

## SAFETY DATA SHEET

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

Product name: Diphtheria Toxoid  
IUPAC name: -  
Product number: NAT41586-100 / NAT41586-500  
CAS number:

Company: The Native Antigen Company  
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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.  
Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

#### Label elements

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

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Purified diphtheria toxin from *Corynebacterium diphtheria* strain NCTC 10648; converted to inactive toxoid form. Sample is of biological origin and is presented lyophilised in a vial. Each vial contains no more than 1000µg.

Inactivation method: Formaldehyde No specific biological hazards are known to be associated with this product. However, it should be handled with appropriate safety precautions for biological materials.

Additional components present: 0.01 M Tris pH 7.5 and 0.001 M Na<sub>2</sub>EDTA.

Toxoids are made by chemical or genetic inactivation and are generally considered non-toxic. Toxicity is significantly decreased relative to the fully active toxins; however, some residual toxicity is expected. This toxoid is tested and results are described in the product Certificate of Analysis.



#### 4. FIRST AID MEASURES

- If inhaled:** Remove person to fresh air, seek medical advice if breathing becomes difficult.
- In case of skin contact:** Wash off with soap and water.
- In case of eye contact:** Rinse at eyewash station.
- If swallowed:** No treatment required

#### 5. FIRE-FIGHTING MEASURES

##### Suitable extinguishing media

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

##### Special protective equipment for fire-fighters

None required.

#### 6. ACCIDENTAL RELEASE MEASURES

##### Personal precautions

Wear gloves.

##### Environmental precautions

Prevent further leakage or spillage if safe to do so.

##### Methods and materials for containment and cleaning up

Pick up using absorbent tissue and arrange for safe disposal. Keep in suitable, closed containers for disposal.

#### 7. HANDLING AND STORAGE

##### Precautions for safe handling

Avoid contact with skin and eyes.

##### Conditions for safe storage

Recommended storage temperature:  
Short term: Store lyophilised or resuspended at +4°C.  
Long-term: +4°C.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

##### Personal protective equipment

##### Respiratory protection



None necessary.

#### **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 if desired

#### **Skin and body protection**

Laboratory coat

#### **Hygiene measures**

Avoid contact with skin, eyes and clothing.

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

#### **Appearance**

Lyophilised

#### **Safety data**

pH:	7.5
Melting point:	no data available
Boiling point:	no data available
Flash point:	no data available
Ignition temperature:	no data available
Lower explosion limit:	no data available
Upper explosion limit:	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**

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**

<b>Inhalation</b>	None
<b>Ingestion</b>	None
<b>Skin</b>	None
<b>Eyes</b>	May cause eye irritation.

**Signs and Symptoms of Exposure**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

**Additional Information****12. ECOLOGICAL INFORMATION****Toxicity**

No data available

**Persistence and degradability**

Degrades easily

**Bioaccumulative potential**

Low

**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. Can be disposed of down sink.

**Contaminated packaging**

Dispose of as unused product.

**14. TRANSPORT INFORMATION**

Not dangerous goods, no transport limitations.

**15. REGULATORY INFORMATION**

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

**16. OTHER INFORMATION**

None

**Last updated:** 15/10/2020

**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.