

MATERIAL SAFETY DATA SHEET

1. Product and Company Identification

Material name Ampicillin & Sulbactam for Injection
Revision date 01-24-2012
Version # 01
CAS # Mixture
Product code NDC CODE: 55150-116-20, 55150-117-20, 55150-118-20(for 1.5g, 3g, 15g)
Product use Antibacterial/Beta lactam, Penicillins.
Manufacturer/Supplier AuroMedics
6 Wheeling Road, Dayton NJ 08810
vandolina@aurobindousa.com
Contact Person: Vincent Andolina
Telephone 609-642-1136
Emergency 732-823-8084

2. Hazards Identification

Physical state Powder.
Appearance White to off-white powder.
Emergency overview WARNING
May cause allergic respiratory and skin reactions.

Potential health effects

Routes of exposure Eye contact. Inhalation. Skin contact.
Eyes May cause eye irritation on direct contact.
Skin May cause allergic skin reaction.
Inhalation May cause allergic respiratory reaction.
Ingestion Ingestion may cause irritation and malaise. May cause serious or fatal hypersensitivity (anaphylactic) reactions in some individuals.

Target organs Eyes. Skin. Lungs. Blood.

Potential environmental effects No data available.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Ampicillin sodium	69-52-3	60-70
Sulbactam sodium	69388-84-7	30-40

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First Aid Measures

First aid procedures

Eye contact Immediately flush with plenty of water for at least 15 minutes occasionally lifting upper and lower eyelids. If easy to do, remove contact lenses. Get medical attention if symptoms persist.
Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash contaminated clothing before reuse.
Inhalation Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen and monitor closely. Get medical attention immediately.
Ingestion DO NOT induce vomiting. If victim is fully conscious, give a cupful of water. Never give anything by mouth to an unconscious person. If vomiting occurs, keep head lower than the hips to help prevent aspiration. Call a physician or poison control center immediately.

Notes to physician Treat symptomatically.
Exposure may aggravate pre-existing skin or respiratory disorders.

5. Fire Fighting Measures

Flammable properties	The product is not flammable.
Extinguishing media	
Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Fire fighting equipment/instructions	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Hazardous combustion products	Carbon oxides. Nitrogen Oxides Sulfur oxides.

6. Accidental Release Measures

Personal precautions	Wear appropriate personal protective equipment (See Section 8).
Environmental precautions	Do not allow to enter drains, sewers or watercourses.
Methods for cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation.

7. Handling and Storage

Handling	Wear protective clothing as described in Section 8 of this safety data sheet. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Use only with adequate ventilation. Wash thoroughly after handling. Minimize dust generation and accumulation.
Storage	Store at controlled room temperature at 20–25 °C (68-77°F). Store away from incompatible materials (See Section 10).

8. Exposure Controls / Personal Protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Engineering controls	Provide adequate ventilation.
Personal protective equipment	
Eye / face protection	Wear safety glasses with side shields (or goggles).
Skin protection	Wear protective gloves. Wear protective clothing appropriate for the risk of exposure.
Respiratory protection	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134. Respirator type: Use high efficiency particulate respirator with appropriate filter.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical & Chemical Properties

Appearance	White to off-white powder.
Color	White to off-white.
Odor	Not available.
Odor threshold	Not available.
Physical state	Solid.
Form	Powder.
pH	Not available.
Melting point	Not available.
Freezing point	Not available.
Boiling point	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.

Vapor pressure	Not available.
Vapor density	Not available.
Specific gravity	Not available.
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	Heat. Water, moisture. Minimize dust generation and accumulation. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Carbon oxides. Nitrogen oxides. Sulfur oxides.
Possibility of hazardous reactions	Will not occur.

11. Toxicological Information

Toxicological data

Components	Test Results
Ampicillin sodium (69-52-3)	Acute Oral LD50 Rat: > 5314 mg/kg
Acute effects	May cause eye irritation on direct contact. Ingestion may cause irritation and malaise. May cause serious or fatal hypersensitivity (anaphylactic) reactions in some individuals.
Sensitization	May cause allergic respiratory and skin reactions.
Carcinogenicity	This material is not classified as a carcinogen by IARC, ACGIH, NTP or OSHA.

12. Ecological Information

Ecotoxicity	This material has not been tested for environmental effects.
Persistence and degradability	Not available.
Bioaccumulation / Accumulation	No data available.
Partition coefficient (n-octanol/water)	Not available.
Mobility in environmental media	No data available.

13. Disposal Considerations

Disposal instructions	Dispose of contents/container in accordance with local/regional/national/international regulations.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport Information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

TDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations

TSCA Section 12(b) Export Notification(40 CFR 707, Subpt. D)

Not regulated.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance (40 CFR 355, Appendix A)
No

Section 311/312 (40 CFR 370)
No

Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)
Not controlled

Canadian regulations
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

WHMIS status
Non-controlled

WHMIS labeling



Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

Mexico regulations
This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

HMIS® ratings
Health: 2*
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 2
Flammability: 0
Instability: 0

Disclaimer
The information in the sheet was written based on the best knowledge and experience currently available.

