

SAFETY DATA SHEETS

This SDS packet was issued with item:

078705543

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078377139 078705469 078705477



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Alpha-7™ Injection
Product No. : 7410.01
GHS Product Identifier: Not applicable

Synonyms: Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D
Bacterin-Toxoid Vaccine
Molecular Formula: Mixture, not applicable
Molecular Weight: Not applicable
CAS Number: Mixture, not applicable
Chemical Family: Vaccine

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

Emergency Telephone:
Transportation Emergency: (800) 424-9300

Medical Emergency (24HR): (800)530-5432

Intended Use:
Seven-way Clostridia Vaccine for healthy, susceptible cattle, including bred heifers, lactating beef and dairy cattle, against disease caused by *Clostridium chauvoei*, *CI septicum*, *CI novyi*, *CI sordellii*, and *CI perfringens* Types C and D.

Non-emergency Telephone: (800) 821-7467

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Liquid; Multi-dose vials: 20 mL (10 doses); 100 mL (50 doses); 500mL (250 doses)

Color: White

Odor: No data available



WARNING!

For cattle injection only.

Not for human use.

May cause allergic skin reaction.

Precautionary Statements:

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

Keep only in original container.

Keep at a temperature not exceeding 7° 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.

Wear suitable gloves and eye/face protection.

Spills: Cover with absorbent or contain. Collect and dispose.

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.

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:

Swelling at injection site may occur.

Precautions/Contraindications:

Use entire contents when first opened. Do not vaccinate within 60 days of slaughter.

Overdosage: None known.

ADVERSE REACTIONS TO PRODUCT: Anaphylactoid reactions may occur.

Potential Health Effects

Inhalation: Not expected to be an inhalation hazard.

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

Skin Contact: Can cause hypersensitive reactions. May cause skin sensitization by contact.

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

Injection: Swelling at injection site may occur.

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

Target Organ(s): Immune System

Potential Physical Effects: Can cause skin sensitization.

OSHA Regulatory Status: Nonhazardous, exempt

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Mineral oil	2323842	8012-95-1	55	----	----
Formaldehyde	2000018	50-00-0	.5	Xi, R43	----
Gentamicin sulfate	2157789	1405-41-0	30 mcg/mL	----	----
<i>Clostridium chauvoei</i>	----	N/A	proprietary	----	----
<i>Clostridium septicum</i>	----	N/A	proprietary	----	----
<i>Clostridium novyi</i>	----	N/A	proprietary	----	----
<i>Clostridium perfringens</i> , Type C	----	68583-13-1	proprietary	----	----
<i>Clostridium perfringens</i> , Type D	----	68583-14-2	proprietary	----	----
Deionized water	2317912	7732-18-5	proprietary	----	----
Montanide 888	----	mixture	proprietary	----	----

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. 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. Get medical attention if symptoms occur.

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.

Antidote: Epinephrine is indicated for anaphylactoid reactions.

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.

Spill Cleanup Methods: Small liquid spill: Use a non-combustible material like vermiculite, earth or sand to soak up the product and place into container for later disposal. For large liquid spill: Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers.

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. Avoid accidental injection. Wash thoroughly with soap and water after handling. Use only with adequate ventilation.

Storage: Keep only in the original container. Store at 2°-7° C (35°-45° F). Avoid freezing. Keep out of reach of children. Keep away from food, drink, and animal feedstuffs.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

For Exposures:

Exposure Limits:

Chemical Name	Source	Type	Exposure Limits	Notes
<i>Clostridium chauvoei</i>	----	----	N/A	----
<i>Clostridium septicum</i>	----	----	N/A	----
<i>Clostridium novyi</i>	----	----	N/A	----
<i>Clostridium perfringens</i> , Type C	----	----	N/A	----
<i>Clostridium perfringens</i> , Type D	----	----	N/A	----
Formaldehyde	ACGIH	8-HR TWA	0.3 ppm	Irritation, cancer
Formaldehyde	OSHA	Action Level	.75 ppm	Cancer-suspect agent
Formaldehyde	Alberta	8-HR TWA	.75 ppm	Irritation
Formaldehyde	British Columbia	8-HR TWA	0.3 ppm	Capable of causing respiratory, dermal or conjunctival sensitization.
Formaldehyde	Ontario	8-HR TWA	1 ppm	----
Formaldehyde	Quebec	Ceiling Exposure Value	2 ppm	----
Formaldehyde	Austria MAK List (Annex I)	TWA	.06 mg/m ³	Justifiably suspected of carcinogenic potential. Skin absorption. Sensitizer
Formaldehyde	Belgium	15-minute STEL	0.38 mg/m ³	Irritant
Formaldehyde	Denmark	Ceiling	0.4 mg/ m ³	----
Formaldehyde	Finland	8-HR Limit	.37 mg/m ³	----
Formaldehyde	France	Short Term Limit (VLE)	1 ppm	----
Formaldehyde	Greece	8-HR TWA	2.5 mg/m ³	----
Formaldehyde	Iceland	8-HR TWA	0.4 mg/ m ³	Allergenic substance
Formaldehyde	Ireland	8-HR TWA	2.5 mg/m ³	----
Formaldehyde	Italy	Ceiling limit	.3 ppm	---
Formaldehyde	Netherlands	MAC TWA	1.5 mg/m ³	----
Formaldehyde	Norway	TLV	0.6 mg/m ³	Allergenic substance
Formaldehyde	Portugal	OELs	3 ppm	Sensitizer,

				suspected human carcinogen
Formaldehyde	Spain	15-minute STEL	.37 mg/m ³	----
Formaldehyde	Sweden	Level Limit Value	0.6 mg/m ³	----
Formaldehyde	Switzerland	TWA	.37 mg/m ³	----
Formaldehyde	United Kingdom	TWA	2.5 mg/m ³	----
Montanide 888	----	----	N/A	----
Oil mist, mineral	ACGIH	8-HR TWA	5.0 mg/m ³	Lung
Oil mist (mineral)	OSHA	PEL	5.0 mg/m ³	----
Oil mist (mineral)	Belgium	8-HR TWA	5.0 mg/m ³	----
Oil mist (mineral)	Denmark	8-HR TWA	1 mg/m ³	----
Oil mist (mineral)	Finland	8-HR limit	5.0 mg/m ³	----

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.

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

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

Hand Protection: Wear suitable gloves.

Skin Protection: Wear protective clothing appropriate for the risk of exposure.

Hygiene Measures: Eye bath, washing facilities, shower

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: White

Odor: Odorless

Odor Threshold: No data available

Physical State: Liquid; Multi-dose vials: 20 mL (10 doses); 100 mL (50); 500mL (250) doses

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: None known

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Hazardous polymerization will not occur

11 TOXICOLOGICAL INFORMATION

Specified Substances

Acute Toxicity

Chemical Name	Test Results
Formaldehyde	Oral LD ₅₀ (rat): 100 mg/kg Oral LD ₅₀ (rat): 500 mg/kg Dermal LD ₅₀ (rabbit): 270 mg/kg Inhalation TCLo (rat) : 40 ppm (effects on embryo or fetus: fetotoxicity (except death, e.g., stunted fetus) Oral LD ₅₀ (mouse): 500 mg/kg Subcutaneous LD ₅₀ (mouse): 300 mg/kg Eye irritation (rabbit): 10 mg: severe irritation Eye irritation (human): 1ppm/6M rinse : mild irritation Skin irritation (human): 150µg/3D-I : mild irritation Skin irritation (rabbit) 2mg/24hr: severe irritation
Gentamicin Sulfate	Oral LD ₅₀ (rat): > 5,000 mg/kg Oral LD ₅₀ (mouse): > 11,269 mg/kg Intramuscular LD ₅₀ (rat): 245 mg/kg
Mineral Oil	Oral LD ₅₀ (rat): 22 gm/kg Eye Irritation (rabbit) : 500mg, moderate irritation Skin Irritation (guinea pig) : 100mg/24hr, mild irritation

Listed Carcinogens

Chemical Name	IARC	NTP	OSHA	ACGIH
Formaldehyde	1	Anticipated 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 and federal 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 storage disposal.

RCRA Information: EPA Hazardous U-number Formaldehyde: U122, D001.

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: Noncontrolled, exempt

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.

Canada CEPA Schedule 1 - Formaldehyde**US Regulations****CERCLA Hazardous Substance List (40 CFR 302.4):**

Component	Reportable Quantity
Formaldehyde	100 lbs

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

Component	Reportable Quantity	Threshold Planning Quantity
Formaldehyde	100 lbs	500 lbs

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Formaldehyde**State Regulations****California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**

Formaldehyde (gas)

Massachusetts Right-To-Know List: Oil mist, (mineral), Formaldehyde, Formalin

Minnesota Hazardous Substances List: Oil mist, (mineral), Formaldehyde

New Jersey Right-To-Know List: Mineral oil, Formaldehyde

Pennsylvania Right-To-Know List: Mineral oil mist, Formaldehyde

Rhode Island Right-To-Know List: Mineral oil, Formaldehyde

European Regulations

Austria MAK List (Annex I): Formaldehyde: Carcinogens Group IIIB (Justifiably suspected of carcinogenic potential-Special danger of skin absorption).

Denmark (Annex 3.6, April 2005): Carcinogens: Formaldehyde

Germany (Dangerous Substances Ordinance 2004, Annex III): Formaldehyde

Norway (List of Dangerous Substance): Formaldehyde

Sweden (Sensitizers- Annex 3): Formaldehyde

Switzerland (Toxins List 1): Formaldehyde: Toxicity Category 3

16	OTHER INFORMATION
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Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1*	0	0

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

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

Xi - Irritant

R43 - May cause sensitization by skin contact.

S24 - Avoid contact with skin.

S37 – Wear suitable gloves.

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. Formaldehyde, Gentamycin and Mineral Oil.
2. Alpha-7™ Product Label, Boehringer Ingelheim Vetmedica, Inc.
3. Alpha-7™ Clostridia Vaccine, Product Information.
www.bi-vetmedica.com/product_sites/Alpha7/reference.html
4. RTECS – Formaldehyde. RTECS No. LP8925000
5. RTECS - Gentamycin, sulfate. RTECS No. LY26225000
6. RTECS – Mineral Oil. RTECS No. PY8030000
7. Food & Drug Administration. www.fda.gov
8. GHS Manual

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

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

Issue Date: 07/07/06

Supersedes Date: 3/21/05

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MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Alpha-CD™

Product No. : N/A

MSDS ID# : 8201.02

GHS Product Identifier: Not applicable

Synonyms: Clostridium Perfringens Types C & D Toxoid

Molecular Formula: Mixture, not applicable

Molecular Weight: Not applicable

CAS Number: Mixture, not applicable

Chemical Family: Vaccine

Manufacturer:

Boehringer Ingelheim Vetmedica, Inc.

2621 North Belt Hwy

St. Joseph, MO 64506-2002

Emergency Telephone:

Transportation Emergency: (800) 424-9300

Medical Emergency (24HR): (800)530-5432

Intended Use:

Vaccination of healthy, susceptible cattle as an aid in the reduction of enterotoxemia caused by *Clostridium perfringens* Types C and D toxins.

Non-emergency Telephone: (800) 821-7467

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Liquid; Multi-dose vials: 20 mL (10 doses); 100 mL (50 doses), 500 mL (250 doses)

Color: White

Odor: Not available



WARNING!

For cattle injection only.

Not for human use.

May cause allergic skin reaction.

Precautionary Statements:

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

Keep only in original container.

Keep at a temperature not exceeding 7° 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.

Wear suitable gloves and eye/face protection.

Spills: Cover with absorbent or contain. Collect and dispose.

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.

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:

Swelling at injection site may occur.

Precautions/Contraindications:

Use entire contents when first opened. Do not vaccinate within 60 days of slaughter.

Overdosage: None known.

ADVERSE REACTIONS TO PRODUCT: Anaphylactoid reactions may occur.

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 eye irritation.

Skin Contact: Can cause hypersensitive reactions. May cause skin sensitization by contact.

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

Injection: Swelling at injection site may occur.

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

Target Organ(s): Immune System

Potential Physical Effects: Can cause skin sensitization.

OSHA Regulatory Status: Nonhazardous, exempt

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Mineral oil	2323842	8012-95-1	55	----	----
Formaldehyde	2000018	50-00-0	.5	Xi, R43	----
Gentamicin sulfate	2157789	1405-41-0	30 mcg/mL	----	----
<i>Clostridium perfringens</i> , Type C	----	68583-13-1	proprietary	----	----
<i>Clostridium perfringens</i> , Type D	----	68583-14-2	proprietary	----	----
Montanide 888	----	mixture	proprietary	----	----
Deionized water	2317912	7732-18-5	proprietary	----	----

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. 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. Get medical attention if symptoms occur.

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.

Antidote: Epinephrine is indicated for anaphylactoid reactions.

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.

Spill Cleanup Methods: Small liquid spill: Use a non-combustible material like vermiculite, earth or sand to soak up the product and place into container for later disposal. For large liquid spill: Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers.

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. Avoid accidental injection. Wash thoroughly with soap and water after handling. Use only with adequate ventilation.

Storage: Keep only in the original container. Store at 2°-7° C (35°-45° F). Avoid freezing. Keep out of reach of children. Keep away from food, drink, and animal feedstuffs.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

For Exposures:

Exposure Limits:

Chemical Name	Source	Type	Exposure Limits	Notes
<i>Clostridium perfringens</i> Type C	----	----	N/A	----
<i>Clostridium perfringens</i> Type D	----	----	N/A	----
Formaldehyde	ACGIH	8-HR TWA	0.3 ppm	Irritation, cancer
Formaldehyde	OSHA	Action Level	.75 ppm	Cancer-suspect agent
Formaldehyde	Austria	TWA	.06 mg/m ³	Justifiably suspected of carcinogenic potential. Skin absorption.

				Sensitizer
Formaldehyde	Alberta	8-HR TWA	.75 ppm	Irritation
Formaldehyde	British Columbia	8-HR TWA	0.3 ppm	Capable of causing respiratory, dermal or conjunctival sensitization.
Formaldehyde	Ontario	8-HR TWA	1 ppm	----
Formaldehyde	Quebec	Ceiling Exposure Value	2 ppm	----
Formaldehyde	Belgium	15-minute STEL	0.38 mg/m ³	Irritant
Formaldehyde	Denmark	Ceiling	0.4 mg/ m ³	----
Formaldehyde	Finland	8-HR Limit	.37 mg/m ³	----
Formaldehyde	France	Short Term Limit (VLE)	1 ppm	----
Formaldehyde	Greece	8-HR TWA	2.5 mg/m ³	----
Formaldehyde	Iceland	8-HR TWA	0.4 mg/ m ³	Allergenic substance
Formaldehyde	Ireland	8-HR TWA	2.5 mg/m ³	----
Formaldehyde	Italy	Ceiling limit	.3 ppm	---
Formaldehyde	Netherlands	MAC TWA	1.5 mg/m ³	----
Formaldehyde	Norway	TLV	0.6 mg/m ³	Allergenic substance
Formaldehyde	Portugal	OELs	3 ppm	Sensitizer, suspected human carcinogen
Formaldehyde	Spain	15-minute STEL	.37 mg/m ³	----
Formaldehyde	Sweden	Level Limit Value	0.6 mg/m ³	----
Formaldehyde	Switzerland	TWA	.37 mg/m ³	----
Formaldehyde	United Kingdom	TWA	2.5 mg/m ³	----
Gentamicin	----	----	N/A	----
Montanide 888	----	----	N/A	----
Oil mist, mineral	ACGIH	8-HR TWA	5.0 mg/m ³	Lung
Oil mist (mineral)	OSHA	PEL	5.0 mg/m ³	----
Oil mist (mineral)	Belgium	8-HR TWA	5.0 mg/m ³	----
Oil mist (mineral)	Denmark	8-HR TWA	1 mg/ m ³	----
Oil mist (mineral)	Finland	8-HR limit	5.0 mg/m ³	----

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: 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.

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

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

Hand Protection: Wear suitable gloves.

Skin Protection: Wear protective clothing appropriate for the risk of exposure.

Hygiene Measures: Eye bath, washing facilities, shower

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: White

Odor: No data available

Odor Threshold: No data available

Physical State: Liquid; Multi-dose vials: 20 mL (10 doses); 100 mL (50 doses), 500 mL (250 doses)

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: None known

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

11 TOXICOLOGICAL INFORMATION

Specified Substances

Acute Toxicity

Chemical Name	Test Results
Formaldehyde	Oral LD ₅₀ (rat): 100 mg/kg Oral LD ₅₀ (rat): 500 mg/kg Dermal LD ₅₀ (rabbit): 270 mg/kg Inhalation TCLo (rat) : 40 ppm (effects on embryo or fetus: fetotoxicity (except death, e.g., stunted fetus) Oral LD ₅₀ (mouse): 500 mg/kg Subcutaneous LD ₅₀ (mouse): 300 mg/kg Eye irritation (rabbit): 10 mg: severe irritation Eye irritation (human): 1ppm/6M rinse : mild irritation Skin irritation (human): 150µg/3D-I : mild irritation Skin irritation (rabbit) 2mg/24hr: severe irritation
Gentamicin Sulfate	Oral LD ₅₀ (rat): > 5,000 mg/kg Oral LD ₅₀ (mouse): > 11,269 mg/kg Intramuscular LD ₅₀ (rat): 245 mg/kg
Mineral Oil	Oral LD ₅₀ (rat): 22 gm/kg Eye irritation (rabbit) : 500mg, moderate irritation Skin irritation (guinea pig) : 100mg/24hr, mild irritation

Listed Carcinogens

Chemical Name	IARC	NTP	OSHA	ACGIH
Formaldehyde	1	Anticipated 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 and federal 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 storage disposal.

RCRA Information: EPA Hazardous U-number Formaldehyde: U122, D001.

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

14	TRANSPORT INFORMATION
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DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15	REGULATORY INFORMATION
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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: Noncontrolled, exempt

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.

Canada CEPA Schedule 1 - Formaldehyde

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4):

Component	Reportable Quantity
Formaldehyde	100 lbs

SARA Title III

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):

Component	Reportable Quantity	Threshold Planning Quantity
Formaldehyde	100 lbs	500 lbs

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

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

Formaldehyde (gas)

Massachusetts Right-To-Know List: Oil mist, (mineral), Formaldehyde, Formalin**Minnesota Hazardous Substances List:** Oil mist, (mineral), Formaldehyde**New Jersey Right-To-Know List:** Mineral oil, Formaldehyde**Pennsylvania Right-To-Know List:** Mineral oil mist, Formaldehyde**Rhode Island Right-To-Know List:** Mineral oil, Formaldehyde**European Regulations****Austria MAK List (Annex I):** Formaldehyde: Carcinogens Group IIIB (Justifiably suspected of carcinogenic potential-Special danger of skin absorption).**Denmark (Annex 3.6, April 2005):** Carcinogens: Formaldehyde**Germany (Dangerous Substances Ordinance 2004, Annex III):** Formaldehyde**Norway (List of Dangerous Substance):** Formaldehyde**Sweden (Sensitizers- Annex 3):** Formaldehyde**Switzerland (Toxins List 1):** Formaldehyde: Toxicity Category 3**16 OTHER INFORMATION****Hazard Ratings**

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1*	0	0

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

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

Xi - Irritant

R43 - May cause sensitization by skin contact.

S24 - Avoid contact with skin.

S37 – Wear suitable gloves.

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. Formaldehyde, Gentamycin and Mineral Oil.
2. Alpha-CD™ Product Label, Boehringer Ingelheim Vetmedica, Inc.

3. Alpha-CD™, Product Information. http://www.bi-vetmedica.com/product_sites/AlphaCD/reference.html
4. RTECS – Formaldehyde. RTECS No. LP8925000
5. RTECS - Gentamycin, sulfate. RTECS No. LY26225000
6. RTECS – Mineral Oil. RTECS No. PY8030000
7. Food & Drug Administration. www.fda.gov
8. GHS Manual

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

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