



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: ToxiVac® AD&E
Product No.: Not applicable
MSDS ID#: N7054.00
GHS Product Identifier: Not applicable

Molecular Formula: Mixture, not applicable
 Molecular Weight: Mixture, not applicable
 CAS Number: Mixture, not applicable
 Chemical Family: Vaccine

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

Transportation Emergency: For Chemical
 Emergency Spill, Leak, Fire, Exposure, or
 Accident Call CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300
 Outside USA and Canada: +1 703-527-3887
 (collect calls accepted)

Medical Emergency (24HR): (866) 638-2226
Non-Emergency Telephone: (800) 821-7467

Intended Use: For use in swine as an aid in
 the prevention of disease due to infection by
Bordetella bronchiseptica, *Erysipelothrix*
rhusiopathiae, and toxigenic strains of
Pasteurella multocida types A and D.

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Inactivated bacterin-toxoid in a liquid saline solution, packaged in 100mL bottle.
Color: White, cream or light tan opaque
Odor: No data available



DANGER!
 Contains a component that may cause cancer.
 Allergic reactions can occur.

**In vaccines, chronic exposure potential is not expected.
For use in pigs only.
Not for human use.**

Precautionary Statements

Prevention:

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Use personal protective equipment as required.

Response:

If exposed or concerned: Get medical advice/attention.

Storage:

Store locked up.

Disposal:

Dispose of contents/container according to applicable federal and local regulations.

Additional statements:

Keep only in original container.
Keep at a temperature between 2 - 7°C.
Do not freeze.
Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.
Avoid contact with eyes, skin and clothing.
Wash thoroughly with soap and water after handling.
Wear suitable gloves and eye/face protection.
Spills: Cover with absorbent or contain. Collect and incinerate.
If swallowed, seek medical advice immediately and show this container or label.
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.
Keep out of reach of children.
Keep away from food, drink, and animal feedstuffs.

Potential Health Effects

Inhalation: Not expected to be an inhalation hazard with prescribed use.

Eye Contact: Not expected to be a hazard to the eye with prescribed use. Exposure to liquid in eye may cause mild transient eye irritation.

Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions. May cause skin sensitization by contact.

Ingestion: Not expected to be an ingestion hazard with prescribed use. Ingestion may cause nausea and systemic effects.

Injection: Swelling at injection site may occur.

Chronic Health Effects: Possible hypersensitization (development of abnormal sensitivity). Contains formaldehyde. Formaldehyde has a carcinogenic potential and is a known skin and respiratory sensitizer. In vaccines, the chronic exposure potential is negligible.

Target Organ(s): Skin

OSHA Regulatory Status: Hazardous (Exempt)

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS-No.	Concentration	Classification	Notes
<i>Pasteurella multocida</i> , bacterin-toxoid antigen	----	----	proprietary	----	---
<i>Bordetella bronchiseptica</i> , inactivated bacterin-toxoid	----	----	proprietary	----	---
<i>Erysipelothrix rhusiopathiae</i> , inactivated bacterin-toxoid	----	----	proprietary	----	---
Formaldehyde	200-001-8	50-00-0	<= 0.2 %	T; C; C3 R23/24/25, R34, R40, R43	*

* Used to inactivate bacterin and subsequently removed from solution. Concentration represents maximum remaining amount by percent weight which is below USDA allowable limits.

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

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. Treat symptomatically. Get medical attention if symptoms persist.

Eye Contact: Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

Skin Contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. If skin irritation or rash occurs, seek medical advice. Wash contaminated clothing 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.

Injection: In case of accidental injection, wash the site thoroughly. Contact a physician 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, nitrogen oxides

6 ACCIDENTAL RELEASE MEASURES

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

Spill Cleanup Methods: STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED: Absorb or cover with dry earth, sand or other non-combustible material. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

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

7 HANDLING AND STORAGE

Handling: HANDLING SIGNIFICANT QUANTITIES OF PRODUCT: Avoid contact with eyes, skin or clothing. Avoid accidental injection. Wash hand thoroughly after handling.

Storage: Store at 2°-7° C (35°-45° F). Do not freeze. Store out of direct sunlight to protect product integrity. Shake well before using.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

Chemical Name	Source	Type	Exposure Limits	Notes
Formaldehyde	ACGIH	Ceiling Exposure Limit	0.3 ppm	Sensitizer, Suspected cancer hazard, Upper respiratory and eye irritation
Formaldehyde	OSHA	Action Level	0.5 ppm	Cancer-suspect agent
Formaldehyde	OSHA	TWA	0.75 ppm	----
Formaldehyde	OSHA	STEL	2 ppm	----

Where lower governmentally imposed exposure limits exist, such limits should take precedence.

Engineering Controls: Not generally required when handling vials or containers. Good 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: Not generally required when handling vials or containers. 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: NIOSH approved organic vapor respirator.

Europe: Wear appropriate personal protective equipment according to the Council Directive 89/686/EEC (4) and the appropriate CEN standards.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely wear:

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

Hand Protection: Wear suitable gloves.

Skin Protection: Wear lab coat, apron or appropriate clothing to prevent skin contact.

Hygiene Measures: Eye bath, washing facilities

9	PHYSICAL AND CHEMICAL PROPERTIES
----------	---

Color: White, cream or light tan opaque

Odor: No data available

Odor Threshold: No data available

Physical State: Inactivated bacterin-toxoid in a liquid saline solution, packaged in 100mL bottle.

pH: No data available

Melting Point: No data available

Freezing Point: No data available

Boiling Point: No data available

Flash Point: No data available

Flammability Limit – Upper (%): No data available

Flammability Limit – Lower (%): No data available

Evaporation rate: No data available

Vapor Pressure: No data available

Vapor Density (Air=1): No data available

Specific Gravity: No data available

Solubility: No data available

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: Temperatures below 2° C (35° F)

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: Nitrogen oxides

Possibility of Hazardous Reactions: Will not occur.

11	TOXICOLOGICAL INFORMATION
-----------	----------------------------------

ToxiVac® AD&E is considered non-toxic.

Specified Substances

Acute Toxicity

Chemical Name	Test Results
Formaldehyde	Administration into the eye (rabbit): 750 ug, Severe Irritant Administration onto the skin (rabbit): 2 mg/24 h, Severe Irritant Oral LD50 (rat): 800 mg/kg Dermal LD50 (rabbit): 630 mg/kg Inhalation LC50 (rat): 0.48 mg/l/4 hours

Chronic Toxicity – Possible hypersensitization (development of abnormal sensitivity). Contains formaldehyde. Formaldehyde has a carcinogenic potential and is a known skin and respiratory sensitizer. In vaccines, the chronic exposure potential is negligible.

Listed Carcinogens:

Chemical Name	IARC	NTP	OSHA	ACGIH
Formaldehyde	1: Carcinogenic to humans	Known carcinogen	Cancer suspect agent	A2: Suspected Human Carcinogen

12	ECOLOGICAL INFORMATION
-----------	-------------------------------

Ecotoxicity: No data available

Persistence and degradability: No data available

Mobility in soil: No data available

Other adverse effects: No data available

Germany WGK: Formaldehyde ID No: 112; Class 2: water-endangering.

13	DISPOSAL CONSIDERATIONS
-----------	--------------------------------

General Information: Dispose of in accordance with local, state, federal, national or international regulations.

Disposal Methods: No specific disposal method required. Do not empty into drains. Dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by disposal.

RCRA Information: Not applicable

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: D/2/A, Exempt

Inventory Status

This material is **not** listed on the following inventories: TSCA, DSL, AICS, EINECS, IECSC, ENCS, PICCS, KECI, and NZIoC. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

Canada CEPA Schedule 1 – Formaldehyde

US Regulations

FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

CERCLA Hazardous Substance List (40 CFR 302.4):

Component	Reportable Quantity
Formaldehyde	100lbs

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):

Formaldehyde

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):

Component	Reportable Quantity Code	Reportable Quantity
Formaldehyde	B	100lbs

SARA Title III**Section 302 Extremely Hazardous Substances (40 CFR 355, Appendix A):**

Component	Reportable Quantity
Formaldehyde	100lbs

Section 311/312 (40 CFR 370):

Acute (Immediate)
 Chronic (Delayed)
 Fire
 Reactive
 Pressure Generating

Section 313 Toxic Release Inventory (40 CFR 372):

Component	CAS No	Weight %
Formaldehyde	50-00-0	<= 0.2

State Regulations**California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**

Formaldehyde (gas)

Massachusetts Right-To-Know List: Formaldehyde**Minnesota Hazardous Substances List:** Formaldehyde**New Jersey Right-To-Know List:** Formaldehyde**Pennsylvania Right-To-Know List:** Formaldehyde**Rhode Island Right-To-Know List:** Formaldehyde**European Regulations****Austria MAK List (Annex I):** Formaldehyde**Denmark (Annex 3.6):** Formaldehyde**Germany (Dangerous Substances Ordinance 2004, Annex III):** Formaldehyde**Norway (List of Dangerous Substance):** Formaldehyde**Sweden (Annex 3):** Formaldehyde**Switzerland (Toxins List 1):** Formaldehyde**16 OTHER INFORMATION****Hazard Ratings**

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1*	1	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	1	1	0	N/A

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

EU Symbol and R Phrase Definitions

T – Toxic

C – Corrosive

C3 – Carcinogen category 3

R23/24/25 – Toxic by inhalation, in contact with skin and if swallowed.

R34 – Causes burns.

R40 – Limited evidence of a carcinogenic effect.

R43 – May cause sensitization by skin contact.

ABBREVIATIONS:

BIV – Boehringer Ingelheim Vetmedica, Inc.

N/A – Not applicable

N/E – Not established

pph – parts per hour

ppm – parts per million

References:

1. ToxiVac® AD&E MSDS and Label
2. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
3. GHS Manual

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

Issue Date: 10/12/2011

Revision Information: New

Disclaimer: The information provided herein is offered by Boehringer Ingelheim Vetmedica, Inc. (“BIV”) in good faith as accurate as of the date hereof, but without guarantee. This information includes information which has been generated by other parties and provided to BIV, and which BIV has not independently verified. The information provided herein relates only to the specific product designated, and may not be valid where such product is used in combination with any other materials or in any process. The information provided herein is offered solely for your consideration, investigation and verification, and Boehringer Ingelheim Vetmedica, Inc. (“BIV”) expressly disclaims all liability for reliance thereon. BIV EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE (INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) WITH RESPECT TO THE USE OR SUITABILITY OF THE PRODUCT. In addition, since the conditions of use and suitability of the product for particular uses are beyond BIV’s control, ALL RISKS OF USE OF THE PRODUCT ARE THEREFORE ASSUMED BY THE USER, AND BIV EXPRESSLY DISCLAIMS ANY AND ALL LIABILITY AS TO ANY RESULTS OBTAINED OR ARISING FROM ANY USE OF THE PRODUCT. Use or transmission of the information contained herein in any other format than the format as presented is strictly prohibited. Nothing herein shall be construed as permission or recommendation for the use of the product in a manner that might infringe an existing patent. BIV neither represents nor warrants that the format, content or product formulas contained in this document comply with the laws of any other country except the United States of America.

© Copyright 2011 Boehringer Ingelheim Vetmedica, Inc. All rights reserved.