

## 1. Identification

<b>Product identifier</b>	<b>3FLEX®</b>
<b>Other means of identification</b>	
<b>Product code</b>	APHIS Code – 49K9.R0 , Family Code - 299
<b>Recommended use</b>	Vaccine for use in animals.
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Manufacturer</b>	Boehringer Ingelheim Vetmedica, Inc.
<b>Address</b>	2621 North Belt Hwy St. Joseph, MO 64506-2002
<b>Transportation emergency</b>	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)
<b>Medical Emergency (24HR):</b>	(866)638-2226
<b>Non-Emergency calls:</b>	(800) 821-7467

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Sensitization, skin	Category 1
	Carcinogenicity	Category 1
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



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

## 3. Composition/information on ingredients

### Mixtures

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

Inactivated bacterin - Mycoplasma hyopneumoniae	Proprietary
Inactivated baculo-expressed PCV2 ORf2	Proprietary
Porcine Reproductive & Respiratory Syndrome-Circovirus, Reproductive & Respiratory Form, Type 2 (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

<b>Inhalation</b>	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.
<b>Skin contact</b>	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.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	May cause an allergic skin reaction. Dermatitis. Rash. Ingestion of a large quantity may cause vomiting, nausea, dizziness, drowsiness and other systemic effects.
<b>Indication of immediate medical attention and special treatment needed</b>	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.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

#### 5. Fire-fighting measures

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

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	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. 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.
<b>Environmental precautions</b>	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

Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Use care in handling/storage.

### Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store away from foodstuffs. Store in the dark at 2°C to 7°C (35°F to 45°F). Avoid freezing. Shake Well. Protect from direct sunlight. Store away from incompatible materials, see Section 10 of the SDS.

## 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

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. Not normally needed.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

#### Skin protection

##### Hand protection

Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier. Wear protective gloves.

##### Skin protection

##### Other

Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended. Wear protective gloves.

#### Respiratory protection

None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

#### 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. 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. Contaminated work clothing should not be allowed out of the workplace.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Liquid.
<b>Form</b>	Modified live viruses supplied in a glass vial and two solutions of inactivated vaccines.
<b>Color</b>	Clear to slightly turbid brown

**Odor** Not available.

**Odor threshold** Not available.

**pH** Not available.

**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.

### Other information

**Explosive properties** Not explosive.

**Oxidizing properties** Not oxidizing.

## 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** Contact with incompatible materials. Excessive heat. Keep from freezing.

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition products** No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

**Inhalation** No adverse effects due to inhalation are expected.

**Skin contact** May cause an allergic skin reaction.

**Eye contact** Direct contact with eyes may cause temporary irritation.

**Ingestion** Expected to be a low ingestion hazard.

**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.

### Information on toxicological effects

<b>Acute toxicity</b>	May cause an allergic skin reaction.		
<b>Components</b>	<b>Species</b>	<b>Test Results</b>	
Formaldehyde (CAS 50-00-0)			
<b>Acute</b>			
<b>Dermal</b>			
LD50	Rat	270 mg/kg	
<b>Inhalation</b>			
LC50	Rat	0.578 mg/l, 4 hours	
<b>Oral</b>			
LD50	Rat	100 mg/kg	
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.		
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation.		
<b>Respiratory or skin sensitization</b>			
<b>ACGIH sensitization</b>			
FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization		Respiratory sensitization
<b>Respiratory sensitization</b>	Not a respiratory sensitizer.		
<b>Skin sensitization</b>	May cause an allergic skin reaction.		
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.		
<b>Carcinogenicity</b>	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.		
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>			
Formaldehyde (CAS 50-00-0)	1 Carcinogenic to humans.		
<b>NTP Report on Carcinogens</b>			
Formaldehyde (CAS 50-00-0)	Known To Be Human Carcinogen.		
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)</b>			
Formaldehyde (CAS 50-00-0)	Cancer		
<b>Reproductive toxicity</b>	This product is not expected to cause reproductive or developmental effects.		
<b>Specific target organ toxicity - single exposure</b>	Not classified.		
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.		
<b>Aspiration hazard</b>	Not an aspiration hazard.		
<b>Chronic effects</b>	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)			
<b>Aquatic</b>			
Crustacea	EC50	Water flea (Daphnia pulex)	4.3 - 7.8 mg/l, 48 hours
Fish	LC50	Striped bass (Morone saxatilis)	10.302 - 16.743 mg/l, 96 hours
<b>Persistence and degradability</b>	No data is available on the degradability of this product.		
<b>Bioaccumulative potential</b>			
<b>Partition coefficient n-octanol / water (log Kow)</b>			
Formaldehyde (CAS 50-00-0)	0.35		
<b>Mobility in soil</b>	Diluent and end-product expected to be slightly to moderately mobile in soil.		
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.		

### 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	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

<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	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](http://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)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
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**

<b>Issue date</b>	24-January-2017
<b>Revision date</b>	24-January-2017
<b>Version #</b>	02
<b>Further information</b>	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the American Coatings Association (ACA). A HMIS® Health rating including an * indicates a chronic hazard.

**HMIS® ratings**

Health: 2\*  
Flammability: 0  
Physical hazard: 0

**NFPA ratings****Disclaimer**

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