

## Ampicillin Formulation

Version            Revision Date:            SDS Number:            Date of last issue: -  
1.0                10/27/2021              10082439-00001        Date of first issue: 10/27/2021

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### SECTION 1. IDENTIFICATION

Product name                                : Ampicillin Formulation

#### Manufacturer or supplier's details

Company name of supplier                : Merck & Co., Inc  
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@merck.com

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

Recommended use                         : Veterinary product

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

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.  
P285 In case of inadequate ventilation wear respiratory protection.  
**Response:**  
P304 + P341 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.  
P342 + P311 If experiencing respiratory symptoms: Call a doctor.  
**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

#### Other hazards

None known.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

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Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Ampicillin	69-53-4	10.3

**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 (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  
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.

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Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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### 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.

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### 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.

Conditions for safe storage : 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

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**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 <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.

**Personal protective equipment**

**Respiratory protection** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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.

**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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

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Appearance	:	suspension
Color	:	white to off-white
Odor	:	No data available
Odor 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
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

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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.
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.

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**Components:****Ampicillin:**

Routes of exposure : Inhalation  
Result : Sensitizer

**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  
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)

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Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### 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 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



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

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Ampicillin:**

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

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Exposure time: 72 h  
Method: OECD Test Guideline 201

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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**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.

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

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

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**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****49 CFR**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

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**SECTION 15. REGULATORY INFORMATION****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards**            :    Respiratory or skin sensitization

**SARA 313**                                :    This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**US State Regulations****Pennsylvania Right To Know**

Glycerides, mixed decanoyl and octanoyl	73398-61-5
Ampicillin	69-53-4

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

AICS                                        :    not determined

DSL    :    not determined

IECSC                                        :    not determined

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**SECTION 16. OTHER INFORMATION****Further information**

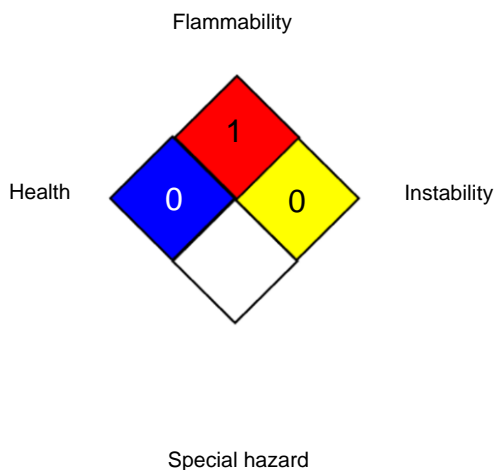
# SAFETY DATA SHEET



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### NFPA 704:



### HMIS® IV:

HEALTH	*	0
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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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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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.

US / Z8