



| Version 3.1 | Revision Date: 2023/09/30 | | S Number:)792-00017 | Date of last issue: 2023/04/04 Date of first issue: 2016/05/02 |
|----------------|-------------------------------|-------|--------------------------------|---|
| | | | | |
| | | | | |
| 1. PRODU | ICT AND COMPANY IDI | ENT | IFICATION | |
| Produ | uct name | : | Daptomycin I | njection Formulation |
| Manu | Ifacturer or supplier's d | letai | ils | |
| Comp | bany | : | MSD | |
| Addre | ess | : | 126 E. Lincol Rahway, Nev | n Avenue v Jersey U.S.A. 07065 |
| Telep | hone | : | 908-740-400 |) |
| Emer | gency telephone number | • : | 1-908-423-60 | 00 |
| E-ma | il address | : | EHSDATAST | EWARD@msd.com |
| Reco | mmended use of the ch | nem | ical and restri | ctions on use |
| | mmended use ictions on use | : | Pharmaceution Not applicabl | |
| 2 HA7AR | DS IDENTIFICATION | | | |

| GHS Classification | | |
|---|---|---|
| Specific target organ toxicity - repeated exposure (Dermal) | : | Category 2 (muscle, Kidney, Nervous system) |
| GHS label elements | | |
| Hazard pictograms | : | |
| Signal word | : | Warning |
| Hazard statements | : | H373 May cause damage to organs (muscle, Kidney, Nervous system) through prolonged or repeated exposure in contact with skin. |
| Precautionary statements | : | Prevention: P260 Do not breathe dust. |
| | | Response: |
| | | P314 Get medical advice/ attention if you feel unwell. |
| | | Disposal: |
| | | P501 Dispose of contents/ container to an approved waste |
| | Specific target organ toxicity - repeated exposure (Dermal) GHS label elements Hazard pictograms Signal word Hazard statements | Specific target organ toxicity - repeated exposure (Dermal):GHS label elements Hazard pictograms:Signal word:Hazard statements: |



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disposal plant.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

| Substance / Mixture | : | Mixture |
|---------------------|---|---------|
|---------------------|---|---------|

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------|-------------|-----------------------|
| Daptomycin | 103060-53-3 | >= 60 -<= 100 |

4. FIRST AID MEASURES

| General advice | : | In the case of accident or if you feel unwell, seek medical ad- vice 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 | : | May cause damage to organs through prolonged or repeated |
| and effects, both acute and | | exposure in contact with skin. |
| delayed | | Contact with dust can cause mechanical irritation or drying of |
| | | the skin. |
| | | Dust contact with the eyes can lead to mechanical irritation. |
| 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. |
| 5. FIREFIGHTING MEASURES | | |
| 5. FIREFIGHTING MEASURES | | |
| Suitable extinguishing media | : | Water spray |
| Suitable extinguishing media | • | Alcohol-resistant foam |
| | | |
| | | Carbon dioxide (CO2) Dry chemical |
| Linguitable extinguishing | | None known. |
| Unsuitable extinguishing media | · | |
| | | |

Specific hazards during fire- : Avoid generating dust; fine dust dispersed in air in sufficient



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| fighting | | | potential dust exp | nd in the presence of an ignition source is a losion hazard. bustion products may be a hazard to health. | |
| | Hazard ucts | ous combustion prod- | : | Carbon oxides | |
| | Specific extinguishing meth- ods | | : | cumstances and t Use water spray t | measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do |
| | Special for firefi | protective equipment ghters | : | | e, wear self-contained breathing apparatus. ective equipment. |
| 6. A | CCIDEN | ITAL RELEASE MEAS | SUF | RES | |
| | tive equ | al precautions, protec- ipment and emer- procedures | : | | ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8). |
| | Environ | mental precautions | : | Retain and dispos | akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages |
| | | s and materials for ment and cleaning up | : | tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the atr Local or national r posal of this mate employed in the c mine which regula Sections 13 and 1 | dust in the air (i.e., clearing dust surfaces |
| 7. H | ANDLIN | IG AND STORAGE | | | |
| | Local/T | cal measures | : | causing an explose Provide adequate and bonding, or in Use only with ade | precautions, such as electrical grounding nert atmospheres. quate ventilation. |
| | Advice | on safe handling | : | Do not get on skir Do not breathe du Do not swallow. | |



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| | tions for safe storage ials to avoid | practice, based of sessment Minimize dust ge Keep container of Keep away from Take precautiona Take care to pre- environment. : Keep in properly Store in accordat | lance with good industrial hygiene and safety on the results of the workplace exposure as- eneration and accumulation. closed when not in use. heat and sources of ignition. ary measures against static discharges. vent spills, waste and minimize release to the labelled containers. nce with the particular national regulations. the following product types: |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis | | | | |
|--|--|--|--|----------|--|--|--|--|
| Daptomycin | 103060-53-3 | TWA | 800 µg/m3 (OEB 2) | Internal | | | | |
| Engineering measures : | compound. All engineerin design and op | g controls should | rols to minimize expo d be implemented by dance with GMP princ d the environment. | facility | | | | |
| Personal protective equipmer | nt | | | | | | | |
| Respiratory protection : Filter type : Hand protection | If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type | | | | | | | |
| Material | Chemical-resi | Chemical-resistant gloves | | | | | | |
| Eye protection : Skin and body protection : Hygiene measures : | 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. Work uniform or laboratory coat. If exposure to chemical is likely during typical use, provide | | | | | | | |
| | eye flushing s ing place. When using d | eye flushing systems and safety showers close to the work- | | | | | | |

Components with workplace control parameters



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| | | | engineering cont appropriate dego | eration of a facility should include review of rols, proper personal protective equipment, owning and decontamination procedures, e monitoring, medical surveillance and the ative controls. |
| 9. PHYSIC | CAL AND CHEMICAL P | ROF | PERTIES | |
| Арре | earance | : | lyophilised cake | |
| Color | ur | : | light brown | |
| Odou | ır | : | No data availab | le |
| Odou | ur Threshold | : | No data availab | le |
| pН | | : | 4.5 - 5 | |
| Melti | ng point/freezing point | : | No data availab | le |
| Initial range | l boiling point and boiling e | : | No data availab | le |
| Flash | n point | : | Not applicable | |
| Evap | oration rate | : | No data availab | le |
| Flam | mability (solid, gas) | : | May form explosed dling or other m | sive dust-air mixture during processing, han- eans. |
| Flam | mability (liquids) | : | No data availab | le |
| | er explosion limit / Upper nability limit | : | No data availab | le |
| | er explosion limit / Lower nability limit | : | No data availab | le |
| Vapo | our pressure | : | No data availab | e |
| Relat | tive vapour density | : | No data availab | e |
| Relat | tive density | : | No data availab | le |
| Dens | iity | : | No data availab | le |
| | bility(ies) /ater solubility | : | No data availab | le |
| octar | tion coefficient: n- nol/water | : | Not applicable No data availab | |
| Auto | -ignition temperature | • | ino uala availad | |

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| | | | |
| De | ecomposition temperature | : No data availa | ble |
| Vi | scosity Viscosity, kinematic | : No data availa | able |
| E> | plosive properties | : Not explosive | |
| O | xidizing properties | : The substance | e or mixture is not classified as oxidizing. |
| Pa | article size | : No data availa | ble |
| | | | |

10. STABILITY AND REACTIVITY

| Reactivity Chemical stability Possibility of hazardous reac- tions | : : | Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents. |
|---|-----|--|
| Conditions to avoid | : | Heat, flames and sparks. Avoid dust formation. |
| Incompatible materials Hazardous decomposition products | : | Oxidizing agents No hazardous decomposition products are known. |

11. TOXICOLOGICAL INFORMATION

| Information on likely routes of | : | Inhalation |
|---------------------------------|---|--------------|
| exposure | | Skin contact |
| | | Ingestion |
| | | Eye contact |

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Components:

Daptomycin:

| Species | : | Rabbit |
|---------|---|----------------------|
| Result | : | Mild skin irritation |

Serious eye damage/eye irritation

Not classified based on available information.



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| Com | oonents: | | |
| Dapto | omycin: | | |
| Speci Resul | es | : Rabbit : Mild eye irritati | on |
| | | | |
| - | iratory or skin sens | itisation | |
| | sensitisation lassified based on av | ailable information | |
| | iratory sensitisatior | | |
| - | lassified based on av | | |
| Germ | cell mutagenicity | | |
| Not c | lassified based on av | ailable information. | |
| Com | ponents: | | |
| - | omycin: | | |
| Geno | toxicity in vitro | : Test Type: Bao Result: negativ | cterial reverse mutation assay (AMES) /e |
| | | Test Type: Chi Result: negativ | romosome aberration test in vitro /e |
| | | | vitro mammalian cell gene mutation test nouse lymphoma cells ve |
| | | | A damage and repair, unscheduled DNA syn- malian cells (in vitro) /e |
| Geno | toxicity in vivo | cytogenetic as Species: Mous | se ute: Intraperitoneal injection |
| | | mammalian liv Species: Hams | ster ute: Intraperitoneal injection |

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.



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| | | | |
| Com | ponents: | | |
| Dapte | omycin: | | |
| Effec | ts on fertility | Species: Rat Application Ro Fertility: NOA | rtility/early embryonic development oute: Intravenous injection EL: 150 mg/kg body weight ects on fertility |
| Effec ment | ts on foetal develop- | Species: Rat Application Ro Developmenta | nbryo-foetal development oute: Intravenous injection al Toxicity: NOAEL: 75 mg/kg body weight inificant adverse effects were reported |
| | | Species: Rabl Application Ro Developmenta | nbryo-foetal development bit oute: Intravenous injection al Toxicity: NOAEL: 75 mg/kg body weight nificant adverse effects were reported |

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

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

Components:

Daptomycin:

| Target Organs | : | muscle, Kidney, Nervous system |
|---------------|---|--|
| Assessment | : | May cause damage to organs through prolonged or repeated |
| | | exposure. |

Repeated dose toxicity

Components:

Daptomycin:

| Species | : | Dog |
|---|-----------|---|
| NOAEL | : | 20 mg/kg |
| LOAEL | : | 40 mg/kg |
| Application Route | : | Intravenous |
| Exposure time | : | 3 Months |
| Target Organs | : | Skeletal muscle |
| Species NOAEL Application Route Exposure time Remarks | : : : : : | Monkey 10 mg/kg Intravenous 1 Months No significant adverse effects were reported |



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| Expo | cation Route sure time et Organs otoms | : Dog : Intravenous : 28 Days : Skeletal musc : muscle twitchi : Juvenile dog | le, Nervous system ng |
| LÖAE Applio Expos | | : 50 mg/kg : Intravenous : 28 Days | le, Nervous system |
| Not c | ration toxicity lassified based on avai rience with human ex | | |
| Dapte | ponents: omycin: eral Information | : Symptoms: Ra | ash, Diarrhoea, vaginitis |
| 12. ECOL | OGICAL INFORMATIC |)N | |
| | oxicity ata available | | |
| | stence and degradab ata available | ility | |
| | ccumulative potential ata available | | |
| | lity in soil ata available | | |
| | r adverse effects ata available | | |
| 13. DISPC | SAL CONSIDERATIO | NS | |
| - | osal methods | | |
| Waste | e from residues | | e of waste into sewer. accordance with local regulations. |
| Conta | aminated packaging | : Empty contain dling site for re | ers should be taken to an approved waste han- ecycling or disposal. e specified: Dispose of as unused product. |

14. TRANSPORT INFORMATION

International Regulations



| ersion 1 | Revision Date: 2023/09/30 | SDS Number: 650792-00017 | Date of last issue: 2023/04/04 Date of first issue: 2016/05/02 |
|--|---|--|---|
| Prope Class Subsi | umber er shipping name diary risk ng group | Not applicable | |
| Class Subsi Packi Label Packi aircra Packi |) No. er shipping name diary risk ng group s ng instruction (cargo | Not applicable | |
| UN nu Prope Class Subsi Packi Label EmS | diary risk ng group s | Not applicable | |
| | sport in bulk according | | POL 73/78 and the IBC Code |
| Spec | ial precautions for use | | |

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

| Government Regulation No. | 74 of 2001 on the | Management of I | Hazardous and 1 | oxic Sub- |
|----------------------------------|-------------------|-----------------|-----------------|-----------|
| stances | | | | |

| Hazardous substances approved for use | |
|---------------------------------------|--|
|---------------------------------------|--|

: Not applicable





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| | | | |
| Prohibited su | Ibstances | | : Not applicable |
| | | | |
| Restricted su | Ibstances | | : Not applicable |
| Regulation of Materials | of the Ministry o | f Trade No. 7 of 20 | 22 on Distribution and Control of Hazardo |
| Type of haza control, Anne | | subject to distribution | n and : Not applicable |
| | | | |
| Type of haza control, Anne | rdous materials s ex II | subject to distribution | n and : Not applicable |
| | | subject to distribution | n and : Not applicable |
| control, Anne | ex II | | |
| control, Anne | ex II | | in the following inventories: |
| Control, Anne | ex II | duct are reported i | in the following inventories: |
| The compor | ex II | duct are reported i : not determined | in the following inventories: |
| The compor AICS DSL | ex II | duct are reported i : not determined : not determined | in the following inventories: |
| The compor AICS DSL | ex II | duct are reported i : not determined : not determined | in the following inventories: |
| The compor AICS DSL IECSC | ex II nents of this pro | duct are reported i : not determined : not determined | in the following inventories: |
| The compor AICS DSL IECSC OTHER INFO | ex II nents of this pro RMATION | duct are reported i : not determined : not determined : not determined | in the following inventories: |
| The compor AICS DSL IECSC OTHER INFO Revision Dat Further info | e RMATION e rmation ey data used to | duct are reported i : not determined : not determined : not determined : 2023/09/30 : Internal technic | an the following inventories: |
| The compor AICS DSL IECSC OTHER INFO Revision Dat Further info Sources of k compile the S | e RMATION e rmation ey data used to | duct are reported i : not determined : not determined : not determined : 2023/09/30 : Internal technic eChem Portal s | an the following inventories: |

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

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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; TECI - 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

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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