-white  
**Odour** : No data available

May cause allergy or asthma symptoms or breathing difficulties if inhaled. Toxic to aquatic life.  
Harmful to aquatic life with long lasting effects.

#### GHS Classification

Respiratory sensitisation : Category 1

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 3

#### GHS label elements

Hazard pictograms : 

Signal word : Danger

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Hazard statements	: H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H401 Toxic to aquatic life. H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	: <b>Prevention:</b> P233 Keep container tightly closed. P261 Avoid breathing mist or vapours. P273 Avoid release to the environment. P284 Wear respiratory protection. <b>Response:</b> P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P316 If experiencing respiratory symptoms: Get emergency medical help immediately. <b>Disposal:</b> P501 Dispose of contents/ container to an approved waste disposal plant.

### Physical and chemical hazards

Not classified based on available information.

### Health hazards

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

### Environmental hazards

Toxic to aquatic life. Harmful to aquatic life with long lasting effects.

### 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)
ampicillin	69-53-4	>= 10 -< 20

## 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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	If breathing is difficult, give oxygen. Get medical attention.
In case of skin contact	: Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: 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.
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

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Nitrogen oxides (NO <sub>x</sub> ) Carbon oxides Sulphur oxides
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).
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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.

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## 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.

Avoidance of contact : Oxidizing agents

### Storage

Conditions for safe storage : Keep in properly labelled containers. Keep tightly closed. Keep in a cool, well-ventilated place.

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Materials to avoid	Store in accordance with the particular national regulations. : Do not store with the following product types: Strong oxidizing agents
Packaging material	: Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
ampicillin	69-53-4	TWA	0.6 mg/m <sup>3</sup> (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.
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### 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.
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Filter type	: Combined particulates and organic vapour type
Eye/face 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.
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Hand protection	
Material	: Chemical-resistant gloves

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.
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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available

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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

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## 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.

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## 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

### Acute toxicity

Not classified based on available information.

### Components:

#### **ampicillin:**

Acute oral toxicity : LD50 (Rat): 10,000 mg/kg  
LD50 (Mouse): 15,200 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 6,200 mg/kg  
Application Route: Intravenous  
LD50 (Mouse): 4,600 mg/kg  
Application Route: Intravenous

### **Skin corrosion/irritation**

Not classified based on available information.

### **Serious eye damage/eye irritation**

Not classified based on available information.

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### 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:

##### ampicillin:

Exposure routes	:	Inhalation
Result	:	Sensitiser

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### ampicillin:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells Result: negative
		Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Result: negative
		Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative
		Test Type: Chromosomal aberration Test system: Human lymphocytes Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Rat Application Route: Oral Result: negative

### Carcinogenicity

Not classified based on available information.

#### Components:

##### ampicillin:

Species	:	Rat
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Application Route	:	Oral
Exposure time	:	2 Years
	:	750 mg/kg body weight
Tumor Type	:	adrenal, Leukaemia, breast tumors
Species	:	Mouse
Application Route	:	Oral
Exposure time	:	2 Years
	:	3,000 mg/kg body weight
Tumor Type	:	Lungs
Remarks	:	Benign tumor(s)
Carcinogenicity - Assessment	:	Weight of evidence does not support classification as a carcinogen

### Reproductive toxicity

Not classified based on available information.

### Components:

#### **ampicillin:**

Effects on fertility	:	Test Type: Fertility Species: Guinea pig Target Organs: Uterus (including cervix)
Effects on foetal development	:	Test Type: Development Species: Rat Developmental Toxicity: NOAEL: 250 mg/kg body weight Result: No effects on foetal development

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

### Components:

#### **ampicillin:**

Species	:	Rat
LOAEL	:	3,000 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Symptoms	:	Diarrhoea
Species	:	Mouse
LOAEL	:	2,000 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks

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Symptoms	:	Diarrhoea
Species	:	Rat
LOAEL	:	750 mg/kg
Application Route	:	Oral
Exposure time	:	2 yr
Target Organs	:	Thyroid, forestomach
Symptoms	:	Diarrhoea, Salivation, decreased activity
Species	:	Mouse
LOAEL	:	2,000 mg/kg
Application Route	:	Oral
Exposure time	:	2 yr
Target Organs	:	forestomach
Symptoms	:	Ulceration, Inflammation, fungal infections

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### **ampicillin:**

Inhalation	:	Symptoms: Asthma, Hay fever Remarks: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Ingestion	:	Symptoms: skin rash, Nausea, Diarrhoea, Vomiting, colitis, urticaria

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### **ampicillin:**

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 1,000 mg/l Exposure time: 96 h
		LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Anabaena flos-aquae): 190 µg/l Exposure time: 72 h Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 13 µg/l

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Exposure time: 72 h  
Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC: 9 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

##### **ampicillin:**

Biodegradability : Result: rapidly degradable  
Biodegradation: 35 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### Bioaccumulative potential

#### Components:

##### **ampicillin:**

Partition coefficient: n-octanol/water : log Pow: -2.0  
pH: 7

### Mobility in soil

No data available

### Other adverse effects

No data available

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### 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

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.

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### 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. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

##### 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 : no

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### National Regulations

##### GB 6944/12268

UN number : Not applicable  
Proper shipping name : Not applicable

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Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Marine pollutant : no

### Special precautions for user

Not applicable

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## 15. REGULATORY INFORMATION

### National regulatory information

#### Law on the Prevention and Control of Occupational Diseases

#### Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218) : Not listed

Hazardous Chemicals for Priority Management under SAWS : Not listed

Catalogue of Specially Controlled Hazardous Chemicals : Not listed

List of Explosive Precursors : Not listed

#### Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

#### Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export : Not listed

#### Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

#### Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

#### Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import : Not listed

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and Export  
List of Controlled Ozone Depleting Substances : Not listed

### Environmental Protection Law

List of Priority Controlled Chemicals : Not listed  
List of Key Controlled New Pollutants : Not listed

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

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

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## 16. OTHER INFORMATION

Revision Date : 2025/04/14

### 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 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

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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

### Disclaimer

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.

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