

## 1. Identification

<b>Product identifier</b>	<b>FLEXcombo®</b>
<b>Other means of identification</b>	
<b>Product code</b>	APHIS Code- 49K5.R1, Family Code - 295
<b>Recommended use</b>	Veterinary Vaccine
<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.	

### Label elements



<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. Do not handle until all safety precautions have been read and understood. 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.
<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>	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
Additives	Proprietary	Proprietary

Inactivated bacterin - Mycoplasma hyopneumoniae	Proprietary
Inactivated baculo-expressed PCV2 ORf2	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. Swelling at injection site may occur.
<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>	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

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed. Combustion products may include: carbon monoxide and carbon dioxide.
<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. 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.
<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. 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.
<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

<b>Precautions for safe handling</b>	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.
<b>Conditions for safe storage, including any incompatibilities</b>	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

Liquid solution of inactivated bacterin.

#### Physical state

Liquid.

#### Form

Liquid.

#### Color

Clear to yellow to slightly turbid rose to 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.

**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
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\*Formaldehyde (CAS 50-00-0)

**Acute****Dermal**

LD50	Rat	270 mg/kg
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**Inhalation**

LC50	Rat	0.578 mg/l, 4 hours
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**Oral**

LD50	Rat	100 mg/kg
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**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

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

#### 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

<b>Reproductive toxicity</b>	This product is not expected to cause reproductive or developmental effects.
<b>Specific target organ toxicity - single exposure</b>	No data available.
<b>Specific target organ toxicity - repeated exposure</b>	No data available.
<b>Aspiration hazard</b>	Not classified, however droplets of the product may be aspirated into the lungs through ingestion or vomiting and may cause a serious chemical pneumonia.
<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 ( <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](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)	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	22-May-2017
Revision date	12-February-2018
Version #	02
HMIS® ratings	Health: 2 Flammability: 0 Physical hazard: 0

## NFPA ratings



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