

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>FluSure™ XP/Farrowsure® GOLD B</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	FluSure XP / Farrowsure GOLD B * Parvovirus-Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Bratislava-Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
<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>	1-800-366-5288
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (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(s) 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.

### Precautionary statement

<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.

**Other hazards** None known.

**Supplemental information** Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an allergic reaction may occur. Contains Formaldehyde. May produce an allergic reaction. 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	%
Aluminum hydroxide gel		21645-51-2	1-3
Formaldehyde		50-00-0	<0.1
Erysipelothrix rhusiopathiae		Not assigned	*
Gentamicin		1403-66-3	##
Leptospira bratislava		Not assigned	*
Leptospira canicola		Not assigned	*
Leptospira grippotyphosa		Not assigned	*
Leptospira hardjo		Not assigned	*
Leptospira icterohaemorrhagiae		Not assigned	*
Leptospira pomona		Not assigned	*
Porcine Parvovirus		Not assigned	*
Swine Influenza Virus A, strain H1N1		Not assigned	*
Swine Influenza Virus A, strain H3N2		Not assigned	*

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

**Composition comments** \* Non-hazardous Ingredients  
## Trace

### 4. First-aid measures

#### Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

#### 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 centre 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.

#### Indication of immediate medical attention and special treatment needed

Treat symptomatically. 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

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 (CO<sub>2</sub>).

#### 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

Use water spray to cool unopened containers.

#### 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. 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. 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.

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.

### Environmental precautions

## 7. Handling and storage

### Precautions for safe handling

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

### Conditions for safe storage, including any incompatibilities

Store away from direct sunlight. @ 2 - 7°C (36 - 45°F). Do not freeze. Store in original tightly closed container. Keep away from heat, sparks and open flame. 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	Form
Aluminum hydroxide gel (CAS 21645-51-2)	TWA	1 mg/m <sup>3</sup>	Respirable fraction.
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	

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

Components	Type	Value	Form
Aluminum hydroxide gel (CAS 21645-51-2)	TWA	3 mg/m <sup>3</sup>	Respirable particles.
		10 mg/m <sup>3</sup>	Total particulate.
Formaldehyde (CAS 50-00-0)	Ceiling	1.3 mg/m <sup>3</sup>	
	TWA	1 ppm	
		0.9 mg/m <sup>3</sup>	
		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)	Ceiling	1 ppm
	TWA	0.3 ppm

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

Components	Type	Value	Form
Aluminum hydroxide gel (CAS 21645-51-2)	TWA	1 mg/m <sup>3</sup>	Respirable fraction.
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	

#### 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

**Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)**

Components	Type	Value	Form
Aluminum hydroxide gel (CAS 21645-51-2)	TWA	10 mg/m3	Total dust.
Formaldehyde (CAS 50-00-0)	Ceiling	3 mg/m3	
		2 ppm	

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

Components	Type	Value
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>	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. 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 impervious gloves if skin contact is possible.
<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. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. 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**

<b>Appearance</b>	Freeze-dried preparation plus liquid bacterin
<b>Physical state</b>	Solid, Liquid.
<b>Form</b>	Solid. Liquid.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour 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 available.
<b>Upper/lower flammability or explosive limits</b>	
<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>Vapour pressure</b>	Not available.
<b>Vapour 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>Oxidising properties</b>	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. Sunlight. High temperatures. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
<b>Incompatible materials</b>	Strong oxidising agents. This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	No adverse effects due to inhalation are expected.
<b>Skin contact</b>	Prolonged skin contact may cause temporary irritation.
Formaldehyde	Species: Rabbit Severity: Moderate Severe
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
Gentamicin	Species: Rabbit Severity: Non-irritating
Formaldehyde	Species: Rabbit Severity: Severe

**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, 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.

### 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
Aluminum hydroxide gel (CAS 21645-51-2)		
<b>Acute</b>		
<b>Other</b>		
LD50	Rat	150 mg/kg
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
<b>Oral</b>		
LD50	Rat	6600 mg/kg
<b>Subcutaneous</b>		
LD50	Rat	710 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>		
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 sensitization Respiratory sensitisation	
<b>Canada - British Columbia OELs: Respiratory or skin sensitiser</b>		
Formaldehyde (CAS 50-00-0)	Capable of causing respiratory, dermal or conjunctival sensitization.	
<b>Canada - Manitoba OELs Hazard: Dermal sensitization</b>		
Formaldehyde (CAS 50-00-0)	Dermal sensitization	
<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>	Not a respiratory sensitizer.	
<b>Skin sensitisation</b>	This product is not expected to cause skin sensitisation.	
<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	

**Mutagenicity**  
Formaldehyde

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

**Carcinogenicity**

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. No known carcinogens are present at greater than 0.1%.

**ACGIH Carcinogens**

Aluminum hydroxide gel (CAS 21645-51-2)  
Formaldehyde (CAS 50-00-0)

A4 Not classifiable as a human carcinogen.  
A2 Suspected human carcinogen.

**Canada - Alberta OELs: Carcinogen category**

Formaldehyde (CAS 50-00-0)

Suspected human carcinogen.

**Canada - Manitoba OELs: carcinogenicity**

Aluminum hydroxide gel (CAS 21645-51-2)  
Formaldehyde (CAS 50-00-0)

Not classifiable as a human carcinogen.  
Suspected 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**

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**

Allergic reactions are possible. The antigens included in this product are non-infectious. All have been prepared from modified or inactivated preparations of microorganisms. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

**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>		
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>	No data available.	
<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>	None known.
<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>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

#### TDG

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

**Canadian regulations** 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.

#### Controlled Drugs and Substances Act

Not regulated.

#### Export Control List (CEPA 1999, Schedule 3)

Not listed.

#### Greenhouse Gases

Not listed.

#### Ontario. Toxic Substances. Toxic Reduction Act, 2009. Regulation 455/09 (July 1, 2011)

Formaldehyde (CAS 50-00-0)

#### Precursor Control Regulations

Not regulated.

#### International regulations

##### Stockholm Convention

Not applicable.

##### Rotterdam Convention

Not applicable.



**Kyoto protocol**

Not applicable.

**Montreal Protocol**

Not applicable.

**Basel Convention**

Not applicable.

**International Inventories**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
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
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** 15-April-2017**Version No.** 01

**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** Product and Company Identification: Synonyms  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties: Multiple Properties