

Dalbavancin for Injection

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Issue date: 04/04/2024

Version: 1.0

SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : Dalbavancin for Injection

1.2. Recommended use and restrictions on use

Use of the substance/mixture : Pharmaceuticals

1.3. Supplier

Long Grove Pharmaceuticals, LLC.
9450 W. Bryn Mar Ave., Suite 200
Rosemont, IL 60018 - USA
T 847-999-0600

1.4. Emergency telephone number

Emergency number : CHEMTREC +1 (800) 424-9300 (Toll Free) +1 (703) 527-3887 (Local) 24/7

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Repr. 2 H361
STOT RE 2 (Liver, Kidney) H373
Aquatic Acute 1 H400
Aquatic Chronic 1 H410
Comb. Dust

2.2. GHS Label elements, including precautionary statements

GHS US labelling

Hazard pictograms (GHS US) :



Signal word (GHS US) : Warning

Hazard statements (GHS US) :
May form combustible dust concentrations in air
H361 - Suspected of damaging fertility or the unborn child.
H373 - May cause damage to organs through prolonged or repeated exposure (Liver, Kidney).
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Precautionary statements (GHS US) :
P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust.
P273 - Avoid release to the environment.
P280 - Wear protective gloves, protective clothing, chemical goggles, & face protection.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P314 - Get medical advice/attention if you feel unwell.
P391 - Collect spillage.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

Dalbavancin for Injection

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

3.2. Mixtures

| Name | Product identifier | %* |
|---------------------|-----------------------|---------|
| Dalbavancin | (CAS-No.) 171500-79-1 | 30 – 70 |
| Lactose monohydrate | (CAS-No.) 10039-26-6 | 10 – 20 |

*In accordance with paragraph (i) of the OSHA Hazard Communication Standard (29 CFR §1910.1200), the specific chemical identity or exact weight % has been withheld as a trade secret.

SECTION 4: First-aid measures

4.1. Description of first aid measures

- First-aid measures general : If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.
- First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if breathing is affected. If breathing is difficult, supply oxygen.
- First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes. If irritation develops or persists, get medical attention.
- First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. Continue rinsing if pain, blinking, or irritation develops or persists, get medical attention. Continue rinsing.
- First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. Get medical attention if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/effects : Suspected of damaging fertility. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure (Liver, Kidney).
- Symptoms/effects after inhalation : May cause respiratory irritation.
- Symptoms/effects after skin contact : May cause skin irritation.
- Symptoms/effects after eye contact : May cause eye irritation.
- Symptoms/effects after ingestion : May cause gastrointestinal irritation.
- Chronic symptoms : Suspected of damaging fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure (Liver, Kidney).

4.3. Immediate medical attention and special treatment, if necessary

No additional information available

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Carbon dioxide. Dry chemical powder. Foam. Water spray.

5.2. Specific hazards arising from the chemical

- Fire hazard : Dust may be combustible under specific conditions.
- Explosion hazard : Product is not explosive.
- Reactivity : No data available.

5.3. Special protective equipment and precautions for fire-fighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not dispose of fire-fighting water in the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area. Ventilate area. Keep upwind. Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.1.1. For non-emergency personnel

- Protective equipment : Wear Protective equipment as described in Section 8.
- Emergency procedures : Evacuate unnecessary personnel. Keep upwind.

6.1.2. For emergency responders

Protective equipment : For further information refer to section 8: "Exposure controls/personal protection".

Dalbavancin for Injection

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment : Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Prevent entry to sewers and public waters.

Methods for cleaning up : In case of spill, sweep up spilled material and dispose of properly. If necessary, wear personal protective equipment as described in Section 8 during cleanup activities. Avoid the generation of dusts during clean-up. Shovel or sweep up and put in a closed container for disposal.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not handle until all safety precautions have been read and understood. Handle in accordance with good industrial hygiene and safety procedures. Wear recommended personal protective equipment. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid accidental injection.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Store in a dry, cool and well-ventilated place. Protect from light.

Storage temperature : 25 °C (77°F); excursions permitted to 15° to 30°C (59° to 86°). [See USP Controlled Room Temperature]

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| Lactose monohydrate (10039-26-6) | | |
|----------------------------------|----------------|----------------------|
| ACGIH | Remark (ACGIH) | OELs not established |
| OSHA | Remark (OSHA) | OELs not established |
| Dalbavancin (171500-79-1) | | |
| ACGIH | Remark (ACGIH) | OELs not established |
| OSHA | Remark (OSHA) | OELs not established |

8.2. Appropriate engineering controls

Appropriate engineering controls : Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment symbol(s):



Personal protective equipment:

Safety glasses. Gloves. Wear chemically impervious apron over labcoat and full coverage clothing.

Hand protection:

Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Gloves should be classified and selected according to regional or national standards. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate PVC, or vinyl. Suitable gloves should be recommended by the glove supplier.

Eye protection:

Wear eye protection, including chemical splash goggles and a face shield when possibility exists for eye contact due to spraying liquid or airborne particles

Dalbavancin for Injection

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Skin and body protection:

Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure.

Respiratory protection:

Use NIOSH (or other equivalent national standard) -approved dust/particulate respirator. Where vapor, mist, or dust exceed PELs or other applicable OELs, use NIOSH-approved respiratory protective equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|----------------------------------|
| Physical state | : Solid |
| Appearance | : Powder. |
| Color | : White to off white Pale yellow |
| Odor | : No data available |
| Odor threshold | : No data available |
| pH | : No data available |
| Melting point | : No data available |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Flammability (solid, gas) | : No data available |
| Vapor pressure | : No data available |
| Relative vapor density at 20°C | : No data available |
| Relative density | : No data available |
| Solubility | : No data available |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosive limits | : No data available |
| Explosive properties | : No data available |
| Oxidising properties | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Heat, flames, sparks, and other sources of ignition. Avoid electro-static discharges.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

None under normal use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Dalbavancin for Injection

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

| | |
|-------------------------------------|---|
| Acute toxicity (oral) | : Not classified |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |
| Skin corrosion/irritation | : Not classified |
| Serious eye damage/irritation | : Not classified |
| Respiratory or skin sensitisation | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Suspected of damaging fertility or the unborn child. |
| STOT-single exposure | : Not classified |
| STOT-repeated exposure | : May cause damage to organs through prolonged or repeated exposure (Liver, Kidney). |
| Aspiration hazard | : Not classified |
| Viscosity, kinematic | : No data available |
| Symptoms/effects | : Suspected of damaging fertility. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure (Liver, Kidney). |
| Symptoms/effects after inhalation | : May cause respiratory irritation. |
| Symptoms/effects after skin contact | : May cause skin irritation. |
| Symptoms/effects after eye contact | : May cause eye irritation. |
| Symptoms/effects after ingestion | : May cause gastrointestinal irritation. |
| Chronic symptoms | : Suspected of damaging fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure (Liver, Kidney). |

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Very toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

No additional information available.

12.3. Bioaccumulative potential

No additional information available.

12.4. Mobility in soil

No additional information available.

12.5. Other adverse effects

Other information : No data available.

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Do not discharge to public wastewater systems without permit of pollution control authorities. No discharge to surface waters is allowed without a permit.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Transport document description (DOT) : UN3077 Environmentally hazardous substances, solid, n.o.s. (Contains: Dalbavancin Hydrochloride), 9, III

UN-No.(DOT) : UN3077

Proper Shipping Name (DOT) : Environmentally hazardous substances, solid, n.o.s. (Contains: Dalbavancin Hydrochloride)

Class (DOT) : 9 - Class 9 - Miscellaneous hazardous material 49 CFR 173.140

Packing group (DOT) : III - Minor Danger

Dalbavancin for Injection

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Hazard labels (DOT) : 9 - Class 9 (Miscellaneous dangerous materials)



Dangerous for the environment : Yes

Marine pollutant : Yes



DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) : No limit

DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) : No limit

DOT Vessel Stowage Location : A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel.

Emergency Response Guide (ERG) Number : 171

Other information : No supplementary information available.

Transport by sea (IMDG)

Transport document description (IMDG) : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Contains: Dalbavancin Hydrochloride), 9, III

UN-No. (IMDG) : 3077

Proper Shipping Name (IMDG) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Class (IMDG) : 9 - Miscellaneous dangerous substances and articles

Packing group (IMDG) : III - substances presenting low danger

Limited quantities (IMDG) : 5 kg

Marine pollutant : Yes



Air transport (IATA)

Transport document description (IATA) : UN 3077 Environmentally hazardous substance, solid, n.o.s. (Contains: Dalbavancin Hydrochloride), 9, III

UN-No. (IATA) : 3077

Proper Shipping Name (IATA) : Environmentally hazardous substance, solid, n.o.s.

Class (IATA) : 9 - Miscellaneous Dangerous Substances and Articles

Packing group (IATA) : III - Low danger

SECTION 15: Regulatory information

15.1. US Federal regulations

Dalbavancin for Injection

This product is regulated under the United States Federal Food, Drug, and Cosmetic Act (FDCA) and is exempt from listing on TSCA

SARA Section 311/312 Hazard Classes

Health hazard - Reproductive toxicity

Health hazard - Specific target organ toxicity (single or repeated exposure)

15.2. International regulations

No additional information available

15.3. US State regulations

Dalbavancin for Injection

Safety Data Sheet

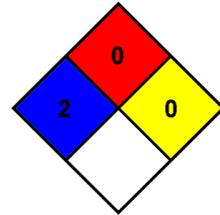
according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

This product does not contain any substances known to the state of California to cause cancer and/or reproductive harm

| Component | State or local regulations |
|-------------------------------|--|
| Sodium hydroxide (1310-73-2) | U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) List; U.S. - Massachusetts - Right To Know List |
| Hydrogen chloride (7647-01-0) | U.S. - Massachusetts - Right To Know List; U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List |
| Nitrogen (7727-37-9) | U.S. - Massachusetts - Right To Know List; U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) List |

SECTION 16: Other information

| | |
|--------------------|---|
| Other information | : Author: JMM. |
| NFPA health hazard | : 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. |
| NFPA fire hazard | : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand. |
| NFPA reactivity | : 0 - Material that in themselves are normally stable, even under fire conditions. |
| HMIS Hazard Rating | |
| Health | : 2 |
| Flammability | : 0 |
| Physical | : 0 |



This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.