

SUPPORTING INFECTIOUS DISEASE RESEARCH

Issue Date 07-Aug-2019

Revision Date Not applicable

Version 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Delamanid
Product Code NR-51636

Other means of identification

Synonyms OPC-67683; Delytba™

Recommended use of the chemical and restrictions on use

Recommended Use Material is authorized for research, non-commercial purposes only.
Uses Advised Against Not for human use.

Details of the supplier of the safety data sheet

Supplier Address

BEI Resources
 10801 University Blvd.,
 Manassas, VA,
 USA, 20110-2204

Emergency telephone number

Company Phone Number (800) 359-7370/ (703) 365-2727
24 Hour Emergency Phone Number Chemtrec (US): 1-800-424-9300
 Domestic: (703) 365-2710
 International: +1(703)-527-3887

2. HAZARDS IDENTIFICATION

Classification

Explosives: Not classified.
 Acute toxicity (oral): Not classified.
 Chronic aquatic toxicity: Category 4.

Health Hazards

Not classified.

Physical Hazards

Not classified.

OSHA Regulatory Status

This product is not considered hazardous by the 2012 OSHA Hazard Communication Standard/Globally Harmonized System of Classification and Labelling of Chemicals (GHS); (29 CFR 1910.1200; Revision 3).

Label elements

Emergency Overview

Normal precautions common to safe manufacturing practice should be followed in handling and storage.

Appearance White to pale yellow solid. **Physical State** Solid. **Odor** Odorless.

Precautionary Statements - Prevention

Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Avoid release to the environment.

Precautionary Statements - Response

IF SWALLOWED: rinse mouth.
IF SWALLOWED: Call a POISON CENTER or doctor/physician.

Precautionary Statements - Storage

Store in a well-ventilated area away from light and heat.

Precautionary Statements - Disposal

Dispose of contents and container in accordance with applicable regional, national and local laws and regulations.

Hazards Statement

May cause long lasting harmful effects to aquatic life.

Hazards not otherwise classified (HNOC)

Biosafety Level 1

Other information

Fine particles, such dust and mists, may fuel fires/explosions.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is not considered hazardous by the 2012 OSHA Hazard Communication Standard/Globally Harmonized System of Classification and Labelling of Chemicals (GHS); (29 CFR 1910.1200; Revision 3).

Common name	Delamanid
Chemical name	(R)-2-Methyl-6-nitro-2-[(4-{4-[4-(trifluoromethoxy)phenoxy]piperidin-1-yl}phenoxy)methyl]-2,3-dihydroimidazo[2,1-b]oxazole.
Chemical Family	Bicyclic nitro-imidazooxazole.
Formula	C ₂₅ H ₂₅ F ₃ N ₄ O ₆
Chemical nature	Antimicrobial effective against <i>Mycobacterium tuberculosis</i> (<i>M. tuberculosis</i>); inhibits the synthesis of key mycolic acids.

Chemical Name	CAS No.	Weight-%
Delamanid	681492-22-8	100

4. FIRST AID MEASURES

First aid measures

Eye Contact	Rinse eyes cautiously with lukewarm, gently flowing water for several minutes, while holding the eyelids open. Remove contact lenses, if present and easy to do. Continue rinsing for a duration of 15-20 minutes. Take care not to rinse contaminated water into the unaffected eye or onto the face. If eye irritation persists, get medical advice/attention.
Skin Contact	Take off immediately all contaminated clothing, shoes and leather goods (e.g. watchbands, belts). Wash with plenty of lukewarm, gently flowing water and soap for several minutes or until medical aid is available. Remove contaminated clothing and wash before re-use or discard. If skin irritation occurs, get medical advice/attention.
Inhalation	Remove source of exposure or move person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER/doctor. If breathing is difficult, trained personnel should administer emergency oxygen if advised to do so by the POISON CENTER/doctor. Immediately call a POISON CENTER/doctor.
Ingestion	If swallowed, rinse mouth. Immediately call a POISON CENTER/doctor. If breathing has

stopped, do not give anything by mouth and immediately start cardiopulmonary resuscitation (CPR) or automated external defibrillation (AED).

Most important symptoms and effects, both acute and delayed

Symptoms Insomnia, headache and somnolence. Palpitations, chest discomfort, chest pain [QT prolongation]

Indication of any immediate medical attention and special treatment needed

Note to Physicians Cardiovascular monitoring should be started immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use media such as carbon dioxide, dry chemical, water spray, or "alcohol" foam. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media None known.

Specific hazards arising from the chemical

Avoid generating dust. May emit fumes when exposed to heat or fire.

Hazardous Combustion Products Toxic or corrosive gases, in particular carbon oxides, and fluorinated compounds could be emitted.

Explosion data

Not explosive as the result of Test Series 2 in Part I of the *UN Recommendations on the Transport of Dangerous Goods*. UN gap test, Koenen test, and Time/Pressure test results are negative.

Sensitivity to Mechanical Impact None known.

Sensitivity to Static Discharge None known.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Stay upwind and evacuate personnel away from the fumes. Avoid release of extinguishing waters into the environment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Do not breath dust. Wear appropriate personal protective equipment (see Section 8). Keep unnecessary personnel away. Ensure adequate ventilation, especially in confined areas. Avoid dust formation.

Environmental precautions

Environmental Precautions Do not discharge into the environment. See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so. Avoid dispersion of dust. Remove all sources of ignition. Use only non-sparking tools.

Methods for Cleaning Up Patient/Victim: Wash with soap and water. Work clothes should be laundered separately. Launder contaminated clothing before re-use. Do not take clothing home.
Equipment/Environment: Sweep up spilled material using a broom and dustpan or a HEPA-filtered vacuum suitable for explosive atmospheres. Keep spilled material in a tightly closed

and labeled container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling

Avoid open handling and dust formation. In case of spills, sweep up and keep in a tightly closed container for disposal. Do not get in eyes, on skin or on clothing. Do not breathe dust, vapors or mist. Use good personal hygiene practices. Eating, drinking and smoking in work areas is prohibited. Remove contaminated clothing and protective equipment before entering eating areas. Eyewash stations and showers should be available in areas where this material is used and stored. Frequent and careful hand-washing and laboratory decontamination should be strictly enforced. Ventilation Requirements: Use only with adequate ventilation to control air contaminants to their exposure limits. Required HEPA-filtered vacuum lines suitable for explosive atmospheres. Should be handled by trained laboratory personnel using good laboratory practices. Use aseptic procedures.

Conditions for safe storage, including any incompatibilities

Storage Conditions

All containers must be properly labelled. Store in approved containers at room temperature and protect from light, humidity, heat, sparks, flames and physical damage. Keep containers securely sealed in a dry and well-ventilated place when not in use. Containers that have been opened must be carefully resealed to prevent leakage. Empty containers retain residue and may be dangerous.

Packaging materials

Packaged aseptically in glass serum vials.

Incompatible materials

Strong acids, bases, and oxidizing/reducing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

This product does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region-specific regulatory bodies.

Appropriate engineering controls

Engineering Controls

The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable. Safety shower, eye-wash and hand-wash equipment should be installed and in good working order.

Individual protection measures, such as personal protective equipment

Eye/Face Protection

In laboratory, medical or industrial settings, safety glasses with side shields are highly recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin and Body Protection

In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hoods or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory Protection

Not required for normal handling of packed product. A dust respirator or powered air purifying respirator is required for certain laboratory and manufacturing tasks if engineering

controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance indicated by OSHA Standard 29 CFR 1910.134.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Solid.	Odor	Odorless.
Appearance	Crystals or crystalline powder.	Odor Threshold	Not available.
Color	White to pale yellow.		
<u>Property</u>	<u>Values</u>	<u>Remarks</u>	
pH	Not available.	Lower Explosive Limit of Dust:	80 g/m ³
Melting Point/Freezing Point	195°C (decomposition)		
Boiling Point/Boiling Range	Not available.		
Flash Point	Not available.		
Evaporation Rate	Not available.		
Flammability (solid, gas)	Not highly flammable.		
Flammability Limit in Air			
Upper Flammability Limit:	Not available.		
Vapor Pressure	Not available.		
Specific Gravity	Not available.		
Water Solubility	< 0.000001%.		
Solubility in Other Solvents	MeOH: 0.184%; DMSO: 14.0%.		
Octanol/Water Partition Coefficient	log Kow: 3.69 (HPLC); 1.87 (shake-flask).		
Autoignition Temperature	Not available.		
Decomposition Temperature	245.2°C (SC-DSC), 155.6°C (ARC).		
Explosive Properties	Not explosive.		
Oxidizing Properties	Not available.		
<u>Other information</u>			
Softening Point	Not available.		
Molecular Weight	534.48		
VOC Content (%)	Not available.		
Density	Not available.		
Bulk Density	Not available.		

10. STABILITY AND REACTIVITY

Reactivity
Not available.

Chemical stability
Stable under recommended storage conditions.

Possibility of hazardous reactions
Nothing in particular.

Hazardous Polymerization No data available.

Conditions to avoid
Prevent the formation of dust.

Incompatible materials

Oxidizing agents.

Hazardous decomposition products

Carbon oxides, nitrogen oxides and fluorinated compounds.

11. TOXICOLOGICAL INFORMATION**Product Information****Acute Toxicity** The approximate lethal dose oral is ≥ 1000 mg/kg (rat) and ≥ 900 mg/kg (dog).**Information on toxicological effects****Symptoms** Soft stool.**Delayed and immediate effects as well as chronic effects from short- and long-term exposure****Skin Corrosion/Irritation** Not irritating.**Serious Eye Damage/Eye Irritation** Not irritating.**Sensitization** No data available.**Germ Cell Mutagenicity**Gene MutationNegative 5 mg/plate (*in vitro*; bacteria).Negative 100 mg/L (*in vitro*; mouse cell).Chromosomal Damage

Negative (oral) 1000 mg/kg (rat).

Carcinogenicity Negative (oral) 300 mg/kg (mouse).

Negative (oral) 300 mg/kg (rat).

Reproductive Toxicity Negative (oral) 300 mg/kg (rat).**STOT - Single Exposure** No data available.**STOT - Repeated Exposure** No data available.**Aspiration Hazard** No data available.**12. ECOLOGICAL INFORMATION****Ecotoxicity**

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Delamanid 681492-22-8	EC ₅₀ (72h): > 0.00030 mg/L; NOEC: \geq 0.00030 mg/L (<i>Pseudokirchneriella subcapitata</i>). EC ₅₀ (72h): > 0.00042 mg/L; NOEC: \geq 0.00042 mg/L (<i>Anabaena flos-aquae</i>).	Early stage NOEC: \geq 0.00071 mg/L [zebra fish (<i>Brachydanio rerio</i>)].		NOEC: \geq 0.00059 mg/L (<i>Daphnia magna</i>).

Persistence and degradability

Ready biodegradation (28D): 7.3%; Not Biodegradable – unlikely to undergo rapid biodegradation in the environment.

BioaccumulationBioconcentration factor at steady state (BCF_{ss}): 565 (bluegill sunfish).

Mobility

No data available.

Other adverse effects

No data available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of Wastes Disposal should be in accordance with applicable regional, national and local laws and regulations. Incineration is recommended for the elimination of this substance. Do not discharge wastewater into the environment.

Contaminated Packaging Disposal should be in accordance with applicable regional, national and local laws and regulations. Do not reuse container.

U.S. EPA Waste Number Not available.

California Hazardous Waste Codes Not available.

This product does not contain substances that are listed with the State of California as hazardous waste.

14. TRANSPORT INFORMATION

DOT Not regulated.
UN/ID No. Not available.
Proper shipping name Delamanid
Hazard Class Not regulated.
Packing Group Not regulated.

IATA Not regulated.
UN/ID No. Not available.
Proper shipping name Delamanid
Hazard Class Not regulated.
Packing Group Not regulated.

Special Precautions: On transportation, avoid direct sunlight and load without breakage, corrosion and leakage and prevent collapse of cargo securely. Do not put heavy cargo on top.

15. REGULATORY INFORMATION

U.S. Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations**California Proposition 65**

No component is on the Prop 65 list.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable.

16. OTHER INFORMATION

Prepared By	BEI Resources
Issue Date	07-Aug-2019
Revision Date	Not applicable.
Revision Note	New SDS.

Disclaimer

BEI Resources considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals. BEI Resources is not to be held liable for any loss, injury or damage from contact with the product.

End of Safety Data Sheet