according to the Globally Harmonized System



Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.5 30.09.2023 10082470-00006 Date of first issue: 27.10.2021

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ampicillin Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

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

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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

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.

according to the Globally Harmonized System



Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.5 30.09.2023 10082470-00006 Date of first issue: 27.10.2021

Precautionary statements : Prevention:

P261 Avoid breathing mist or vapours. P273 Avoid release to the environment. P284 Wear respiratory protection.

Response:

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

keep comfortable for breathing.

P342 + P316 If experiencing respiratory symptoms: Get emer-

gency medical help immediately.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

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 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. Flush eyes with water as a precaution.

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 : May cause aller

and effects, both acute and

delayed

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).

according to the Globally Harmonized System



Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.5 30.09.2023 10082470-00006 Date of first issue: 27.10.2021

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Nitrogen oxides (NOx)

Carbon oxides Sulphur oxides

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.

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, protec: :

tive equipment and emer-

gency procedures

Use personal protective equipment.

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

tective 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 absor-

bent.

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

according to the Globally Harmonized System



Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 30.09.2023 10082470-00006 Date of first issue: 27.10.2021 15

Technical measures See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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

Conditions for safe storage Keep in properly labelled containers.

Keep tightly closed.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

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			

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Combined particulates and organic vapour type

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.

according to the Globally Harmonized System



Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.5 30.09.2023 10082470-00006 Date of first issue: 27.10.2021

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.

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.

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

according to the Globally Harmonized System



Ampicillin Formulation

Revision Date: Version SDS Number: Date of last issue: 04.04.2023 1.5 30.09.2023 10082470-00006 Date of first issue: 27.10.2021

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 size Not applicable

10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

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.

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

according to the Globally Harmonized System



Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.5 30.09.2023 10082470-00006 Date of first issue: 27.10.2021

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

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.

according to the Globally Harmonized System



Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.5 30.09.2023 10082470-00006 Date of first issue: 27.10.2021

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

Weight of evidence does not support classification as a car-

cinogen

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 develop-

ment

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

according to the Globally Harmonized System



Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.5 30.09.2023 10082470-00006 Date of first issue: 27.10.2021

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-

ing 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

Exposure time: 72 h

according to the Globally Harmonized System



Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.5 30.09.2023 10082470-00006 Date of first issue: 27.10.2021

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

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

according to the Globally Harmonized System



Ampicillin Formulation

Revision Date: Date of last issue: 04.04.2023 Version SDS Number: 30.09.2023 10082470-00006 Date of first issue: 27.10.2021 1.5

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

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

AICS not determined

DSL not determined

IECSC not determined

16. OTHER INFORMATION

Revision Date 30.09.2023

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 Agen-

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

Date format dd.mm.yyyy

Full text of other abbreviations

according to the Globally Harmonized System



Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 1.5 30.09.2023 10082470-00006 Date of first issue: 27.10.2021

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

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.

IN / EN