



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Calvenza™ 03 EIV/EHV (Killed Virus)

Product No.: Not applicable

MSDS ID#: 1515.2A

GHS Product Identifier: Not applicable

Synonyms:

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): (866) 638-2226

Intended Use: For the vaccination of healthy, susceptible horses 6 months of age or older, including pregnant mares, as an aid in the reduction of respiratory disease caused by equine herpesvirus type 1 (EHV-1) and type 4 (EHV-4), and by equine influenza virus types A2 North American and A2 Eurasian.

Non-emergency Telephone: (800) 821-7467

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Suspension of inactivated virus supplied in high density plastic bottles.

Color: Opaque

Odor: No data available



WARNING!

For use in horses only.

Not for human use.

Allergic reactions can occur.**Precautionary Statements:**

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

Keep only in original container.

Keep at a temperature between 2 - 7° C.

Do not freeze.

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 incinerate.

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.

Description: Recommended for the vaccination of healthy, susceptible horses 6 months of age or older, including pregnant mares, as an aid in the reduction of respiratory disease caused by equine herpesvirus type 1 (EHV-1) and type 4 (EHV-4), and by equine influenza virus types A2 North American and A2 Eurasian.

Shake well before use. Use entire contents when first opened. Using aseptic technique, inoculate horses intramuscularly with a 2 mL dose. Administer a second 2 mL dose intramuscularly in 3-4 weeks using a different injection site. Administer a third 2 mL dose in 3-4 weeks by either the intramuscular or intranasal route. Revaccinate annually and prior to anticipated exposure, by either the intramuscular or intranasal route.

Acute effect: Rarely, severe allergic reactions may occur that require immediate veterinary care. Antidote: Epinephrine.

Precautions/Contraindications: Do not vaccinate within 21 days before slaughter.

Overdosage: None known.

ADVERSE REACTIONS TO PRODUCT: Anaphylactoid reactions may occur following use.

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).

Target Organ(s): Cardiovascular system, respiratory system, skin

Potential Physical Effects: Can cause skin sensitization.

OSHA Regulatory Status: Nonhazardous

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS-No.	Concentration	Classification	Notes
Inactivated equine rhinopneumonitis-influenza virus	----	----	proprietary	----	---
Inactivated equine herpesvirus	----	----	proprietary	----	---
Gentamicin	----	----	proprietary	----	---
Thimerosal (merthiolate)	----	54-64-8	< 0.01	T+; N R26/27/28, R33, R50/53	---

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 use in horses only. Not for human use. Status of immunization should be reviewed. Emergency procedures should be symptomatic and supportive.

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, mercury

Flammability Class: 0

6 ACCIDENTAL RELEASE MEASURES

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

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. Incinerate. For large liquid spill: Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers. Incinerate.

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: Store at 2°-7° C (35°-45° F). Do not freeze. Shake well before using.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

For Industrial Exposures:

Exposure Limits: None established.

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: Air-purifying respirator with an appropriate, government approved (where applicable), air-purifying filter, cartridge or canister. Contact health and safety professional or manufacturer for specific information.

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 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: Opaque

Odor: No data available

Odor Threshold: No data available

Physical State: Solution of inactivated virus supplied in high density plastic bottles.

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: None known

Possibility of Hazardous Reactions: Will not occur.

11 TOXICOLOGICAL INFORMATION

Calvenza™ 03 EIV/EHV (Killed Virus) is considered nontoxic.

Listed Carcinogens: None

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: Not applicable

13 DISPOSAL CONSIDERATIONS

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

Disposal Methods: Incinerate containers and unused contents. 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: Noncontrolled, 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. In the United States, this product is regulated by the USDA Animal and Plant Health Inspection Service (APHIS).

Canada CEPA Schedule 1 – Mercury compounds

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4): None

SARA Title III

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None

Section 311/312 (40 CFR 370): None

Section 313 Toxic Release Inventory (40 CFR 372): None

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): None

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): None

State Regulations

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

Mercury and mercury compounds

Massachusetts Right-To-Know List: None

Minnesota Hazardous Substances List: None

New Jersey Right-To-Know List: None

Pennsylvania Right-To-Know List: None

Rhode Island Right-To-Know List: None

European Regulations

Austria MAK List (Annex I): None

Denmark (Annex 3.6, April 2005): None

Germany (Dangerous Substances Ordinance 2004, Annex III): None

Norway (List of Dangerous Substance): None

Sweden (Sensitizers- Annex 3): None

Switzerland (Toxins List 1): None

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

R and S Phrase Definitions

T+ - Very toxic.

N – Dangerous for the environment.

R26/27/28 – Very toxic by inhalation, in contact with skin and if swallowed

R33 – Danger of cumulative effects.

R50/53 – Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S(1/2) – Keep locked up and out of reach of children.

S13 – Keep away from food, drink and animal feeding stuffs.

S28 – After contact with skin, wash immediately with plenty of water and seek medical advice.

S36 – Wear suitable protective clothing.

S45 – In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S60 – This material and its container must be disposed of as hazardous waste.

S61 – Avoid release to the environment. Refer to special instructions/safety data sheets.

ABBREVIATIONS:

BIV - Boehringer Ingelheim Vetmedica, Inc.

N/A - Not applicable

N/E - Not established

pph – parts per hour

References:

1. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
2. GHS Manual
3. Calvenza™ 03 EIV/EHV (Killed Virus) Label

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

Issue Date: 2/8/2008

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 2001 Boehringer Ingelheim Vetmedica, Inc. All rights reserved.