

SAFETY DATA SHEET

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

Product name: Diphtheria Toxoid (Frozen)
IUPAC name: -
Product number: NAT41609-1000 / NAT41609-100
CAS number:

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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

Diphtheria toxoid is a formaldehyde-inactivated toxin purified from *Corynebacterium diphtheriae*. Sample is of biological origin and is presented as a liquid in a vial. Each vial contains no more than 1000µg.

Inactivation method: Incubation with formaldehyde for 3-weeks. Cytotoxicity assay is used to confirm loss of activity. Toxoid is tested by measuring its effect on cell viability in Chinese Hamster Ovary (CHO) cells. 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 Na₂EDTA

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: 1 week at +4°C.
Long-term: -80°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

Colourless liquid

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

Inhalation	None
Ingestion	None
Skin	None
Eyes	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: 15/07/2020

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.