

Issue Date 22-Apr-2024

Revision Date Not applicable

Version 1

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

Product identifier

Product Name Pretomanid
Product Code NR-59591

Other means of identification

Synonyms PA-824; (S)-PA-824; Dovprela®

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

Acute toxicity (oral): Category 4.
 Skin corrosion/irritation: Category 2.
 Eye damage/irritation: Category 2.
 Specific target organ toxicity, single exposure; respiratory tract irritation: Category 3.

Label elements



Hazard Statements

Harmful if swallowed.
 Causes skin irritation.
 Causes serious eye irritation.

Emergency Overview

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

Appearance White to off-white powder.

Physical State Solid.

Odor Odorless.

Precautionary Statements - Prevention

Avoid breathing dust and use only in a well-ventilated area.
Wash face, hands and any exposed skin thoroughly after handling.
Do not eat, drink or smoke when using this product.
Wear skin, eye and face protection.

Precautionary Statements - Response

IF SWALLOWED: Rinse mouth. Call a POISON CENTER or doctor/physician.
IF ON SKIN: Wash with plenty of water and soap. Take off contaminated clothing and wash it before reuse. If skin irritation occurs, seek medical attention.
IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. If eye irritation persists, seek medical attention.

Precautionary Statements - Storage

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

Precautionary Statements - Disposal

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

Hazards not otherwise classified (HNOC)

Biosafety Level 1

Other information

No information available.

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	Pretomanid (PA-824)
Chemical name	(6S)-2-Nitro-6-[[4-(trifluoromethoxy)benzyl]oxy]-6,7-dihydro-5H-imidazo[2,1-b][1,3]oxazine; (6S)-6,7-Dihydro-2-nitro-6-[[4-(trifluoromethoxy)phenyl]methoxy]-5H-imidazo[2,1-b][1,3]oxazine
Chemical Family	Bicyclic nitroimidazooxazine
Formula	C ₁₄ H ₁₂ F ₃ N ₃ O ₅
Chemical nature	Antimycobacterial used in treating multidrug-resistant tuberculosis (MDR-TB).

Chemical Name	CAS No.	Weight-%
Pretomanid (PA-824)	187235-37-6	> 98%

4. FIRST AID MEASURES

First aid measures

Eye Contact	Rinse eyes immediately with lukewarm, gently flowing water while holding the eyelids wide open. Remove contact lenses. Continue rinsing for at least 15 minutes. If eye irritation persists, get medical advice/attention. Do not rub affected area.
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. If skin irritation occurs, get medical advice/attention. Wash contaminated clothing before re-use or discard.
Inhalation	Remove source of exposure or move person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms, immediately call a POISON CENTER/doctor. If breathing is difficult or has stopped, immediately start cardiopulmonary resuscitation (CPR) or automated external defibrillation (AED); avoid mouth-to-mouth resuscitation.
Ingestion	Do NOT induce vomiting. If swallowed, rinse mouth with water and drink plenty of water afterward. Immediately call a POISON CENTER/doctor. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Symptoms Headache, nausea and vomiting.

Indication of any immediate medical attention and special treatment needed

Note to Physicians/First Aider Treat symptomatically. In case of an accident or if you feel unwell, seek medical advice immediately, showing the label if possible.

5. FIRE-FIGHTING MEASURES**Suitable extinguishing media**

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

Unsuitable Extinguishing Media Not known.

Specific hazards arising from the chemical

Hazardous Combustion Products Carbon oxides, nitrogen oxides (NO_x), sodium oxides, and hydrogen fluoride.

Explosion data

Not explosive, but dust can form an explosive mixture with air.

Sensitivity to Mechanical Impact Not known.

Sensitivity to Static Discharge Not 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. 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 Avoid breathing dust. Avoid contact with skin, eyes or clothing. Wear appropriate personal protective equipment (PPE; see Section 8). Keep unnecessary personnel away. Ensure adequate ventilation, especially in confined areas.

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. Keep away from drains, waterways or the soil.

Methods for Cleaning Up Use appropriate PPE. Carefully shovel or sweep up spilled material suitable for explosive atmospheres. Avoid generating or breathing dust. Soak up spills with an inert absorbent material. Use clean non-sparking tools to collect absorbed material. Keep spilled material in a tightly closed and labeled container for disposal.

7. HANDLING AND STORAGE**Precautions for safe handling**

Advice on Safe Handling Use good personal hygiene and safety practices. Eating, drinking and smoking in work areas are prohibited. Remove contaminated clothing and protective equipment before entering eating areas; wash it before reuse. Wear suitable gloves and eye/face protection. Eyewash stations and showers should be available in areas where this material is used and stored. Frequent and careful handwashing and laboratory decontamination should be strictly enforced.

Conditions for safe storage, including any incompatibilities

Storage Conditions	All containers must be properly labeled. Store in approved containers at room temperature and protect from light, humidity, heat and physical damage. Keep containers securely sealed in a dry, cool and well-ventilated place when not in use. Empty containers retain residue and may be dangerous.
Packaging materials	Packaged in plastic cryovials.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Control parameters**

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

Engineering Controls	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, eyewash and hand-wash equipment should be installed and in good working order. Do not let product enter drains.
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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, impervious 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	Use appropriate respiratory protection. 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	Not available.
Appearance	Off-white powder	Odor Threshold	Not available.
Color	Off-white to pale yellow		

<u>Property</u>	<u>Values</u>	<u>Remarks</u>
pH	Not available.	
Melting Point/Freezing Point	Not available.	
Boiling Point/Boiling Range	Not available.	
Flash Point	Not available.	
Evaporation Rate	Not available.	
Flammability (solid, gas)	Not available.	

Flammability Limit in Air	Not available.
Upper Flammability Limit:	Not available.
Lower Flammability Limit:	Not available.
Vapor Pressure	Not available.
Vapor Density	Not available.
Specific Gravity	Not available.
Water Solubility	Not available.
Solubility in Other Solvents	Not available.
Partition Coefficient	Not available.
Autoignition Temperature	Not available.
Decomposition Temperature	Not available.
Kinematic Viscosity	Not available.
Dynamic Viscosity	Not available.
Explosive Properties	Not available.
Oxidizing Properties	Not available.

Other information

Molecular Weight	359.25
VOC Content (%)	Not available.
Density	Not available.
Relative Density	1.58 g/cm ³

10. STABILITY AND REACTIVITY**Reactivity**

Hazardous reactions will not occur under normal conditions.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Extreme temperatures and direct sunlight.

Incompatible materials

Strong acids, bases, and oxidizing agents.

Hazardous decomposition products

Under fire conditions, may decompose and emit toxic fumes.

11. TOXICOLOGICAL INFORMATION**Product Information**

Acute Toxicity The approximate median lethal dose (LD50) is > 1000 mg/kg (oral; rat).

Information on toxicological effects

Symptoms Headache, nausea and vomiting.

Delayed and immediate effects as well as chronic effects from short- and long-term exposure

Skin Corrosion/Irritation Irritating to skin.

Serious Eye Damage/Eye Irritation Irritating to eyes.

Sensitization No data available.

Germ Cell Mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	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. 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. OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
Reproductive Toxicity	No data available.
STOT - Single Exposure	No data available.
STOT - Repeated Exposure	No data available.
Aspiration Hazard	Based on available data, the classification criteria are not met.

12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available.

Persistence and degradability

No data available.

Bioaccumulation

No data available.

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.

14. TRANSPORT INFORMATION

<u>DOT</u>	Not regulated.
<u>IATA</u>	Not regulated.

15. REGULATORY INFORMATION

U.S. Federal Regulations

SARA 302

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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

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

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

U.S. State Right-to-Know Regulations

Pretomanid (CAS No. 187235-37-6) is listed under New Jersey and Pennsylvania Right to Know Components.

16. OTHER INFORMATION

Prepared By	BEI Resources
Issue Date	22-Apr-2024
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