

SAFETY DATA SHEET

1. Identification

Product identifier	FLEXMycoPRRS
Other means of identification	
Product code	APHIS Code- 49R8.21, Family Code - 780
Recommended use	Veterinary Vaccine
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	Boehringer Ingelheim Vetmedica, Inc.
Address	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 calls:	(800) 821-7467

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Sensitization, skin	Category 1
	Carcinogenicity	Category 1
OSHA defined hazards	Not classified.	

Label elements



Signal word	Danger
Hazard statement	May cause cancer. May cause an allergic skin reaction.
Precautionary statement	
Prevention	Avoid breathing mist or vapor. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. Do not handle until all safety precautions have been read and understood. Obtain special instructions before use.
Response	If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Storage	Store away from incompatible materials. Keep at a temperature between 2 - 7°C Do not freeze. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Contains formaldehyde. May produce an allergic reaction.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
*Formaldehyde	50-00-0	<= 0.74 g/L

Inactivated bacterin - Mycoplasma hyopneumoniae	Proprietary
Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) Modified live virus	Proprietary

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

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	May cause an allergic skin reaction. Dermatitis. Rash. Ingestion of a large quantity may cause vomiting, nausea, dizziness, drowsiness and other systemic effects. Swelling at injection site may occur.
Indication of immediate medical attention and special treatment needed	Not for human use. For use in animals only. Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. Persons developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.
General information	Persons developing anaphylactic (life threatening) reactions, such as a as difficulty in breathing or unconsciousness, must receive immediate medical attention. If anaphylactoid reactions occur, epinephrine may be used as an antidote.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed. Combustion products may include: carbon monoxide and carbon dioxide.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.
Environmental precautions	Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Shake well before using. Avoid accidental injection. Do not handle until all safety precautions have been read and understood. Obtain special instructions before use.
Conditions for safe storage, including any incompatibilities	Keep away from food, drink and animal feedingstuffs. Store at 2°-7° C (35°-45° F). Do not freeze.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Components	Type	Value
*Formaldehyde (CAS 50-00-0)	STEL	2 ppm
	TWA	0.75 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
*Formaldehyde (CAS 50-00-0)	STEL	0.3 ppm
	TWA	0.1 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
*Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm
	TWA	0.016 ppm

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Not generally required when handling vials or containers. 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.

Individual protection measures, such as personal protective equipment

Eye/face protection

Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection

Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear suitable gloves.

Other

Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear lab coat, apron or appropriate clothing to prevent skin contact.

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 29 CFR 1910.134. Respirator type: NIOSH approved organic vapor respirator.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Contains two liquid solutions: One solution is clear to slightly turbid rose to brown liquid. Other solution is a cloudy colored liquid.

Physical state

Liquid.

Form

Liquid.

Color

Not available.

Odor

Not available.

Odor threshold

Not available.

pH

6 - 8

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Temperatures below 2°C.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation May cause inhalation hypersensitivity (occupational asthma) in sensitive individuals.

Skin contact May cause an allergic skin reaction.

Eye contact Direct contact with eyes may cause temporary irritation.

Ingestion Ingestion may cause irritation and stomach discomfort.

Symptoms related to the physical, chemical and toxicological characteristics May cause an allergic skin reaction. Dermatitis. Rash. Ingestion of a large quantity may cause vomiting, nausea, dizziness, drowsiness and other systemic effects. Swelling at injection site may occur.

Information on toxicological effects

Acute toxicity May cause an allergic skin reaction.

Components	Species	Test Results
------------	---------	--------------

*Formaldehyde (CAS 50-00-0)

Acute

Dermal

LD50	Rat	270 mg/kg
------	-----	-----------

Inhalation

LC50	Rat	0.578 mg/l, 4 hours
------	-----	---------------------

Oral

LD50	Rat	100 mg/kg
------	-----	-----------

Skin corrosion/irritation May cause an allergic skin reaction.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

ACGIH sensitization

FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization
----------------------------	----------------------

Respiratory sensitization

Respiratory sensitization Exposure to formaldehyde may cause respiratory sensitization in some individuals or aggravate pre-existing asthmatic conditions.

Skin sensitization May cause an allergic skin reaction.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity Contains a component that is listed as an IARC 1 (Known Human Carcinogen), a NTP Known Carcinogen and an ACGIH A2 (Suspected Human Carcinogen). In vaccines, the chronic exposure potential is negligible.

IARC Monographs. Overall Evaluation of Carcinogenicity

*Formaldehyde (CAS 50-00-0) 1 Carcinogenic to humans.

NTP Report on Carcinogens

*Formaldehyde (CAS 50-00-0) Known To Be Human Carcinogen.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

*Formaldehyde (CAS 50-00-0) Cancer

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure No data available.

Specific target organ toxicity - repeated exposure No data available.

Aspiration hazard Not classified, however droplets of the product may be aspirated into the lungs through ingestion or vomiting and may cause a serious chemical pneumonia.

Chronic effects Possible hyper sensitization (development of abnormal sensitivity).

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components	Species	Test Results
*Formaldehyde (CAS 50-00-0)		
Aquatic		
Crustacea	EC50 Water flea (<i>Daphnia pulex</i>)	4.3 - 7.8 mg/l, 48 hours
Fish	LC50 Striped bass (<i>Morone saxatilis</i>)	10.302 - 16.743 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol / water (log Kow)

*Formaldehyde (CAS 50-00-0) 0.35

Mobility in soil Diluent and end-product expected to be slightly to moderately mobile in soil.

Other adverse effects This product contains one or more substances identified as hazardous air pollutants (HAPs) per the US Federal Clean Air Act (see section 15).

13. Disposal considerations

Disposal instructions This material and its container must be disposed of in a safe way. Burn container and all unused contents. Do not discharge into drains, water courses or onto the ground. Do not contaminate water, food, or feed by disposal.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.**15. Regulatory information****US federal regulations**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
 One or more components are not listed on TSCA.
 Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.
FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

*Formaldehyde (CAS 50-00-0) Listed.

SARA 304 Emergency release notification

*Formaldehyde (CAS 50-00-0) 100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

*Formaldehyde (CAS 50-00-0)
 Cancer
 Skin sensitization
 Respiratory sensitization
 Eye irritation
 Skin irritation
 respiratory tract irritation
 Acute toxicity
 Flammability

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
*Formaldehyde	50-00-0	100	500		

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Respiratory or skin sensitization
 Carcinogenicity

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
*Formaldehyde	50-00-0	<= 0.74 g/L

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

*Formaldehyde (CAS 50-00-0)

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

*Formaldehyde (CAS 50-00-0)

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****US. Massachusetts RTK - Substance List**

*Formaldehyde (CAS 50-00-0)

US. New Jersey Worker and Community Right-to-Know Act

*Formaldehyde (CAS 50-00-0)

US. Pennsylvania Worker and Community Right-to-Know Law

*Formaldehyde (CAS 50-00-0)

US. Rhode Island RTK

*Formaldehyde (CAS 50-00-0)

California Proposition 65



WARNING: This product can expose you to *Formaldehyde, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Carcinogenic substance

*Formaldehyde (CAS 50-00-0)

Listed: January 1, 1988

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

*Formaldehyde (CAS 50-00-0)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	20-April-2017
Revision date	12-February-2018
Version #	02
HMIS® ratings	Health: 2 Flammability: 0 Physical hazard: 0

NFPA ratings



Disclaimer

The information provided herein is offered by Boehringer Ingelheim Vetmedica, Inc. ("BIVI") 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 BIVI, and which BIVI 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. ("BIVI") expressly disclaims all liability for reliance thereon. BIVI 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 BIVI's control, ALL RISKS OF USE OF THE PRODUCT ARE THEREFORE ASSUMED BY THE USER, AND BIVI 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. BIVI 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.