

Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: -
1.0 27.10.2021 10082472-00001 Date of first issue: 27.10.2021

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ampicillin Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Address : 126 E. Lincoln Avenue
 : Rahway, New Jersey U.S.A 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Respiratory sensitization : Category 1

GHS label elements

Hazard pictograms :



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 vapors.
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 or doctor/ physician.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Ampicillin Formulation

Version 1.0 Revision Date: 27.10.2021 SDS Number: 10082472-00001 Date of last issue: -
 Date of first issue: 27.10.2021

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

SECTION 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.
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 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive 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).
- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING 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 products : Nitrogen oxides (NO_x)
Carbon oxides
Sulfur 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	27.10.2021	10082472-00001	Date of first issue: 27.10.2021

SECTION 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 diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

- 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 vapors. 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 sensitized individuals should consult their physician regarding working with respiratory irritants or sensitizers. Take care to prevent spills, waste and minimize release to the environment.
- 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

Ampicillin Formulation

Version 1.0 Revision Date: 27.10.2021 SDS Number: 10082472-00001 Date of last issue: -
Date of first issue: 27.10.2021

Conditions for safe storage : use of administrative controls.
Keep in properly labeled 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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/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 vapor type

Hand protection
Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Color : white to off-white

Odor : No data available

Odor Threshold : No data available

pH : No data available

Ampicillin Formulation

Version 1.0 Revision Date: 27.10.2021 SDS Number: 10082472-00001 Date of last issue: -
Date of first issue: 27.10.2021

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
Vapor pressure	:	No data available
Relative vapor 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
Autoignition 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

SECTION 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.

Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	27.10.2021	10082472-00001	Date of first issue: 27.10.2021

Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 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
		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 sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

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

Components:**Ampicillin:**

Routes of exposure	:	Inhalation
Result	:	Sensitizer

Germ cell mutagenicity

Not classified based on available information.

Components:**Ampicillin:**

Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	27.10.2021	10082472-00001	Date of first issue: 27.10.2021

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
Application Route : Oral
Exposure time : 2 Years
: 750 mg/kg body weight
Tumor Type : adrenal, Leukemia, 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

Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	27.10.2021	10082472-00001	Date of first issue: 27.10.2021

Target Organs: Uterus (including cervix)

Effects on fetal development : Test Type: Development
 Species: Rat
 Developmental Toxicity: NOAEL: 250 mg/kg body weight
 Result: No effects on fetal 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 : Diarrhea

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

Species : Rat
 LOAEL : 750 mg/kg
 Application Route : Oral
 Exposure time : 2 y
 Target Organs : Thyroid, forestomach
 Symptoms : Diarrhea, Salivation, decreased activity

Species : Mouse
 LOAEL : 2,000 mg/kg
 Application Route : Oral
 Exposure time : 2 y
 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.

Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	27.10.2021	10082472-00001	Date of first issue: 27.10.2021

Ingestion : Symptoms: skin rash, Nausea, Diarrhea, Vomiting, colitis, urticaria

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:**Ampicillin:**

<p>Toxicity to fish</p> <p>Toxicity to daphnia and other aquatic invertebrates</p> <p>Toxicity to algae/aquatic plants</p>	<p>: LC50 (<i>Oryzias latipes</i> (Japanese medaka)): > 1,000 mg/l Exposure time: 96 h</p> <p>LC50 (<i>Oncorhynchus mykiss</i> (rainbow trout)): > 100 mg/l Exposure time: 96 h</p> <p>: EC50 (<i>Daphnia magna</i> (Water flea)): > 100 mg/l Exposure time: 48 h</p> <p>: EC50 (<i>Anabaena flos-aquae</i>): 190 µg/l Exposure time: 72 h Method: OECD Test Guideline 201</p> <p>NOEC (<i>Anabaena flos-aquae</i>): 13 µg/l Exposure time: 72 h Method: OECD Test Guideline 201</p> <p>EC50 (<i>Pseudokirchneriella subcapitata</i> (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</p> <p>NOEC (<i>Pseudokirchneriella subcapitata</i> (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</p> <p>: EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</p> <p>NOEC: 9 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</p>
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Persistence and degradability

Components:**Ampicillin:**

Biodegradability	: Result: rapidly degradable Biodegradation: 35 % Exposure time: 28 d
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Ampicillin Formulation

Version 1.0 Revision Date: 27.10.2021 SDS Number: 10082472-00001 Date of last issue: -
Date of first issue: 27.10.2021

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

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation**NOM-002-SCT**

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	27.10.2021	10082472-00001	Date of first issue: 27.10.2021

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

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

SECTION 16. OTHER INFORMATION**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; TECl - 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

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
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Revision Date	:	27.10.2021
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SAFETY DATA SHEET



Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	27.10.2021	10082472-00001	Date of first issue: 27.10.2021

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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