

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Fostera PCV MH</b>
<b>Other means of identification</b>	None.
<b>Recommended use</b>	Veterinary vaccine
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name (USA)</b>	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
<b>Rocky Mountain Poison and Drug Center</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-888-963-8471
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (CA)</b>	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
<b>Emergency telephone number</b>	International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	productsupport@zoetis.com
<b>Product Support</b>	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

**Supplier** Not available.

## 2. Hazard identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Not classified.

### Label elements

<b>Hazard symbol</b>	None.
<b>Signal word</b>	None.
<b>Hazard statement</b>	The mixture does not meet the criteria for classification.
<b>Precautionary statement</b>	
<b>Prevention</b>	Observe good industrial hygiene practices.
<b>Response</b>	Wash hands after handling.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of waste and residues in accordance with local authority requirements.

**Supplemental information** Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an allergic reaction may occur. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

**Other hazards** None known.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Formaldehyde		50-00-0	<0.03
Thimerosal		54-64-8	<0.01
Chimeric Porcine Circovirus (cPCV) 1-2		Not assigned	
Gentamicin		1403-66-3	##
Mycoplasma Hypopneumoniae		Not assigned	

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

**Composition comments** ## Trace

#### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
<b>Skin contact</b>	In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
<b>Ingestion</b>	Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
<b>Most important symptoms/effects, acute and delayed</b>	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically. Symptoms may be delayed. Where parenteral oil-adjuvanted vaccine exposure has occurred, the patient should be promptly evaluated for the development of vasospasm and/or compartment syndrome.
<b>General information</b>	For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

#### 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>	Do not use water jet as an extinguisher, as this will spread the fire.
<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. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained.
<b>Methods and materials for containment and cleaning up</b>	Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination.  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

Wear appropriate personal protective equipment. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Wash contaminated clothing before reuse. Avoid release to the environment.

### Conditions for safe storage, including any incompatibilities

Store in a cool, dry place out of direct sunlight. @ 2 - 8°C (36 - 46°F). Do not allow material to freeze. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. ACGIH Threshold Limit Values

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	0.3 ppm
	TWA	0.1 ppm
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3

#### Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	1.3 mg/m3
		1 ppm
	TWA	0.9 mg/m3
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
		0.75 ppm

#### Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	0.3 ppm
	TWA	0.1 ppm
Thimerosal (CAS 54-64-8)	Ceiling	0.1 mg/m3
	STEL	0.03 mg/m3

#### Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	0.3 ppm
	TWA	0.1 ppm
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3

#### Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	1.5 ppm
	STEL	1 ppm
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3

#### Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	3 mg/m3
		2 ppm
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3

**Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)**

<b>Components</b>	<b>Type</b>	<b>Value</b>
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).	
<b>Control banding approach</b>	Gentamicin: Zoetis OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3)	
<b>Appropriate engineering controls</b>	Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate.	
<b>Individual protection measures, such as personal protective equipment</b>		
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.	
<b>Skin protection</b>		
<b>Hand protection</b>	Wear appropriate chemical resistant gloves.	
<b>Other</b>	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.	
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment.	
<b>Thermal hazards</b>	Not applicable.	
<b>General hygiene considerations</b>	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**

<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Colour</b>	Pale to milky white

**Odour** Not available.

**Odour 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**

**Explosive limit - lower (%)** Not available.

**Explosive limit – upper (%)** Not available.

**Vapour pressure** Not available.

**Vapour 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.

**Oxidising properties** Not oxidising.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidising agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

**Inhalation** Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

**Skin contact** Prolonged skin contact may cause temporary irritation.  
Formaldehyde Species: Rabbit  
Severity: Moderate Severe

**Eye contact** Direct contact with eyes may cause temporary irritation.  
Thimerosal Species: Rabbit  
Severity: Mild

Gentamicin Species: Rabbit  
Severity: Non-irritating

Formaldehyde Species: Rabbit  
Severity: Severe

**Ingestion** May cause discomfort if swallowed. Expected to be a low ingestion hazard.

**Symptoms related to the physical, chemical and toxicological characteristics** Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

### Information on toxicological effects

**Acute toxicity** Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	800 mg/kg
<b>Chronic</b>		
<b>Inhalation</b>		
LOAEL	Mouse	15 ppm, 2 years Tumours
	Rat	15 ppm, 9 days Respiratory system
		6 ppm, 2 years Tumours
Gentamicin (CAS 1403-66-3)		
<b>Acute</b>		
<b>Intramuscular</b>		
LD50	Mouse	167 mg/kg
	Rat	463 mg/kg

Components	Species	Test Results
<b>Oral</b>		
LD50	Rat	6600 mg/kg
<b>Subcutaneous</b>		
LD50	Rat	710 mg/kg
Thimerosal (CAS 54-64-8)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	75 mg/kg
<b>Subcutaneous</b>		
LD50	Rat	98 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>Eye contact</b>		
Thimerosal	Species: Rabbit Severity: Mild	
Gentamicin	Species: Rabbit Severity: Non-irritating	
Formaldehyde	Species: Rabbit Severity: Severe	
<b>Respiratory or skin sensitisation</b>		
<b>ACGIH sensitisation</b>		
Formaldehyde (CAS 50-00-0)	Dermal sensitisation Respiratory sensitisation	
<b>Canada - Manitoba OELs Hazard: Dermal sensitization</b>		
Formaldehyde (CAS 50-00-0)	Dermal sensitisation	
<b>Canada - Manitoba OELs Hazard: Respiratory sensitization</b>		
Formaldehyde (CAS 50-00-0)	Respiratory sensitisation	
<b>Canada - Saskatchewan OELs Hazard Data: Sensitiser</b>		
Formaldehyde (CAS 50-00-0)	Sensitiser.	
<b>Respiratory sensitisation</b>	Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur.	
<b>Skin sensitisation</b>	Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur.	
<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>Mutagenicity</b>		
Formaldehyde	In Vitro Bacterial Mutagenicity (Ames) Result: positive Species: Bacteria	
	In Vitro Chromosome Aberration Result: positive Species: Rodent	
	In Vitro Sister Chromatid Exchange Result: positive Species: Rodent	
	In Vivo Chromosome Aberration Result: positive Species: Not specified	
<b>Carcinogenicity</b>	Due to partial or complete lack of data the classification is not possible. No data available to indicate product or any components present at greater than 0.1% are carcinogenic.	

### ACGIH Carcinogens

Formaldehyde (CAS 50-00-0)

A1 Confirmed human carcinogen.

### Canada - Alberta OELs: Carcinogen category

Formaldehyde (CAS 50-00-0)

Suspected human carcinogen.

### Canada - Manitoba OELs: carcinogenicity

Formaldehyde (CAS 50-00-0)

Confirmed human carcinogen.

### Canada - Quebec OELs: Carcinogen category

Formaldehyde (CAS 50-00-0)

Suspected carcinogenic effect in humans.

### IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0)

1 Carcinogenic to humans.

### US. National Toxicology Program (NTP) Report on Carcinogens

Formaldehyde (CAS 50-00-0)

Known To Be Human Carcinogen.

### Reproductive toxicity

Based on available data, the classification criteria are not met. This product is not expected to cause reproductive or developmental effects.

### Developmental effects

Formaldehyde

185 mg/kg/day Embryo / Fetal Development, Not teratogenic  
Maternal toxicity  
Species: Mouse  
Organ: Oral

40 ppm Embryo / Fetal Development, Not Teratogenic  
Maternal Toxicity  
Species: Rat  
Organ: Inhalation

Gentamicin

75 mg/kg/day Embryo / Fetal Development, Developmental toxicity  
Result: LOAEL  
Species: Rat  
Organ: Intramuscular

### Specific target organ toxicity - single exposure

Not classified.

### Specific target organ toxicity - repeated exposure

Not classified.

### Aspiration hazard

Not an aspiration hazard.

### Further information

The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms.

## 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. Avoid release to the environment.

Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50 Water flea ( <i>Daphnia pulex</i> )	>= 4.3 - <= 7.8 mg/l, 48 hours
Fish	LC50 Bluegill ( <i>Lepomis macrochirus</i> )	8.7 mg/l, 96 hours
<b>Persistence and degradability</b>	No data is available on the degradability of this product.	
<b>Bioaccumulative potential</b>	No data available for this product.	
<b>Mobility in soil</b>	No data available.	
<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>	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. 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>	This product contains trace quantities of mercury, releases to the environment should be avoided.
<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.
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

<b>TDG</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not established.

### 15. Regulatory information

<b>Canadian regulations</b>	This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.	
<b>Controlled Drugs and Substances Act</b>	Not regulated.	
<b>Export Control List (CEPA 1999, Schedule 3)</b>	Thimerosal (CAS 54-64-8)	Substance subject to notification or consent.
<b>Greenhouse Gases</b>	Not listed.	
<b>Ontario. Toxic Substances. Toxic Reduction Act, 2009. Regulation 455/09 (July 1, 2011)</b>	Formaldehyde (CAS 50-00-0)	
	Thimerosal (CAS 54-64-8)	
<b>Precursor Control Regulations</b>	Not regulated.	
<b>International regulations</b>		
<b>Stockholm Convention</b>	Not applicable.	
<b>Rotterdam Convention</b>	Thimerosal (CAS 54-64-8)	Pesticide
<b>Kyoto Protocol</b>	Not applicable.	
<b>Montreal Protocol</b>	Not applicable.	
<b>Basel Convention</b>	Not applicable.	

#### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No



<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
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 that all components of this product comply 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

**Issue date** 06-March-2017

**Revision date** 21-June-2022

**Version No.** 02

**Disclaimer** Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.

**Revision information** This document has undergone significant changes and should be reviewed in its entirety.