

## Daptomycin Injection Formulation - 2nd Generation

Version 1.1      Revision Date: 10/31/2016      SDS Number: 679941-00002      Date of last issue: 05/19/2016  
Date of first issue: 05/19/2016

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### SECTION 1. IDENTIFICATION

Product name : Daptomycin Injection Formulation - 2nd Generation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road  
Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Pharmaceutical

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with 29 CFR 1910.1200

Combustible dust

Specific target organ systemic toxicity - repeated exposure (Dermal) : Category 2 (muscle, Kidney)

#### GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
H373 May cause damage to organs (muscle, Kidney) through prolonged or repeated exposure in contact with skin.

Precautionary Statements : **Prevention:**  
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.  
**Response:**

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P314 Get medical advice/ attention if you feel unwell.

### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
 Contact with dust can cause mechanical irritation or drying of the skin.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 50 - < 70
Daptomycin	103060-53-3	>= 30 - < 50

## 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.  
 Get medical attention if symptoms occur.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
 Get medical attention if symptoms occur.
- In case of eye contact : If in eyes, rinse well with water.  
 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 : Contact with dust can cause mechanical irritation or drying of the skin.  
 Dust contact with the eyes can lead to mechanical irritation.  
 May cause damage to organs through prolonged or repeated exposure in contact with skin.
- 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.
- Notes to physician : Treat symptomatically and supportively.

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### 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 : Carbon 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.
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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice and personal protective equipment recommendations.
- Environmental precautions : Discharge into the environment must be avoided.  
Prevent further leakage or spillage if safe to do so.  
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
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** : Static electricity may accumulate and ignite suspended dust causing an explosion.  
 Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation** : Use only with adequate ventilation.
- Advice on safe handling** : Do not get on skin or clothing.  
 Do not breathe dust.  
 Do not swallow.  
 Avoid contact with eyes.  
 Handle in accordance with good industrial hygiene and safety practice.  
 Minimize dust generation and accumulation.  
 Keep container closed when not in use.  
 Keep away from heat and sources of ignition.  
 Take precautionary measures against static discharges.  
 Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage** : Keep in properly labeled containers.  
 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

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
Daptomycin	103060-53-3	TWA	400 µg/m <sup>3</sup>	Merck
		TWA	OEB 2 (>=100 < 1000ug/m3)	Merck

- Engineering measures** : Ensure adequate ventilation, especially in confined areas.  
 Minimize workplace exposure concentrations.  
 Apply measures to prevent dust explosions.

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Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m<sup>3</sup> - total dust, 5 mg/m<sup>3</sup> - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m<sup>3</sup> - respirable particles, 10 mg/m<sup>3</sup> - inhalable particles.

### 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

Remarks : For prolonged or repeated contact use protective gloves. Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:  
Safety goggles

Skin and body protection : Skin should be washed after contact.

Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	lyophilized cake
Color	:	light brown
Odor	:	No information available.
Odor Threshold	:	No data available
pH	:	6.5 - 7.3 (as aqueous solution)
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
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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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Dust can form an explosive mixture in air.  
Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION**

**Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Ingredients:**

**Sucrose:**

Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Ingredients:**

**Daptomycin:**

Species: Rabbit  
Result: Mild skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Ingredients:**

**Daptomycin:**

Species: Rabbit  
Result: Mild eye irritation

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### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

### Ingredients:

#### Sucrose:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

#### Daptomycin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

: Test Type: Chromosome aberration test in vitro  
Result: negative

: Test Type: In vitro mammalian cell gene mutation test  
Species: mouse lymphoma cells  
Result: negative

: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo  
Species: Hamster  
Application Route: Intraperitoneal injection  
Result: negative

### Carcinogenicity

Not classified based on available information.

#### 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 ingredient of this product present at levels greater than or

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equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

### 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.

### Ingredients:

#### Daptomycin:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Intravenous injection  
Fertility: NOAEL: < 25 mg/kg body weight  
Result: No effects on fertility.

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: < 20 mg/kg body weight  
Result: No significant adverse effects were reported

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 20 mg/kg body weight  
Result: No significant adverse effects were reported

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

May cause damage to organs (muscle, Kidney) through prolonged or repeated exposure in contact with skin.

### Ingredients:

#### Daptomycin:

Routes of exposure: Skin contact  
Target Organs: muscle, Kidney  
Assessment: May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Ingredients:

#### Daptomycin:

Species: Dog  
NOAEL: 20 mg/kg  
Application Route: Intravenous

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Exposure time: 3 Months  
Target Organs: muscle

Species: Monkey  
NOAEL: 10 mg/kg  
Application Route: Intravenous  
Exposure time: 1 Months  
Remarks: No significant adverse effects were reported

### Aspiration toxicity

Not classified based on available information.

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

No data available

### Persistence and degradability

No data available

### Bioaccumulative potential

### Ingredients:

#### Sucrose:

Partition coefficient: n-octanol/water : Pow: < 1

### 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

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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

#### 49 CFR

Not regulated as a dangerous good

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## SECTION 15. REGULATORY INFORMATION

### EPCRA - Emergency Planning and Community Right-to-Know

#### 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** : Fire Hazard  
Chronic Health Hazard

**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

Sucrose	57-50-1
Daptomycin	103060-53-3

**California Prop. 65** This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

#### California Permissible Exposure Limits for Chemical Contaminants

Sucrose	57-50-1
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#### The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

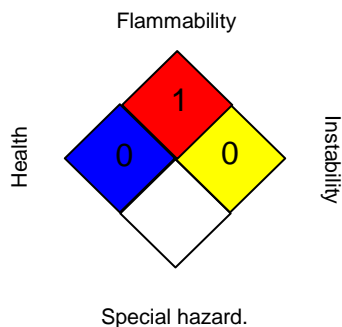
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### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA:



##### HMIS® IV:

<b>HEALTH</b>	*	2
<b>FLAMMABILITY</b>	3	
<b>PHYSICAL HAZARD</b>	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

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; 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

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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; 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

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/>

Revision Date : 10/31/2016

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

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