

SAFETY DATA SHEET

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

Product Name: Clostridium difficile ribotype R027 toxin A
Product Number: NAT41671-50 / NAT41671-100 / NAT41671-500
Company: The Native Antigen Company Ltd.
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2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Acute toxicity, Inhalation (Category 2)
Acute toxicity, Dermal (Category 2)
Acute toxicity, Oral (Category 2)
Skin irritation
Eye irritation
Very toxic by inhalation, in contact with skin and if swallowed. Irritating to eyes, respiratory system and skin.

Label elements

Pictogram



Signal word: Danger

Hazard statement(s)
H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H331 Toxic if inhaled.

Precautionary statement(s)
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing.
P284 Wear respiratory protection when dealing with powder

Hazard symbol(s)	Toxic
R-phrases(s)	R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
S-phrases(s)	S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

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 toxin B purified from *C.difficile*. Sample is of biological origin and is presented as a white lyophilised solid in a glass vial. 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

No data available



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

Toxic if inhaled. May cause respiratory tract irritation.

Harmful if swallowed.

Toxic if absorbed through skin. May cause skin irritation.

Causes eye irritation.

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

UN Number: 3462

Class: 6.1

Packing group: I

Proper shipping name: TOXINS EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S.

Shipped as Excepted Quantity transport class 6.1

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: 09/12/2024**Prepared by:** The Native Antigen Company

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