SAFETY DATA SHEETS

This SDS packet was issued with item:

078716864

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

078378014 078423013 078431715 078717120

MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Express® FP 10
Product No.: Not applicable
MSDS ID#: 4469.23
GHS Product Identifier: Not applicable

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

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 vaccination of healthy, susceptible cattle as an aid in the reduction of respiratory diseases caused by Infectious Bovine Rhinotracheitis (IBR) virus, Bovine Virus Diarrhea (BVD) Types 1 and 2, Parainfluenza$_3$ (PI_3) virus, Bovine Respiratory Syncytial Virus (BRSV), and leptospirosis caused by *Leptospira canicola, L. grippotyphosa, L. hardjo, L. icterohaemorrhagiae,* and *L. pomona.*

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Lyophilized modified live virus is supplied in a glass vial and a solution of inactivated bacterin is supplied in a high density plastic bottle.
Color: White opaque
Odor: No data available

Obtained by Global Safety Management, Inc. (www.globalsafetynet.com)



DANGER!
Contains a component that may cause cancer.
Allergic reactions can occur.
In vaccines, chronic exposure potential is not expected.
For use in cattle 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.

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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
Bovine Rhinotracheitis Virus (modified live)	----	----	proprietary	----	---
Bovine Virus Diarrhea – Type 1 and 2 (modified live)	----	----	proprietary	----	---
Bovine Respiratory Syncytial Virus (modified live)	----	----	proprietary	----	---
Parainfluenza Type 3 (modified live)	----	----	proprietary	----	---
Leptospira canicola (inactivated bacterin)	----	----	proprietary	----	---
Leptospira grippotyphosa (inactivated bacterin)	----	----	proprietary	----	---
Leptospira hardjo (inactivated bacterin)	----	----	proprietary	----	---
Leptospira icterohaemorrhagiae (inactivated bacterin)	----	----	proprietary	----	---
Leptospira pomona (inactivated bacterin)	----	----	proprietary	----	---
Formaldehyde	200-001-8	50-00-0	< 0.2%	T; C; C3 R23/24/25, R34, R40, R43	*

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

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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.

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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.

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Hygiene Measures: Eye bath, washing facilities

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: White opaque
Odor: No data available
Odor Threshold: No data available
Physical State: Lyophilized modified live virus is supplied in a glass vial and a solution of inactivated bacterin is supplied in a high density plastic bottle.
pH: 6.5 – 7.5
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

Express® FP 10 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

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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

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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)	[X]	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

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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

References:

1. Express® FP 10 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.
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