



SAFETY DATA SHEET

Section 1: Identification	
Material	Daptomycin for Injection 350mg
Recommended Use	Pharmaceutical product used as antibiotic agent
Manufacturer	Aspiro Pharma Limited, Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Telangana (S), Siddipet (Dist.)-502281, India.
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statements	May cause damage to organs through prolonged or repeated exposure
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Daptomycin	103060-53-3
Sodium hydroxide	1310-73-2
Water for Injection	7732-18-5
Section 4: First-Aid Measures	
Inhalation	Remove to fresh air. Seek immediate medical attention/advice
Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Section 5: Fire-Fighting Measures	
Suitable extinguishing media	Use carbon dioxide, dry chemical, or water spray
Special hazards arising from the substance or mixture	
Specific hazards arising from the chemical	Fine particles (such as dust and mists) may fuel fires/explosions
Hazardous combustion products	Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides



Advice for firefighters	
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment
Section 6: Accidental Release Measures	
Environmental precautions	
Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and material for containment and cleaning up	
Methods for containment Methods for cleaning up	Prevent further leakage or spillage if safe to do so. Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.
Section 7: Handling and Storage	
<u>Precautions for safe handling</u>	
Advice on safe handling	
Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.	
General hygiene considerations Handle in accordance with good industrial hygiene and safety practice	
Storage conditions	Store as directed by product packaging.
Specific use(s)	Pharmaceutical drug product
Section 8: Exposure Controls/Personal Protection	
Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section
Environmental exposure controls	No information available.
Personal protective equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Eye/face protection	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).



Hand protection	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Skin and body protection	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice

Section 9: Physical and Chemical Properties

Physical Form	Lyophilized powder									
Colour	Pale yellow to Light brown									
Description	<p>Daptomycin for injection is supplied as a sterile, nonpyrogenic, preservative-free, pale yellow to light brown lyophilized cake in single-dose vials as follows:</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">NDC</th> <th style="text-align: left;">Daptomycin for Injection</th> <th style="text-align: left;">Package Factor</th> </tr> </thead> <tbody> <tr> <td>31722-215-01</td> <td>350 mg Single-Dose Vial</td> <td>1 vial per carton</td> </tr> <tr> <td>31722-215-10</td> <td>350 mg Single-Dose Vial</td> <td>10 vials per carton</td> </tr> </tbody> </table> <p>The container closure is not made with natural rubber latex.</p> <p>Storage Conditions</p> <p>Store refrigerated between 2°C and 8°C (36°F and 46° F); avoid excessive heat. Storage conditions for the reconstituted and diluted solutions are described in another section of the prescribing information.</p>	NDC	Daptomycin for Injection	Package Factor	31722-215-01	350 mg Single-Dose Vial	1 vial per carton	31722-215-10	350 mg Single-Dose Vial	10 vials per carton
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31722-215-01	350 mg Single-Dose Vial	1 vial per carton								
31722-215-10	350 mg Single-Dose Vial	10 vials per carton								

Section 10: Stability and Reactivity

Reactivity	No data available
Chemical stability	Stable under normal conditions

Section 11: Toxicological Information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Short term Accidental ingestion may cause effects similar to those seen in clinical use.

Known Clinical Effects: Adverse effects associated with therapeutic use include headache, allergic skin rash, liver effects, effects on musculoskeletal system, muscle pain, muscle weakness, neuromuscular effects. Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

Acute Toxicity: (Species, Route, End Point, Dose)

Daptomycin

Rat Oral Minimum Lethal Dose > 2000 mg/kg

Rat Dermal Minimum Lethal Dose > 200 mg/kg

Mouse IV Minimum Lethal Dose > 700 mg/kg

Rat IV Minimum Lethal Dose > 140 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Citric acid

Mouse Oral LD50 5400 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	--
Citric acid	= 3 g/kg (Rat)	> 2000 mg/kg (Rat)	--

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Section 12: Ecological Information

Environmental Overview: Releases to the environment should be avoided. Environmental properties of the formulation have not been thoroughly investigated.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
Citric acid	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.



Section 13: Disposal Considerations

Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: Regulatory Information

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

Daptomycin

CERCLA/SARA Section 313 de minimus % Not Listed

California Proposition 65 Not Listed

EINECS Not Listed

Standard for Uniform Scheduling of Medicines and

Poisons (SUSMP)

Schedule 4

Sodium hydroxide

CERCLA/SARA Section 313 de minimus % Not Listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available.



Section 16: Other Information

Issue Date : 02-02-2023

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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