

SAFETY DATA SHEET

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

Product Name: Clostridium difficile ribotype R087 toxoid A
Product Number: NAT41674-50 / NAT41674-100 / NAT41674-500
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2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.
This substance is not classified as dangerous according to Directive 67/548/EEC.

Label elements

The product does not need to be labeled in accordance with EC directives or respective national laws.

Precautionary statement(s) P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing.

S-phrases(s) S36 Wear suitable protective clothing.

2.3 Other hazards

This product does not contain substances listed on the ECHA Candidate list or identified as an endocrine disruptor as defined in Delegated Regulations (EC) 2017/2100 or (EC) 2018/605

3. COMPOSITION/INFORMATION ON INGREDIENTS

Native toxoid A purified from C. difficile ribotype 087. Sample is of biological origin and is presented as a white lyophilised solid in a glass vial. The toxoid is a de-toxified version of the active toxin. The sample is non-toxic. Mass as indicated on the label, each vial contains no more than 500µg.

Additional components present: 0.05M HEPES, 0.15M NaCl, 10% Sucrose when reconstituted to 500ug/ml.

4. FIRST AID MEASURES

- If inhaled:** If breathed in, move person into fresh air. If not breathing give artificial respiration.
Consult a physician.
- In case of skin contact:** Wash off with soap and plenty of water. Consult a physician.
- In case of eye contact:** Rinse thoroughly at eyewash station for at least 15 minutes and consult a physician.
- If swallowed:** Never give anything by mouth to an unconscious person. Rinse mouth with water.
Consult a physician.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Wear respiratory protection. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.
Evacuate personnel to safe areas.

Environmental precautions

Prevent further leakage or spillage if safe to do so.

Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Handle liquid in safety cabinet.
Provide appropriate exhaust ventilation at places where dust and aerosols are formed.

Conditions for safe storage

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.
Recommended storage temperature: 2 - 8 °C

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N99 (US) or type P2 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Handle with gloves.

Eye protection

Safety glasses

Skin and body protection

Laboratory coat

Hygiene measures

Avoid contact with skin, eyes and clothing. Wash and dry hands after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information of basic physical and chemical properties

Safety data

Physical State:	Solid
Colour:	White
Odour:	No data available
Odour Threshold (ppm):	No data available
pH:	pH 8.0
Melting Point (°C) / Freezing Point (°C):	No data available
Boiling point/boiling range (°C):	No data available
Flash Point (°C):	No data available
Evaporation rate (BA = 1):	No data available
Flammability (solid, gas):	No data available
Explosive limit ranges:	No data available
Vapour Pressure (mm Hg):	No data available
Vapour Density (Air=1):	No data available
Density (g/ml):	No data available

Solubility (Water):	Soluble
Solubility (Other):	No data available
Partition Coefficient (n-Octanol/water):	No data available
Auto Ignition Temperature (°C):	No data available
Decomposition Temperature (°C):	No data available
Viscosity (mPa.s):	No data available
Explosive properties:	No data available
Oxidising properties:	No data available

9.2 Other information

No data available

10. STABILITY AND REACTIVITY

Chemical stability

Stable under recommended storage conditions.

Conditions to avoid

Avoid multiple freeze thaw cycles

Materials to avoid

Strong oxidizing agents

Hazardous decomposition products

None known

11. TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Toxic activity has chemically been reduced to below measurable levels in a Vero cytotoxicity assay.

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available

Aspiration hazard

No data available

Potential health effects

No data available

Additional Information

RTECS: No data available

11.2 Information on other hazard classes which relates to endocrine disrupting properties.

Not applicable

12. ECOLOGICAL INFORMATION**Toxicity**

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

PBT and vPvB assessment

No data available

Endocrine disrupting properties

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Product

Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

Not dangerous goods

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

16. OTHER INFORMATION

Take special care when working in conjunction with hypodermic needles. If i.v. or i.m. injection should occur, consult a physician.

Last updated: 14/11/2025

Prepared by: The Native Antigen Company

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