

**SAFETY DATA SHEET****1. Identification**

**Product Identifier:** Tetanus and Diphtheria Toxoids Adsorbed

**Synonyms:** Not available.

**National Drug Code (NDC):** 17478-131-01

**Recommended Use:** Pharmaceutical.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

**2. Hazard(s) Identification**

**Physical Hazards:** Not available.  
**Health Hazards:** Not available.  
**Symbol(s):** Not available.

**Signal Word:** Warning.

**Hazard Statement(s):** This product is a vaccine that is non-toxic and non-pathogenic. It contains chemically inactivated toxoid proteins that were purified from bacterial cultures. It is not considered to be toxic for humans.

**Precautionary Statement(s):** Not available.  
**Hazards Not Otherwise Classified:** Not available.  
**Supplementary Information:** Not available.

**3. Composition/Information on Ingredients**

<b>Chemical Name</b>	<b>CAS Number</b>	<b>Synonyms</b>	<b>Chemical Formula</b>	<b>Molecular Weight</b>	<b>Percentage</b>
Tetanus Toxoid	Not Assigned	Data not available	Data not available	Data not available	2 Lf
Diphtheria Toxoid	Not Assigned	Data not available	Data not available	Data not available	2 Lf

\*The formula also contains Aluminum Phosphate, 0.4 g%; Sodium Phosphate; Aluminum Chloride; Thimerosal, ≤0.002 g%; and Formaldehyde, <0.02 g%.

**4. First Aid Measures**

<b>Ingestion:</b>	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
<b>Eye Contact:</b>	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Skin Contact:</b>	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	Not determined.
<b>Medical Conditions Aggravated by Exposure:</b>	The purified protein components contained in this product are generally not considered to cause disease in humans; although pain, tenderness, erythema, induration, pruritus, swelling and warmth, peripheral are possible at the injection site.
<b>Notes to Physician:</b>	Wash and clean injection site.

**5. Firefighting Measures**

<b>Suitable Extinguishing Media:</b>	Aqueous solutions are non-flammable. Use water, carbon dioxide, dry chemical or foam as necessary.
<b>Unsuitable Extinguishing Media:</b>	Not determined.

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### Specific Hazards Arising from the Chemical:

<b>Hazardous Combustion Products:</b>	None known from product, although toxic, corrosive or flammable thermal decomposition products from packaging are possible.
<b>Other Specific Hazards:</b>	Not determined.
<b>Special Protective Equipment/ Precautions for Firefighters:</b>	Wear self-contained breathing apparatus and full and protective gear.
<b>Special Fire Fighting Procedures:</b>	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product, since toxic, corrosive or flammable vapors might evolve from fires involving product and associated packaging, full protective clothing and a self-contained breathing apparatus are recommended for firefighters or other qualified persons. Decontaminate all equipment after use and if possible, contain and collect firefighting water for later disposal.

### 6. Accidental Release Measures

<b>Personal Precautions:</b>	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
<b>Personal Protective Equipment:</b>	For personal protection see section 8.
<b>Methods for Cleaning Up:</b>	Surround spill using spill pillows or other inert absorbents. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal. Dispose of material in a manner that is compliant with federal, state and local laws. Take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Environmental Precautions:</b>	No studies identified. No known significant effects or critical hazards. Local regulations and procedures should be consulted prior to environmental release.
<b>Reference to Other Sections:</b>	Refer to Sections 8, 12 and 13 for further information.

### 7. Handling and Storage

<b>Precautions for Safe Handling:</b>	Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
<b>Conditions for Safe Storage, Including Any Incompatibilities:</b>	Store at 2°C – 8°C (36°F – 46°F). DO NOT FREEZE. Discard product if exposed to freezing. Do not use vaccine after expiration date. Store according to label and/or product insert information.
<b>Specific End Use:</b>	Pharmaceuticals.

**8. Exposure Controls/Personal Protection**

**Occupational Exposure Guidelines:**

<b>Common or Chemical Name</b>	<b>Employee Exposure Limits</b>
Tetanus Toxoid	Not established.
Diphtheria Toxoid	Not established.

**Engineering Controls:** None currently established by OSHA, NIOSH, or ACGIH.

**Respiratory Protection:** Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Eyes Protection:** Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Hand Protection:** Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Skin Protection:** Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

**9. Physical and Chemical Properties**

**Physical State/Color:** Homogenous milky white suspension liquid (after shaking).

**Odor:** No data available.

**Odor Threshold:** No data available.

**pH:** 6.0.

**Melting Point:** No data available.

**Freezing Point:** No data available.

**Boiling Point:** No data available.

**Flash Point:** No data available.

**Evaporation Rate:** No data available.

**Flammability (solid, gas):** No data available.

**Flammability Limit - Lower:** No data available.

**Flammability Limit - Upper:** No data available.

**Vapor Pressure:** No data available.

**Vapor Density:** No data available.

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<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	No data available.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

### 10. Stability and Reactivity

<b>Reactivity:</b>	No data available.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Do not freeze.
<b>Incompatible Materials:</b>	None known.
<b>Hazardous Decomposition Products:</b>	Not expected to occur.
<b>Hazardous Polymerization:</b>	Not expected to occur.

### 11. Toxicological Information

#### Information on the Likely Routes of Exposure:

<b>Inhalation:</b>	No data available.
<b>Ingestion:</b>	No data available.
<b>Skin Contact:</b>	No data available.
<b>Eye Contact:</b>	May cause eye irritation.

#### **Symptoms Related to the Physical, Chemical and Toxicological Characteristics:**

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

#### **Delayed and Immediate Effects of Exposure:**

No data available.

#### **Acute Toxicity:**

Product contains inactivated bacterial protein and is not pathogenic. Adverse health effects are considered unlikely when the product is used as a vaccine or administered according to label directions.

<b>Acute Toxicity – Dermal:</b>	No data available.
<b>Acute Toxicity – Inhalation:</b>	No data available.
<b>Corrosivity:</b>	No data available.
<b>Dermal Irritation:</b>	No data available.
<b>Eye Irritation:</b>	No data available.
<b>Sensitization:</b>	No data available.
<b>Toxicokinetics/Metabolism:</b>	No data available.

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<b>Target Organ Effects:</b>	No data available.
<b>Reproductive Effects:</b>	No data available.
<b>Carcinogenicity:</b>	No data available.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
<b>Mutagenicity:</b>	No data available.
<b>Aspiration Hazard:</b>	No data available.
<b>Repeat Dose Toxicity:</b>	Not considered to be toxic for humans.

### 12. Ecological Information

#### Ecotoxicity

<b>Aquatic:</b>	No data available.
<b>Terrestrial:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.
<b>Other Adverse Effects:</b>	No data available.

### 13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

### 14. Transport Information

<b>UN Number:</b>	Not applicable.
<b>UN Proper Shipping Name:</b>	Not applicable.
<b>Transport Hazard Class(es):</b>	Not applicable.
<b>Packing Group:</b>	Not applicable.
<b>Department of Transportation:</b>	Not regulated as a hazardous material.
<b>International Air Transport Association (IATA):</b>	Not regulated as a dangerous good.
<b>International Maritime Dangerous Good (IMDG):</b>	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA): Not listed.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.  
SARA 302: Not listed.

State Regulations

California Proposition 65: Not listed.

16. Other Information

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