

Issue Date 26-Feb-2018

Revision Date Not applicable.

Version 1

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

Product identifier

Product Name Toxin A (TcdA), Purified from *Clostridium difficile*, Strain VPI 10463
Product Code NR-41658

Other means of identification

UN/ID No. UN3462
Synonyms Not available.

Recommended use of the chemical and restrictions on use

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

Details of the supplier of the safety data sheet

Supplier Address

BEI Resources
 10801 University Blvd.,
 Manassas, VA,
 US, 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

Health Hazards

Not classified.

Physical Hazards

Not classified.

OSHA Regulatory Status

This chemical has biological/pharmaceutical effects on animal or human bodily functions or systems, but does not reach the criteria of any specific GHS classification label. Therefore, it is considered hazardous by "other hazards" but not classified. (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 Lyophilized solid. **Physical State** Solid. **Odor** Not available.

Precautionary Statements - Prevention

Do not eat, drink, or smoke when using this product.
Wash hands and face thoroughly after handling.

Precautionary Statements - Response

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
Specific treatment (see Product Sheet and seek Medical Treatment immediately).
Rinse mouth.

Precautionary Statements - Storage

Store locked up.

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 2

Other information

Not available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200; Revision 3).

| | |
|------------------------|--|
| Common name | <i>Clostridium difficile</i> Toxin A (TcdA). |
| Synonyms | Not available. |
| Chemical Family | Protein. |
| Chemical nature | Bacterial toxin. |

| Chemical Name | CAS No. | Weight-% |
|---|---------|----------|
| Toxin A (TcdA) from <i>C. difficile</i> | N/A | 0.82 |
| Tris buffer | 77-86-1 | 99.18 |

Note: Each vial of NR-41658 contains 2 µg TcdA dehydrated from 20 mM Tris buffer pH 7.4 (0.1 mL / vial), therefore there is no liquid in the vial. The customer is instructed to rehydrate with a 0.1-mL volume of distilled water.

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 for a duration of 15-20 minutes or until medical aid is available. Immediately call a POISON CENTER/doctor. Wash contaminated clothing 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

Rinse mouth. Immediately call a POISON CENTER/doctor. If breathing has stopped, immediately start cardiopulmonary resuscitation (CPR) or automated external defibrillation (AED). Treatment of fluid and electrolyte loss is usually achieved through oral rehydration.

Most important symptoms and effects, both acute and delayed

Symptoms Gastrointestinal symptoms like diarrhea, bloating or blood in stool.

Indication of any immediate medical attention and special treatment needed

Note to Physicians Treat symptomatically.

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

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media None known.

Specific hazards arising from the chemical

None known.

Hazardous Combustion Products Not available.

Explosion data

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.

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures**

Personal Precautions Wear appropriate personal protective equipment (see Section 8). Keep unnecessary personnel away. Ensure adequate ventilation, especially in confined areas.

Environmental precautions

Environmental Precautions 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.

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: Allow aerosols to settle; wearing protective clothing, gently cover spill with paper towel and apply 1% sodium hypochlorite, starting at perimeter and working towards the center; allow sufficient contact time before cleanup (30 min).

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

Advice on Safe Handling Use aseptic procedures. Decontamination of work surfaces daily, after finishing work and following spills (Solutions of sodium hypochlorite 0.1% or sodium hydroxide 0.1 N readily inactivate the toxin). Standard microbiological practices should be followed. Do not get in eyes, on skin or on clothing. Do not breathe 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. Access to the laboratory is restricted when work is being conducted. A biohazard sign with relevant information should be posted at the entrance. "Toxins in Use - Authorized Personnel Only" should be clearly posted. 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.

Conditions for safe storage, including any incompatibilities

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| Storage Conditions | All containers must be properly labelled. Store in approved containers and protect against physical damage. Keep containers securely sealed when not in use. Containers that have been opened must be carefully resealed to prevent leakage. Empty containers retain residue and may be dangerous. If frozen suspension, store intact at -70°C. If the item is freeze-dried, store at -20°C. Freeze-dried products are hygroscopic and must be protected from exposure to moisture and oxygen during storage. |
| Packaging materials | Packed aseptically in plastic cryovials. |
| Incompatible materials | Not available. |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

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| Exposure Guidelines | This product, as supplied, contains the following hazardous materials with occupational exposure limits established by the region-specific regulatory bodies. |
|----------------------------|---|

Appropriate engineering controls

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| 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. |
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Individual protection measures, such as personal protective equipment

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|---------------------------------------|--|
| 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, hood or head coverings may be necessary. Contact a health and safety professional for specific information. |
| Respiratory Protection | Respirators may be 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

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|-----------------------|--------------------|-----------------------|----------------|
| Physical State | Solid. | Odor | Not available. |
| Appearance | Lyophilized solid. | Odor Threshold | Not available. |
| Color | Colorless. | | |

| <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 | | |
| 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

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|-------------------------|----------------|
| Softening Point | Not available. |
| Molecular Weight | 308 kDa |
| VOC Content (%) | Not available. |
| Density | Not available. |
| Bulk Density | Not available. |

10. STABILITY AND REACTIVITY

Reactivity

Not available.

Chemical stability

Undetermined.

Possibility of hazardous reactions

Not available.

Conditions to avoid

Not available.

Incompatible materials

Not available.

Hazardous decomposition products

Not available.

11. TOXICOLOGICAL INFORMATION

Product Information**Acute Toxicity**

| Chemical Name | Oral LD50 | Dermal LD50 | Inhalation LC50 | Intraperitoneal LD50 |
|--|----------------------|-------------|-----------------|----------------------|
| Tris buffer 77-86-1 | = 5900 mg/kg (Rat) | - | - | - |
| Toxin A (TcdA) from <i>C. difficile</i> N/A | - | - | - | 13 ug/kg |

Information on toxicological effects**Symptoms**

Clostridium difficile infection is characterized by several symptoms. It generally presents initially as diarrhea and abdominal pain, or colitis. This is directly caused by the toxins introduced by *Clostridium difficile*. This can lead to fever. Pseudo-membranous colitis is most commonly caused by *Clostridium difficile* infection. If left untreated it is possible for this to progress to toxic megacolon which can lead to sepsis and death

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

Skin Corrosion/Irritation No data available.

Serious Eye Damage/Eye Irritation No data available.

Sensitization No data available.

Germ Cell Mutagenicity No data available.

Carcinogenicity No data available.

Reproductive Toxicity No data available.

STOT - Single Exposure Not classified.

STOT - Repeated Exposure Not classified.

Aspiration Hazard Not applicable.

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

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|---|---|
| Disposal of Wastes | Disposal should be in accordance with applicable regional, national and local laws and regulations. |
| 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

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|-----------------------------|--|
| DOT | Regulated. |
| UN/ID No. | UN3462 |
| Proper shipping name | Toxins, extracted from living sources, solid, n.o.s. (Toxin A from <i>Clostridium difficile</i>). |
| Hazard Class | Class 6.1 |
| Packing Group | I |

| | |
|-----------------------------|--|
| IATA | Regulated. |
| UN/ID No. | UN3462 |
| Proper shipping name | Toxins, extracted from living sources, solid, n.o.s. (Toxin A from <i>Clostridium difficile</i>). |
| Hazard Class | Class 6.1 |
| Packing Group | I |

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 contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, contains the following substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

U.S. State Regulations

California Proposition 65

No component is on the Prop 65 list.

U.S. State Right-to-Know Regulations

This product contains the following substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable.

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| 16. OTHER INFORMATION |
|------------------------------|

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|---------------|-----------------|
| Prepared By | IES Engineers |
| Issue Date | 26-Feb-2018 |
| 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