

The Native Antigen Company Building B Langford Locks Kidlington Oxfordshire OX5 1LH Tel+44 (0)1865 595230

# SAFETY DATA SHEET

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

Product name: Clostridium difficile Toxoid B

Product Number: CDB-TDL

Company: The Native Antigen Company Ltd.

Building B Langford Locks Kidlington Oxfordshire OX5 1LH

Tel+44 (0)1865 595230

E-mail address: contact@thenativeantigencompany.com

### 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-phrase(s) S36 Wear suitable protective clothing.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Toxiod B from Clostridium difficile. Sample is of biological origin and is presented as a white lyophilized solid in a glass vial. Each vial contains no more than 500µg.

Additional components present: 0.05M Hepes, 0.15M NaCl and 5% sucrose.

#### 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.

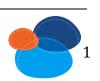
## Special protective equipment for fire-fighters

VAT No: 102038475

Wear self contained breathing apparatus for fire fighting if necessary.

www.thenativeantigencompany.com

contact@thenativeantigencompany.com Registration No. 7386339





#### 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.

## 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

### **Appearance**

White powder, lyophilized

## Safety data

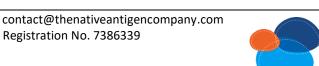
pH: pH 7.2 when resuspended

Melting point:
Boiling point:
Flash point:
Ignition temperature:
Lower explosion limit:
Upper explosion limit:
no data available
no data available
no data available
no data available

Water solubility: soluble

## 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

**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

No data available

Reproductive toxicity

No data available

**Aspiration hazard** 

No data available

Potential health effects

No data available

**Additional Information** 

RTECS: No data available

### 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

Other adverse effects

No data available

## 13. DISPOSAL CONSIDERATIONS

#### **Product**

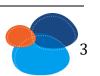
Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

## Contaminated packaging

Dispose of as unused product.

## 14. TRANSPORT INFORMATION

contact@thenativeantigencompany.com Registration No. 7386339





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 update: 22 May 2012

Prepared by: The Native Antigen Company

Although the information, opinions and recommendations contained in this Safety Data Sheet are compiled from sources believed to be reliable, we accept no responsibility for the accuracy, sufficiency, or reliability or for any loss or injury resulting from the use of the information.

