

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Fostera PCV with Metastim</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	FOSTERA™ * Fostera PCV MetaStim * Fostera® PCV MetaStim® * Porcine Circovirus Vaccine, Type 1-Type 2 Chimera, Killed Virus
<b>Recommended use</b>	Veterinary vaccine
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name (US)</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>	1-800-366-5288
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300  International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (EU)</b>	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
<b>Emergency telephone number</b>	International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	VMIPSrecords@zoetis.com

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.
<b>Label elements</b>	
<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.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	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.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Tetrasodium EDTA, dihydrate		10378-23-1	<1
Chimeric Porcine Circovirus (cPCV) 1-2		Not Assigned	
Gentamicin		1403-66-3	##
Merthiolate (as mercury)		54-64-8	##
Phosphate Buffered Saline		Mixture	
Sodium borate		1303-96-4	##

**Composition comments**      ## Trace  
 In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

#### 4. First-aid measures

**Inhalation**      Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

**Skin contact**      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.

**Eye contact**      Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.

**Ingestion**      Rinse mouth. 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.

**Most important symptoms/effects, acute and delayed**      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.

**Indication of immediate medical attention and special treatment needed**      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.

**General information**      IF exposed or concerned: Get medical advice/attention. 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

**Suitable extinguishing media**      Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

**Unsuitable extinguishing media**      Do not use water jet as an extinguisher, as this will spread the fire.

**Specific hazards arising from the chemical**      During fire, gases hazardous to health may be formed.

**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. Wear appropriate protective equipment and clothing during clean-up. 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. 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.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

**Precautions for safe handling** Avoid accidental injection. Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapor. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment.

**Conditions for safe storage, including any incompatibilities** Store out of direct sunlight in dark, dry conditions. @ 2 - 7°C (36 - 45°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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

#### US. OSHA Table Z-2 (29 CFR 1910.1000)

Components	Type	Value
Merthiolate (as mercury) (CAS 54-64-8)	Ceiling	0.04 mg/m3
	TWA	0.01 mg/m3

#### US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	
Sodium borate (CAS 1303-96-4)	STEL	6 mg/m3	Inhalable fraction.
	TWA	2 mg/m3	Inhalable fraction.

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3
Sodium borate (CAS 1303-96-4)	TWA	5 mg/m3

**Biological limit values** No biological exposure limits noted for the ingredient(s).

### Exposure guidelines

#### US - California OELs: Skin designation

Merthiolate (as mercury) (CAS 54-64-8) Can be absorbed through the skin.

#### US - Tennessee OELs: Skin designation

Merthiolate (as mercury) (CAS 54-64-8) Can be absorbed through the skin.

#### US ACGIH Threshold Limit Values: Skin designation

Merthiolate (as mercury) (CAS 54-64-8) Can be absorbed through the skin.

#### US NIOSH Pocket Guide to Chemical Hazards: Skin designation

Merthiolate (as mercury) (CAS 54-64-8) Can be absorbed through the skin.

**Control banding approach** Gentamicin: Zoetis OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3)

**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. General ventilation normally adequate.

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

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended.

#### Skin protection

**Hand protection** Wear appropriate chemical resistant gloves.

**Other** 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. 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.
<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>Color</b>	Pale - Milky. White.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.

### Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.

<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 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. Sunlight. Exposure to light. High temperatures. Do not allow material to freeze.
<b>Incompatible materials</b>	Strong oxidizing agents. This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.

**Hazardous decomposition products**

No hazardous decomposition products are known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

**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.

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

Merthiolate (as mercury) Species: Rabbit  
Severity: Mild

Gentamicin Species: Rabbit  
Severity: Non-irritating

**Ingestion** 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
Gentamicin (CAS 1403-66-3)		
<b>Acute</b>		
<b>Intramuscular</b>		
LD50	Mouse	167 mg/kg
	Rat	463 mg/kg
<b>Oral</b>		
LD50	Rat	6600 mg/kg
<b>Subcutaneous</b>		
LD50	Rat	710 mg/kg
Merthiolate (as mercury) (CAS 54-64-8)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	75 mg/kg
<b>Subcutaneous</b>		
LD50	Rat	98 mg/kg
Sodium borate (CAS 1303-96-4)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	396 mg/kg

**Skin corrosion/irritation** Prolonged skin contact may cause temporary irritation.

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

**Eye Contact**

Merthiolate (as mercury) Species: Rabbit  
Severity: Mild

Gentamicin Species: Rabbit  
Severity: Non-irritating

## Respiratory or skin sensitization

**Respiratory sensitization** Due to partial or complete lack of data the classification is not possible. In the event of accidental injection, an allergic reaction may occur.

**Skin sensitization** Due to partial or complete lack of data the classification is not possible. This product contains merthiolate which is considered to be a skin sensitizer. In the event of accidental injection, an allergic reaction may occur.

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

**Carcinogenicity** No data available to indicate product or any components present at greater than 0.1% are carcinogenic. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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

Not listed.

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

#### Developmental effects

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

Tetrasodium EDTA, dihydrate (CAS 10378-23-1)

#### Aquatic

Fish

LC50

Bluegill (*Lepomis macrochirus*)

472 - 500 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. Not expected to bioaccumulate.

**Mobility in soil** No data available.

**Other adverse effects** 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

### Disposal instructions

Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. 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. This product contains trace quantities of mercury and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP).

**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** 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 not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**  
Not regulated.

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Merthiolate (as mercury) (CAS 54-64-8)

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

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations** WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

#### US - California Proposition 65 - CRT: Listed date/Developmental toxin

Merthiolate (as mercury) (CAS 54-64-8) Listed: July 1, 1990

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

Sodium borate (CAS 1303-96-4)

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No

Country(s) or region	Inventory name	On inventory (yes/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
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, including date of preparation or last revision

<b>Issue date</b>	03-06-2017
<b>Revision date</b>	03-26-2018
<b>Version #</b>	02
<b>Disclaimer</b>	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.
<b>Revision information</b>	This document has undergone significant changes and should be reviewed in its entirety.