



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: cAu-TNF (veterinary)
Product No.: Not applicable
GHS Product Identifier: Not applicable

Synonyms: Not available
Molecular Formula: Mixture, not applicable
Molecular Weight: Not applicable
CAS Number: Mixture, not applicable
Chemical Family: Cytotoxin

Manufacturer:
Ben Venue Laboratories
300 Northfield Rd.
Bedford, OH 44146-0568

Emergency Telephone:
Transportation Emergency: (800) 424-9300
Medical Emergency (24HR): (866) 638-2226

Supplier:
Boehringer Ingelheim Vetmedica, Inc.
2621 North Belt Hwy
St. Joseph, MO 64506-2002

Intended Use: Experimental therapeutic
veterinary oncology drug

Non-emergency Telephone: (800) 821-7467

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Powder; Liquid (reconstituted)
Color: Light purple (lyophilized powder), Dark purple (reconstituted)
Odor: No data available



DANGER!

Experimental Veterinary Oncology Drug - Not for human use.

The physical-chemical and toxicological properties of this material have not been fully investigated.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause allergic skin reaction.

Precautionary Statements:

Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.

Not for use in animals intended for food.

Keep container closed.

Keep at a temperature between 2 - 8 ° C.

Fire-fighting: Use foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling.

Use only with adequate ventilation.

Wear suitable gloves and eye/face protection.

Spills: Cover with absorbent or contain. Collect and dispose. Do NOT wash away into sewer.

Avoid run off to waterways and sewers.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed, seek medical advice immediately and show this container or label.

In case of contact with eyes, rinse immediately with plenty of water for at least 15 minutes. Get medical attention.

This material and its container must be disposed of in a safe way.

Keep out of reach of children.

Keep away from food, drink, and animal feedstuffs.

Acute effect:

Tissue inflammation at IV site.

Precautions/Contraindications:

Hypersensitivity to any other component of the therapeutic system.

Overdosage:

No data available.

ADVERSE REACTIONS TO PRODUCT:

In addition to tissue inflammation, the product may cause immune modulated responses such as: rheumatoid arthritis, weight loss, anorexia, protein catabolism and lipid depletion.

Potential Health Effects

Inhalation: Not fully evaluated. Not expected to be an inhalation hazard with prescribed use. May cause sensitization by inhalation. Exposure may cause asthmatic breathing and other systemic effects.

Eye Contact: Not fully evaluated. Not expected to be a hazard to the eye with prescribed use. Exposure may cause eye tearing, redness, and discomfort.

Skin Contact: Not fully evaluated. May cause skin sensitization by contact. Can be absorbed through the skin. Exposure may cause systemic effects.

Ingestion: Not fully evaluated. Not expected to be an ingestion hazard with prescribed use. Ingestion may cause vomiting, nausea, dizziness, drowsiness or other systemic effects.

Injection: Not fully evaluated. May cause tissue inflammation and other systemic effects.

Chronic Health Effects: Possible hypersensitization (development of abnormal sensitivity).

Target Organ(s): Immune system, skin, lungs

Potential Physical Effects: May cause immune modulated responses (increases) such as rheumatoid arthritis, weight loss, anorexia, protein catabolism and lipid depletion.

OSHA Regulatory Status: Assumed hazardous, not fully evaluated.

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
TNF-alpha concentrate	----	3598-37-6	100 µg/vial	----	----
High purity gold chloride	----	N/A	3.6 mg/vial	----	----
Methoxy PEG-sulhydryl 20K	----	N/A	.3 mg/vial	----	----

The full texts for all R-Phrases are displayed in Section 16.

4 FIRST AID MEASURES

General: Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Skin Contact: Immediately flush skin with plenty of water while removing contaminated clothing and shoes. Get medical attention. Wash contaminated clothing before reuse. Thoroughly clean shoes before reuse.

Ingestion: Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person. Get medical attention immediately.

Injection: In case of accidental injection, wash the site thoroughly. Seek medical attention immediately.

Note to Physician: For animal injection only. Not for human use.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish with foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire & Explosion Hazards: None known

Hazardous Combustion Products: Carbon monoxide, carbon dioxide.

Flammability Class: 0

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate personal protective equipment. (See Section 8)

Spill Cleanup Methods: Small liquid spill: Wear an approved respirator, eye protection, personal protective coverings and gloves. Use HEPA filtered vacuum or wet sweeping to clean up spillage. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

Small powdered spill: Wear an approved respirator, eye protection, personal protective coverings and gloves. Use HEPA filtered vacuum or wet sweeping to clean up spillage. Avoid dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

Large spill: Clean up large spills of hazardous drugs with the help of an environmental services specialist.

Environmental Precautions: Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

7 HANDLING AND STORAGE

Handling: Avoid contact with eyes, skin and clothing. Do not breathe dust, mist or vapor. Avoid accidental injection. Do not taste or swallow. Wash thoroughly with soap and water after handling. Use with adequate ventilation.

Storage: Store in tight container. Store at 2°-8° C (35.6 – 46.4° F). Store away from foodstuffs.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits: None

Engineering Controls: Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Respiratory Protection: If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 63 FR 1152, January 8, 1998. Respirator type: Air-purifying respirator with an appropriate, government approved (where applicable), air-purifying filter, cartridge or canister. (for liquid). Respirator type: Dust (for lyophilized powder). Contact health and safety professional or manufacturer for specific information.

Eye Protection: Wear safety glasses with side shields (or goggles).

Hand Protection: Wear double latex/nitrile gloves.

Skin Protection: Lab coat/apron or disposable long-sleeved gown.

Hygiene Measures: Eye bath, washing facilities, shower

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: Light purple (lyophilized powder), Dark purple (reconstituted)

Odor: No data available

Odor Threshold: No data available

Physical State: Powder, Liquid (reconstituted)

pH: 6.0 – 7.0

Melting Point: No data available

Freezing Point: No data available

Boiling Point: No data available

Flash Point: Not flammable

Flammability Limit – Upper (%): Not applicable

Flammability Limit – Lower (%): Not applicable

Evaporation rate: No data available

Vapor Pressure: No data available

Vapor Density (Air=1): No data available

Specific Gravity: No data available

Solubility: Not applicable

Partition Coefficient (n-Octanol/water): No data available

Autoignition Temperature: Not applicable

Decomposition Temperature: No data available

10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: None known

Incompatible Materials: None known

Hazardous Decomposition Products: No data available

Possibility of Hazardous Reactions: Hazardous polymerization will not occur

11 TOXICOLOGICAL INFORMATION

Specified Substances

Acute Toxicity

Chemical Name	Test Results
TNF-alpha Concentrate	Oral LD ₅₀ (male rat): > 10 mg/kg Oral LD ₅₀ (female rat): 10 mg/kg
Methoxy PEG-sulhydryl 20K	Safety established at 10 g/kg body weight by IV injection.

Listed Carcinogens: None known. Not fully tested.

12 ECOLOGICAL INFORMATION

Ectotoxicity: No data available

Persistence and degradability: No data available

Mobility in soil: No data available

Other adverse effects: No data available

13 DISPOSAL CONSIDERATIONS

General Information: Dispose of in accordance with local, state and federal regulations. Dispose of by biological waste procedures.

Disposal Methods: Do not empty into drains; dispose of this material and its container in a un-safe way. Do not contaminate water, food, or feed by storage disposal.

Container: Since emptied containers retain product residue, follow label warnings even after container is emptied.

14 TRANSPORT INFORMATION

DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15 REGULATORY INFORMATION

Canadian Controlled Products Regulations: This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

WHMIS Classification: D2B

Inventory Status

This material is **not** listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

This material is **not** listed on the DSL Inventory.

US Regulations

FDA Status: None; Experimental Therapeutic Oncology Veterinary Drug

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): None

Massachusetts Right-To-Know List: None

Minnesota Hazardous Substances List: None

New Jersey Right-To-Know List: None

Pennsylvania Right-To-Know List: None

European Regulations: None listed

16 OTHER INFORMATION

Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	2*	0	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	2	0	0	N/A

*- Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

Europe:

Warning! – Substance not fully tested – multiple components.

ABBREVIATIONS:

BIV - Boehringer Ingelheim Vetmedica, Inc.

AIHA- American Industrial Hygiene Association

mppcf – million particles/cubic foot

N/A - Not applicable

N/E - Not established

References:

1. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
2. cAu-TNF (veterinary) MSDS. Boehringer Ingelheim Vetmedica, Inc.
3. GHS Manual
4. RTECS – Colloidal gold – MD5070000

Revision Information: Updated all sections of the MSDS for ANSI, GHS and OSHA Compliance.

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

Issue Date: 06/27/08

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