



Revision Date:06Dec2016

Safety Data Sheet

Section 1: Product & Company Identification

SUPPLIER:

Sarepta Therapeutics, Inc.

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EMERGENCY TELEPHONE NUMBER: Chemtrec 1-800-424-9300

PRODUCT NAME: ETEPLIRSEN- (AVI-4658)

CHEMICAL NAME: Exon -51 Phosphorodiamidate Morpholino Oligomer (PMO)

COMMON NAME: Exon 51 Drug Substance

MOLECULAR WEIGHT: 10305.7 g/mol

CHEMICAL FORMULA: C₃₆₄H₅₆₉N₁₇₇O₁₂₂P₃₀

CAS#: N/A

Section 2: Hazards Identification

EMERGENCY OVERVIEW: Warning! This product is a commercial drug product; the effects in humans will continue to be thoroughly investigated. Some toxicity data is available, however all personnel handling the product should follow the recommendations in this SDS.

2.1 Classification of the substance or mixture: No known physical, health, or environmental hazards.

2.2 GHS Label elements, including precautionary statements

Pictogram: None

Signal Word: Warning

2.3 Hazards not otherwise classified (NHOC) or not covered by GHS: None

ROUTES OF EXPOSURE: Unknown

POTENTIAL HEALTH EFFECTS:

Inhalation: No data available

Eye: No data available

Skin: No data available

Ingestion: No data available

Target Organs: Unknown

MEDICAL CONDITIONS that may be aggravated by CONTACT: Unknown

Section 3: Composition/Information on Ingredients

INGREDIENT NAME	CAS#	EC#	% (wt/wt)
AVI-4658	N/A	N/A	>90%
Residual Water	7732-18-5	231-791-2	<10%



Section 4: First Aid Measures

FOR EYE CONTACT: Immediately flush eyes with large quantities of gently flowing tepid water for at least 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

FOR SKIN CONTACT: Flush with large quantities of cool water for at least 15 minutes. Remove contaminated clothes and wash before re-use. Obtain medical attention if needed or if irritation or other symptoms develop.

FOR INHALATION: If inhaled, remove affected person exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

FOR INGESTION: In case of ingestion, contact poison control center or physician for instructions.

Section 5: Fire-Fighting Measures

FLAMMABLE PROPERTIES: Dilute aqueous solution is not considered a fire hazard.

EXTINGUISHING MEDIA: Use water spray, carbon dioxide, or dry chemical as appropriate for surrounding fire and materials.

SPECIAL FIRE FIGHTING PROCEDURES: As in any fire, firefighters should wear self-contained breathing apparatus (SCBA) and full protective gear.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None

HAZARDOUS DECOMPOSITION PRODUCTS: Oxides of Carbon and Nitrogen may be released when heated to decomposition.

NFPA RATING: HEALTH: NE FIRE: NE REACTIVITY: NE

Section 6: Accidental Release Measures

Personal Precautions: Wear PPE as described in section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

SPILL/LEAK CLEANUP PROCEDURES: Report emergency situations immediately. Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the clean-up of spills should wear the appropriate respiratory protection, gloves, eye protection, protective shoes, and protective coveralls. Ventilate the area. Use proper absorbent material to absorb spill. Clean powder spills in a manner that minimizes raising dusts. Collect material in suitable container for disposal as hazardous drug waste. See section 13 for disposal instructions. Wash affected area with an appropriate solvent (water and soap) before reassuming activities.

ENVIRONMENTAL PRECAUTIONS: Testing of environmental risk has not been done; therefore it is prudent to keep this product away from drains, surface water, ground water, and soil.



Section 7: Handling and Storage

HANDLING AND STORAGE CONDITIONS: Store in 2-8°C in a tightly sealed glass container.

OTHER PRECAUTIONS: The user should be aware that this product is an FDA approved drug product. Handling of solids or solutions should be carried out with extreme care to avoid personal exposure. Use all possible PPE to minimize exposure to any substance. Hazards associated with exposure to this product are unknown at this time. This material should be handled only by those trained in the handling of potentially hazardous materials or drug products.

Section 8: Exposure Controls/Personal Protection

EXPOSURE GUIDELINES: There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits (OELs) currently established for components present in the preparation at concentrations equal to or greater than 1% (0.1% carcinogen).

An OEL has not been established for this product; therefore all necessary precautions should be taken when handling this product.

WORKPLACE CONSIDERATIONS:

Engineering Controls: This preparation is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with eye wash fountain.

PERSONAL PROTECTIVE EQUIPMENT:

Respiratory: A respirator is not required under normal conditions of use.

Eye/Face: Wear appropriate protective safety glasses or face shield.

Skin: Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Gloves: Wear chemical resistant protective gloves.

General: Follow company-specific safety procedures.

Section 9: Physical & Chemical Properties

Appearance: White solid.

Odor: Odorless.

Boiling Point (°C): Not determined

Melting Point: Not determined

Specific Gravity: Not determined

Vapor Pressure (°C): Negligible

Vapor Density: Not determined

Evaporation Rate: Negligible

Particle Size: N/A

Solubility in water: Water-soluble

Flammability/Explosivity Limits in Air, Lower: Not determined

Flammability/Explosivity Limits in Air, Upper: Not determined

Auto-Ignition Temperature: Not determined

Flash Point: Not determined



Section 10: Stability & Reactivity Data

Stability: Stable under normal storage conditions.
Incompatibility: Strong acids or bases cause non-hazardous degradation of product.
Hazardous Polymerization: Will not occur.

Section 11: Toxicological Information

HUMAN SAFETY: *Adverse Clinical/Human Health Effects*

No specific concerns identified after 48 weeks of eteplirsen treatment (weekly IV doses up to 50 mg/kg) in patients with Duchenne muscular dystrophy¹.

HEALTH HAZARDS (ACUTE AND CHRONIC TOXICITY): *Acute/Chronic Toxicity Potential*

Low - weekly IV doses well tolerated for 39 weeks in monkeys (NOAEL=320 mg/kg)² and for 12 weeks in mice (NOAEL=960 mg/kg)³

ACUTE: Avoid contact as a universal precaution.

GENETIC TOXICITY: None – negative in ICH standard battery (Ames, chromosomal aberrations, mouse micronucleus)

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY: Developmental toxicity not assessed.

No reproductive toxicity in males. Reproductive toxicity in females not assessed²

CARCINOGENICITY: Not Assessed⁴

- NATIONAL TOXICOLOGY PROGRAM **NL**
- INT'L AGENCY FOR RESEARCH AND CANCER **NL**
- OSHA REGULATED **NL**

PRIMARY ENTRY ROUTES: None reported

TARGET ORGANS: None reported

¹ Study 4658-us-202

² Study 4658-tox-001

³ Study AVI-4658-GLP-902

⁴ Likely to be negative, since AVI-4658 is non-genotoxic, no preneoplastic or other proliferative lesions were observed in the 39-week monkey study, and oligonucleotides and other biological materials are known to be non-carcinogens



Section 12: Ecological Information

Material is not classified with regard to risk to the aquatic or terrestrial environment. Prevent material from entering drains or surrounding surface waters.

Ecotoxicity: No data available
Persistence & Degradability: No data available
Bioaccumulative Potential: No data available
Mobility in Environmental media: No data available

Section 13: Disposal Considerations

WASTE MANAGEMENT/DISPOSAL: Incineration is the preferred method of disposal. Observe all federal, state and local laws concerning the disposal of hazardous material or waste.

Section 14: Transportation Information

Not classified as a dangerous goods. Non-regulated by U.S. DOT or IATA regulations.

This compound has been approved by the FDA as a drug product.

Section 15: Regulatory Information

SARA REPORTING NOTIFICATION:

This product is not listed under SARA. The following chemicals contained in this product must be considered in determining the thresholds required for reporting of toxic chemical release (section 313 of SARA). None

US Federal Regulations: This pharmaceutical preparation has been approved by the FDA.

RCRA: This material is not regulated as a hazardous waste by the U.S. EPA.

Toxic Substance Control Act (TSCA): This product is not included on the TSCA inventory.

Clean Water Act (CWA): This product is not listed in the Clean Water Act.

Clean Air Act (CAA): This product is not listed under the Clean Air Act.

State Regulations

California: This product contains no chemical know in the State of California to cause cancer.

Canadian Environmental Protection Act: None of the compounds in this mixture are listed on the Canadian Domestic Substances list (DSL).

Canadian Workplace Hazardous Materials Information System (WHMIS): This product in not controlled by the WHMIS

International Regulations: This product is intended for use as an investigational medicinal product. If approved for use in the EU, it is regulated under the Medicinal Products Directive (2001/83/EC) and is exempt from classification under the Dangerous Substances Directive (67/548/EC).



European Inventory of Existing Chemicals (EINECS): The components contained in this product are not included on the European Inventory of Existing Commercial Chemical Substances.

Section 16: Other Information

This SDS has been prepared in accordance with the GHS OSHA standard. Every attempt has been made to adhere to the hazard criteria and content of the U.S. OSHA hazard Communication Standard and the UN Global Harmonized System of classification and Labeling of Chemicals.

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NE = not established NA = not applicable NL= not listed