

# **Ampicillin Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.6 06.04.2024 10082440-00007 Date of first issue: 27.10.2021

**Section 1: Identification** 

**Product identifier** : Ampicillin Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive

Singapore - Singapore 638408

Telephone : +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

## Section 2: Hazard identification

Classification of the substance or mixture

Respiratory sensitisation : Category 1

GHS Label elements, including precautionary statements

Hazard pictograms :

· Danger

Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Precautionary statements : **Prevention:** 

P261 Avoid breathing mist or vapours. P284 Wear respiratory protection.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.





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#### Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

#### Other hazards which do not result in classification

None known.

### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	
ampicillin	69-53-4	>= 10 -< 20	

#### Section 4: First-aid measures

#### Description of necessary first-aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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. 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

Risks : May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

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).

#### Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.





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### Section 5: Fire-fighting measures

**Extinguishing media** 

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Hazardous combustion prod: :

ucts

Nitrogen oxides (NOx)
Carbon oxides

Sulphur oxides

Special protective actions for fire-fighters

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Exposure to combustion products may be a hazard to health.

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

#### Section 6: Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

**Environmental precautions** 

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

Methods for 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 absor-

bent.

Local or national regulations may apply to releases and dis-





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> posal 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.

#### Section 7: Handling and storage

### Precautions for safe handling

Technical measures See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation Use only with adequate ventilation. Avoid breathing mist or vapours. Advice on safe handling

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 as-

sessment

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 respira-

tory irritants or sensitisers.

Take care to prevent spills, waste and minimize release to the

environment.

If exposure to chemical is likely during typical use, provide eye Hygiene measures

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.

#### Conditions for safe storage, including any incompatibilities

Conditions for safe storage Keep in properly labelled containers.

Keep tightly closed.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

#### Section 8: Exposure controls/personal protection

#### Control parameters

#### **Occupational Exposure Limits**





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Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
ampicillin	69-53-4	TWA	0.6 mg/m3 (OEB 2)	Internal	
	Further information: RSEN				

Appropriate engineering control 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.

Individual protection measures, such as personal protective equipment (PPE)

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 protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Combined particulates and organic vapour type

Filter type

Hand protection

Material : Chemical-resistant gloves

#### Section 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



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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

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

## Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

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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#### **Section 11: Toxicological information**

Information on likely routes of : Inhalation

exposure 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.

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





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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
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 - Assess-

ment cinogen

Reproductive toxicity

#### reproductive toxicity

Not classified based on available information.

#### **Components:**

#### ampicillin:

Effects on fertility : Test Type: Fertility

Species: Guinea pig

Target Organs: Uterus (including cervix)

Weight of evidence does not support classification as a car-



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Effects on foetal develop: Test Type: Development

ment 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 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 breath-



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ing difficulties if inhaled.

Ingestion : Symptoms: skin rash, Nausea, Diarrhoea, Vomiting, colitis,

urticaria

#### **Section 12: Ecological information**

**Toxicity** 

**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

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 tox-

icity)

: 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



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#### 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- : log Pow: -2.0

octanol/water pH: 7

Mobility in soil

No data available

Other adverse effects

No data available

#### **Section 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **Section 14: Transport information**

#### International Regulations

**UNRTDG** 

UN number : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

**IATA-DGR** 

UN/ID No. : Not applicable
UN proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable



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Packing group Not applicable Labels Not applicable Packing instruction (cargo Not applicable

aircraft)

Packing instruction (passen-

ger aircraft)

Not applicable

**IMDG-Code** 

**UN** number Not applicable Not applicable UN proper shipping name Not applicable Class Subsidiary risk Not applicable Packing group Not applicable Labels Not applicable **EmS Code** Not applicable Marine pollutant Not applicable

### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

## Special precautions for user

Not applicable

#### Section 15: Regulatory information

#### Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Not applicable

Fire Safety (Petroleum and Flammable Materials)

Regulations

Not applicable

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

**AICS** not determined

**DSL** not determined

**IECSC** not determined

#### **Section 16: Other information**

**Revision Date** 06.04.2024

**Further information** 

Sources of key data used to

compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Sheet cy, http://echa.europa.eu/



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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 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

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SG / EN