

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078912828

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

078912869



# MATERIAL SAFETY DATA SHEET

Revision date: 06-Dec-2006

Version: 1.6

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health  
Pfizer Inc  
235 East 42nd Street  
New York, NY 10017  
Poison Control Center Phone: 1-866-531-8896  
Technical Services Phone: 1-800-366-5288

Pfizer Ltd,  
Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified Live Virus-Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin**

Trade Name: **Bovi-Shield GOLD(R) FP(TM) 5 VL5**  
Chemical Family: Mixture  
Intended Use: Veterinary Vaccine

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Gentamicin	1403-66-3	215-765-8	##
Formaldehyde	50-00-0	200-001-8	0.1 - 1.0
Merthiolate (as mercury)	54-64-8	200-210-4	##

Ingredient	CAS Number	EU EINECS List	%
Bovine Parainfluenza3	NOT ASSIGNED	Not listed	*
Bovine Rhinotracheitis	NOT ASSIGNED	Not listed	*
Bovine Respiratory Syncytial Virus	NOT ASSIGNED	Not listed	*
Bovine Virus Diarrhea	NOT ASSIGNED	Not listed	*
Campylobacter fetus	NOT ASSIGNED	Not listed	*
Leptospira canicola	NOT ASSIGNED	Not listed	*
Leptospira grippotyphosa	NOT ASSIGNED	Not listed	*
Leptospira hardjo	NOT ASSIGNED	Not listed	*
Leptospira icterohaemorrhagiae	NOT ASSIGNED	Not listed	*
Leptospira pomona	NOT ASSIGNED	Not listed	*
Aluminum hydroxide	21645-51-2	244-492-7	*
Water, purified	7732-18-5	231-791-2	>90

### Additional Information:

\* Proprietary  
## Trace  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

Appearance: Liquid solution in multiple-dose vials  
Signal Word: WARNING

## MATERIAL SAFETY DATA SHEET

**Material Name:** Bovine Rhinotracheitis-Virus Diarrhea-  
Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified  
Live Virus-Campylobacter Fetus-Leptospira Canicola-  
Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin  
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**Statement of Hazard:**

Contains formaldehyde: potential cancer hazard.  
May cause sensitization of the skin and respiratory system.  
May cause eye, skin and respiratory tract irritation.

**Additional Hazard Information:**  
**Short Term:**

May cause eye irritation. May cause skin irritation. May cause allergic reaction . In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

**EU Indication of danger:**

Irritant

**EU Hazard Symbols:**



**EU Risk Phrases:**

R43 - May cause sensitization by skin contact.

**Note:**

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 4. FIRST AID MEASURES

**Eye Contact:**

Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:**

Wash skin with soap and water. If irritation occurs or persists, get medical attention.

**Ingestion:**

Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:**

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:**

As for primary cause of fire.

**Hazardous Combustion Products:**

Not known

**Fire Fighting Procedures:**

Dike and collect water used to fight fire.

**Fire / Explosion Hazards:**

Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

## MATERIAL SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-  
Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified  
Live Virus-Campylobacter Fetus-Leptospira Canicola-  
Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin  
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**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

**General Handling:** Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment.

**Storage Conditions:** Store under refrigeration in closed container.

**Storage Temperature:** 2-7°C

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Formaldehyde

OSHA - Final PELs - TWAs:	= 0.75 ppm TWA
OSHA - Specifically Regulated Chemicals	= 0.5 ppm Action Level
	= 0.75 ppm TWA
	= 2 ppm STEL Irritant and potential cancer hazard - see 29 CFR 1910.1048
ACGIH Ceiling Threshold Limit:	= 0.3 ppm Ceiling
ACGIH - Sensitizer Designation	Sensitizer
Australia STEL	= 2 ppm STEL
	= 2.5 mg/m <sup>3</sup> STEL
Australia TWA	= 1 ppm TWA
	= 1.2 mg/m <sup>3</sup> TWA

#### Merthiolate (as mercury)

OSHA - Final PELs - TWAs:	= 0.01 mg/m <sup>3</sup> TWA
ACGIH Threshold Limit Value (TWA)	= 0.01 mg/m <sup>3</sup> TWA
ACGIH Threshold Limit Value (STEL)	= 0.03 mg/m <sup>3</sup> STEL
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia STEL	= 0.03 mg/m <sup>3</sup> STEL
Australia TWA	= 0.01 mg/m <sup>3</sup> TWA

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Exposure monitoring may be necessary to determine requirements.

#### Personal Protective Equipment:

**Hands:** Wear impervious gloves if skin contact is possible.

**Eyes:** Safety glasses or goggles

**Skin:** Wear protective clothing when working with large quantities. Wash hands and arms thoroughly after handling this material.

**Respiratory protection:** In the event of a spill where the applicable Occupational Exposure Limit (OEL) may be exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures below the OEL.

## MATERIAL SAFETY DATA SHEET

**Material Name:** Bovine Rhinotracheitis-Virus Diarrhea-  
Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified  
Live Virus-Campylobacter Fetus-Leptospira Canicola-  
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### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Liquid solution in multiple-dose vials	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solubility:</b>	Soluble: Water (based on components)		
<b>pH:</b>	7.0 +/- 1.5		
<b>Boiling Point (°C):</b>	>100		
<b>Vapor Pressure (kPa):</b>	Expected to be negligible		
<b>Specific Gravity:</b>	1.0 +/-0.2		

### 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable
<b>Conditions to Avoid:</b>	Store at 2°-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
<b>Incompatible Materials:</b>	This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
<b>Hazardous Decomposition Products:</b>	None expected under normal conditions.
<b>Polymerization:</b>	Will not occur

### 11. TOXICOLOGICAL INFORMATION

<b>General Information:</b>	The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The primary hazards are due to the formaldehyde content. The information included in this section describes the potential hazards of the individual ingredients.
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#### Acute Toxicity: (Species, Route, End Point, Dose)

##### **Merthiolate (as mercury)**

Rat	Oral	LD50	75 mg/kg
Rat	Subcutaneous	LD50	98 mg/kg

##### **Gentamicin**

Rat	Oral	LD50	6600 mg/kg
Rat	Subcutaneous	LD50	710 mg/kg
Mouse	IM	LD50	167 mg/kg
Rat	IM	LD50	463 mg/kg

##### **Formaldehyde**

Rat	Oral	LD50	800 mg/kg
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##### **Inhalation Acute Toxicity**

Not determined for this mixture. However, irritation may occur based on effects of individual components.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Merthiolate (as mercury)**

Eye Irritation	Rabbit	Mild
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### Gentamicin

Eye Irritation Rabbit Non-irritating

### Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

### Skin Irritation / Sensitization

This product contains formaldehyde and merthiolate which are considered to be skin sensitizers.

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### Formaldehyde

90 Day(s) Dog Inhalation Not Specified Lungs

90 Day(s) Rat Inhalation Not Specified Lungs

90 Day(s) Monkey Inhalation Not Specified Lungs

9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

#### Subchronic Effects

Rats exposed to 15 ppm formaldehyde vapor for six hours/day for up to nine days showed an acute cell degeneration, necrosis and inflammation in the nasal cavities. Inhalation exposure to formaldehyde for up to 90 days produced interstitial inflammation in the lungs of dogs, rats, monkeys, rabbits and guinea pigs.

#### Chronic Effects/Carcinogenicity

In rats, several inhalation studies have shown that formaldehyde induces squamous-cell carcinomas and necrosis of the nasal cavity. Formaldehyde also showed cocarcinogenic effects when inhaled, ingested, or applied to the skin of rodents.

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Gentamicin

Embryo / Fetal Development Rat Intramuscular 75 mg/kg/day LOAEL Developmental toxicity

#### Formaldehyde

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

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

#### Reproductive Effects

Not considered to be a reproductive hazard.

#### Teratogenicity

Formaldehyde has been tested by inhalation, oral, and dermal routes and has not been shown to be teratogenic in animals.

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### Formaldehyde

*In Vitro* Bacterial Mutagenicity (Ames) Bacteria Positive

*In Vitro* Chromosome Aberration Rodent Positive

*In Vitro* Sister Chromatid Exchange Rodent Positive

*In Vivo* Chromosome Aberration Not specified Positive

#### Mutagenicity

Formaldehyde has been reported to be active in many short-term tests, both in vitro and in vivo.

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors

2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

#### Carcinogen Status:

Contains formaldehyde: potential cancer hazard. See below

## MATERIAL SAFETY DATA SHEET

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### Formaldehyde

IARC:	Group 1
NTP:	Reasonably Anticipated To Be A Carcinogen
OSHA:	Present

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and 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).

### Formaldehyde

RCRA - U Series Wastes

waste number U122

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

EU Symbol:	Xi
EU Indication of danger:	Irritant

**EU Risk Phrases:** R43 - May cause sensitization by skin contact.

**EU Safety Phrases:** S24 - Avoid contact with skin.  
S37 - Wear suitable gloves.

**OSHA Label:**  
WARNING

## MATERIAL SAFETY DATA SHEET

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Contains formaldehyde: potential cancer hazard.  
May cause sensitization of the skin and respiratory system.  
May cause eye, skin and respiratory tract irritation.

### Canada - WHMIS: Classifications

#### **WHMIS hazard class:**

Class D, Division 2, Subdivision A



#### **Gentamicin**

California Proposition 65

Australia (AICS):

Standard for the Uniform Scheduling  
for Drugs and Poisons:

EU EINECS List

Aminoglycosides- developmental

Present

Schedule 4

215-765-8

#### **Formaldehyde**

CERCLA/SARA 313 Emission reporting

CERCLA/SARA Hazardous Substances  
and their Reportable Quantities:

CERCLA/SARA - Section 302 Extremely Hazardous  
TPQs

CERCLA/SARA - Section 302 Extremely Hazardous  
Substances EPCRA RQs

California Proposition 65

OSHA - Specifically Regulated Chemicals

= 0.1 % de minimis concentration

= 100 lb final RQ

= 45.4 kg final RQ

= 500 lb TPQ

= 100 lb EPCRA RQ

carcinogen, initial date 1/1/88 (gas)

= 0.5 ppm Action Level

= 0.75 ppm TWA

= 2 ppm STEL Irritant and potential cancer hazard - see 29 CFR  
1910.1048

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Standard for the Uniform Scheduling  
for Drugs and Poisons:

EU EINECS List

Present

Present

Schedule 2

Schedule 6

200-001-8

#### **Merthiolate (as mercury)**

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

= 1.0 % Supplier notification limit

Developmental

Present

Present

200-210-4

#### **Aluminum hydroxide**

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

Present

Present

244-492-7

#### **Water, purified**

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

Present



## MATERIAL SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-  
Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified  
Live Virus-Campylobacter Fetus-Leptospira Canicola-  
Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin  
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EU EINECS List

231-791-2

### 16. OTHER INFORMATION

**Reasons for Revision:**

Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.  
Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls /  
Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section  
11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section  
15 - Regulatory Information.

**Prepared by:**

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate. While Pfizer provides this information in good faith, it does not expressly or impliedly warrant its accuracy.

**End of Safety Data Sheet**



# MATERIAL SAFETY DATA SHEET

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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Pfizer Inc  
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New York, NY 10017  
Poison Control Center Phone: 1-866-531-8896  
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**Material Name: Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified Live Virus-Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin**

**Trade Name:** Bovi-Shield GOLD(R) FP(TM) 5 VL5  
**Chemical Family:** Mixture  
**Intended Use:** Veterinary Vaccine

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Gentamicin	1403-66-3	215-765-8	##
Formaldehyde	50-00-0	200-001-8	0.1 - 1.0
Merthiolate (as mercury)	54-64-8	200-210-4	##

Ingredient	CAS Number	EU EINECS List	%
Bovine Parainfluenza3	NOT ASSIGNED	Not listed	*
Bovine Rhinotracheitis	NOT ASSIGNED	Not listed	*
Bovine Respiratory Syncytial Virus	NOT ASSIGNED	Not listed	*
Bovine Virus Diarrhea	NOT ASSIGNED	Not listed	*
Campylobacter fetus	NOT ASSIGNED	Not listed	*
Leptospira canicola	NOT ASSIGNED	Not listed	*
Leptospira grippotyphosa	NOT ASSIGNED	Not listed	*
Leptospira hardjo	NOT ASSIGNED	Not listed	*
Leptospira icterohaemorrhagiae	NOT ASSIGNED	Not listed	*
Leptospira pomona	NOT ASSIGNED	Not listed	*
Aluminum hydroxide	21645-51-2	244-492-7	*
Water, purified	7732-18-5	231-791-2	>90

### Additional Information:

\* Proprietary  
## Trace  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION


**Appearance:** Liquid solution in multiple-dose vials  
**Signal Word:** WARNING

## MATERIAL SAFETY DATA SHEET

**Material Name:** Bovine Rhinotracheitis-Virus Diarrhea-  
Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified  
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<b>Statement of Hazard:</b>	Contains formaldehyde: potential cancer hazard. May cause sensitization of the skin and respiratory system. May cause eye, skin and respiratory tract irritation.
<b>Additional Hazard Information:</b> <b>Short Term:</b>	May cause eye irritation. May cause skin irritation. May cause allergic reaction . In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.
<b>EU Indication of danger:</b>	Irritant
<b>EU Hazard Symbols:</b>	
<b>EU Risk Phrases:</b>	R43 - May cause sensitization by skin contact.
<b>Note:</b>	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 4. FIRST AID MEASURES

<b>Eye Contact:</b>	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
<b>Skin Contact:</b>	Wash skin with soap and water. If irritation occurs or persists, get medical attention.
<b>Ingestion:</b>	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Inhalation:</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	As for primary cause of fire.
<b>Hazardous Combustion Products:</b>	Not known
<b>Fire Fighting Procedures:</b>	Dike and collect water used to fight fire.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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## MATERIAL SAFETY DATA SHEET

**Material Name:** Bovine Rhinotracheitis-Virus Diarrhea-  
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**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

**General Handling:** Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment.

**Storage Conditions:** Store under refrigeration in closed container.

**Storage Temperature:** 2-7°C

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Formaldehyde

OSHA - Final PELs - TWAs:	= 0.75 ppm TWA
OSHA - Specifically Regulated Chemicals	= 0.5 ppm Action Level
	= 0.75 ppm TWA
	= 2 ppm STEL     Irritant and potential cancer hazard - see 29 CFR 1910.1048
ACGIH Ceiling Threshold Limit:	= 0.3 ppm Ceiling
ACGIH - Sensitizer Designation	Sensitizer
Australia STEL	= 2 ppm STEL
	= 2.5 mg/m <sup>3</sup> STEL
Australia TWA	= 1 ppm TWA
	= 1.2 mg/m <sup>3</sup> TWA

#### Merthiolate (as mercury)

OSHA - Final PELs - TWAs:	= 0.01 mg/m <sup>3</sup> TWA
ACGIH Threshold Limit Value (TWA)	= 0.01 mg/m <sup>3</sup> TWA
ACGIH Threshold Limit Value (STEL)	= 0.03 mg/m <sup>3</sup> STEL
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia STEL	= 0.03 mg/m <sup>3</sup> STEL
Australia TWA	= 0.01 mg/m <sup>3</sup> TWA

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Exposure monitoring may be necessary to determine requirements.

#### Personal Protective Equipment:

**Hands:** Wear impervious gloves if skin contact is possible.

**Eyes:** Safety glasses or goggles

**Skin:** Wear protective clothing when working with large quantities. Wash hands and arms thoroughly after handling this material.

**Respiratory protection:** In the event of a spill where the applicable Occupational Exposure Limit (OEL) may be exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures below the OEL.

## MATERIAL SAFETY DATA SHEET

**Material Name:** Bovine Rhinotracheitis-Virus Diarrhea-  
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**Revision date:** 06-Dec-2006

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### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Liquid solution in multiple-dose vials	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solubility:</b>	Soluble: Water (based on components)		
<b>pH:</b>	7.0 +/- 1.5		
<b>Boiling Point (°C):</b>	>100		
<b>Vapor Pressure (kPa):</b>	Expected to be negligible		
<b>Specific Gravity:</b>	1.0 +/-0.2		

### 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable
<b>Conditions to Avoid:</b>	Store at 2°-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
<b>Incompatible Materials:</b>	This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
<b>Hazardous Decomposition Products:</b>	None expected under normal conditions.
<b>Polymerization:</b>	Will not occur

### 11. TOXICOLOGICAL INFORMATION

<b>General Information:</b>	The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The primary hazards are due to the formaldehyde content. The information included in this section describes the potential hazards of the individual ingredients.
-----------------------------	--

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### **Merthiolate (as mercury)**

Rat	Oral	LD50	75 mg/kg
Rat	Subcutaneous	LD50	98 mg/kg

##### **Gentamicin**

Rat	Oral	LD50	6600 mg/kg
Rat	Subcutaneous	LD50	710 mg/kg
Mouse	IM	LD50	167 mg/kg
Rat	IM	LD50	463 mg/kg

##### **Formaldehyde**

Rat	Oral	LD50	800 mg/kg
-----	------	------	-----------

##### **Inhalation Acute Toxicity**

Not determined for this mixture. However, irritation may occur based on effects of individual components.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Merthiolate (as mercury)**

Eye Irritation	Rabbit	Mild
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## MATERIAL SAFETY DATA SHEET

**Material Name:** Bovine Rhinotracheitis-Virus Diarrhea-  
Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified  
Live Virus-Campylobacter Fetus-Leptospira Canicola-  
Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin  
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### Gentamicin

Eye Irritation    Rabbit    Non-irritating

### Formaldehyde

Eye Irritation    Rabbit    Severe

Skin Irritation    Rabbit    Moderate Severe

### Skin Irritation / Sensitization

This product contains formaldehyde and merthiolate which are considered to be skin sensitizers.

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### Formaldehyde

90 Day(s)    Dog    Inhalation    Not Specified    Lungs

90 Day(s)    Rat    Inhalation    Not Specified    Lungs

90 Day(s)    Monkey    Inhalation    Not Specified    Lungs

9 Day(s)    Rat    Inhalation    15 ppm    LOAEL    Respiratory system

#### Subchronic Effects

Rats exposed to 15 ppm formaldehyde vapor for six hours/day for up to nine days showed an acute cell degeneration, necrosis and inflammation in the nasal cavities. Inhalation exposure to formaldehyde for up to 90 days produced interstitial inflammation in the lungs of dogs, rats, monkeys, rabbits and guinea pigs.

#### Chronic Effects/Carcinogenicity

In rats, several inhalation studies have shown that formaldehyde induces squamous-cell carcinomas and necrosis of the nasal cavity. Formaldehyde also showed cocarcinogenic effects when inhaled, ingested, or applied to the skin of rodents.

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Gentamicin

Embryo / Fetal Development    Rat    Intramuscular    75 mg/kg/day    LOAEL    Developmental toxicity

#### Formaldehyde

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

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

#### Reproductive Effects

Not considered to be a reproductive hazard.

#### Teratogenicity

Formaldehyde has been tested by inhalation, oral, and dermal routes and has not been shown to be teratogenic in animals.

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### Formaldehyde

*In Vitro* Bacterial Mutagenicity (Ames)    Bacteria    Positive

*In Vitro* Chromosome Aberration    Rodent    Positive

*In Vitro* Sister Chromatid Exchange    Rodent    Positive

*In Vivo* Chromosome Aberration    Not specified    Positive

#### Mutagenicity

Formaldehyde has been reported to be active in many short-term tests, both in vitro and in vivo.

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### Formaldehyde

2 Year(s)    Rat    Inhalation    6 ppm    LOAEL    Tumors

2 Year(s)    Mouse    Inhalation    15 ppm    LOAEL    Tumors

#### Carcinogen Status:

Contains formaldehyde: potential cancer hazard. See below

## MATERIAL SAFETY DATA SHEET

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### Formaldehyde

IARC:	Group 1
NTP:	Reasonably Anticipated To Be A Carcinogen
OSHA:	Present

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and 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).

### Formaldehyde

RCRA - U Series Wastes

waste number U122

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

EU Symbol:	Xi
EU Indication of danger:	Irritant

**EU Risk Phrases:** R43 - May cause sensitization by skin contact.

**EU Safety Phrases:** S24 - Avoid contact with skin.  
S37 - Wear suitable gloves.

**OSHA Label:**  
WARNING

# MATERIAL SAFETY DATA SHEET

**Material Name:** Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified  
Live Virus-Campylobacter Fetus-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin  
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Contains formaldehyde: potential cancer hazard.  
May cause sensitization of the skin and respiratory system.  
May cause eye, skin and respiratory tract irritation.

## Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision A



### Gentamicin

California Proposition 65	Aminoglycosides- developmental
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	215-765-8

### Formaldehyde

CERCLA/SARA 313 Emission reporting	= 0.1 % de minimis concentration
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 100 lb final RQ
	= 45.4 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 100 lb EPCRA RQ
California Proposition 65	carcinogen, initial date 1/1/88 (gas)
OSHA - Specifically Regulated Chemicals	= 0.5 ppm Action Level
	= 0.75 ppm TWA
	= 2 ppm STEL    Irritant and potential cancer hazard - see 29 CFR 1910.1048
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
	Schedule 6
EU EINECS List	200-001-8

### Merthiolate (as mercury)

CERCLA/SARA 313 Emission reporting	= 1.0 % Supplier notification limit
California Proposition 65	Developmental
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-210-4

### Aluminum hydroxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	244-492-7

### Water, purified

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present



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EU EINECS List

231-791-2

### 16. OTHER INFORMATION

**Reasons for Revision:**

Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.  
Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls /  
Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section  
11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section  
15 - Regulatory Information.

**Prepared by:**

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate. While Pfizer provides this information in good faith, it does not expressly or impliedly warrant its accuracy.

**End of Safety Data Sheet**

# SAFETY DATA SHEET



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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified Live Virus-Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin

**Trade Name:** Bovi-Shield GOLD FP 5 VL5  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary Vaccine

### Details of the Supplier of the Safety Data Sheet

**Zoetis Inc.**  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison Control Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

**Zoetis Belgium S.A.**  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

**Appearance:** Liquid solution in multiple-dose vials

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Signal Word:** Not Classified  
**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

### Other Hazards

**Short Term:** May cause eye irritation. May cause skin irritation. May cause allergic reaction. In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.  
**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## SAFETY DATA SHEET

**Material Name:** Bovine Rhinotracheitis-Virus Diarrhea-  
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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Formaldehyde	50-00-0	200-001-8	T; R23/24/25 C; R34 Carc.Cat.3; R40 R43	Acute Tox. 3 (H301) Skin Corr. 1B (H314) Skin Sens. 1 (H317) Carc. 2 (H351) Acute Tox. 3 (H331)	<0.1
Merthiolate (as mercury)	54-64-8	200-210-4	T+; R26/27/28 R33 N; R50/53	Acute Tox. 2 (H330) Acute Tox. 2 (H310) Acute Tox. 1 (H300) STOT RE 2 (H373) Aq. Acute 1 (H400) Aq. Chronic 1 (H410)	##
Gentamicin	1403-66-3	215-765-8	Not Listed	Not Listed	##

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Aluminum hydroxide	21645-51-2	244-492-7	Not Listed	Not Listed	*
Bovine Parainfluenza3	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Campylobacter fetus	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Leptospira canicola	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Leptospira grippytyphosa	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Leptospira hardjo	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Leptospira icterohaemorrhagiae	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Leptospira pomona	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Bovine Respiratory Syncytial Virus	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Bovine Rhinotracheitis	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Bovine Virus Diarrhea	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*

#### Additional Information:

\* Proprietary

## Trace

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

**For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16**

## SAFETY DATA SHEET

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### 4. FIRST AID MEASURES

#### Description of First Aid Measures

<b>Eye Contact:</b>	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
<b>Skin Contact:</b>	Wash skin with soap and water. If irritation occurs or persists, get medical attention.
<b>Ingestion:</b>	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Inhalation:</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
<b>Medical Conditions Aggravated by Exposure:</b>	None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

<b>Notes to Physician:</b>	None
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### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Additional Consideration for Large Spills:</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Keep away from heat, sparks, and flame. Avoid breathing vapor or mist. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Prevent environmental releases. Use appropriate personal protective equipment. Avoid accidental injection.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store under refrigeration in closed container.

**Storage Temperature:** 2-7°C

**Incompatible Materials:** This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.

**Specific end use(s):** No data available

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Aluminum hydroxide

ACGIH Threshold Limit Value (TWA)	1 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup>
	1.5 mg/m <sup>3</sup>
Latvia OEL - TWA	6 mg/m <sup>3</sup>
Lithuania OEL - TWA	6 mg/m <sup>3</sup>
Poland OEL - TWA	2.5 mg/m <sup>3</sup>
	1.2 mg/m <sup>3</sup>
Slovakia OEL - TWA	1.5 mg/m <sup>3</sup>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>

#### Formaldehyde

ACGIH Ceiling Threshold Limit:	0.3 ppm
ACGIH - Sensitizer Designation	Sensitizer
Australia STEL	2 ppm
	2.5 mg/m <sup>3</sup>
Australia TWA	1 ppm
	1.2 mg/m <sup>3</sup>
Austria OEL - MAKs	0.5 ppm
	0.6 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.5 mg/m <sup>3</sup>
Estonia OEL - TWA	0.5 ppm
	0.6 mg/m <sup>3</sup>
Finland OEL - TWA	0.3 ppm
	0.37 mg/m <sup>3</sup>
France OEL - TWA	0.5 ppm
Germany (DFG) - MAK	0.3 ppm
	0.37 mg/m <sup>3</sup> no irritation should occur during mixed exposure
Greece OEL - TWA	2 ppm
	2.5 mg/m <sup>3</sup>

## SAFETY DATA SHEET

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hungary OEL - TWA	0.6 mg/m <sup>3</sup>
Ireland OEL - TWAs	2 ppm
	2.5 mg/m <sup>3</sup>
Japan - OELs - Ceilings	0.2 ppm
	0.24 mg/m <sup>3</sup>
Latvia OEL - TWA	0.5 mg/m <sup>3</sup>
Lithuania OEL - TWA	0.5 ppm
	0.6 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.15 mg/m <sup>3</sup>
Vietnam OEL - TWAs	0.5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	0.75 ppm
OSHA - Specifically Regulated Chemicals	2 ppm
	0.5 ppm
	0.75 ppm
Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Romania OEL - TWA	1 ppm
	1.20 mg/m <sup>3</sup>
Slovakia OEL - TWA	0.3 ppm
	0.37 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.5 ppm
	0.62 mg/m <sup>3</sup>
Sweden OEL - TWAs	0.3 ppm
	0.37 mg/m <sup>3</sup>
Switzerland OEL - TWAs	0.3 ppm
	0.37 mg/m <sup>3</sup>

#### Gentamicin

Bulgaria OEL - TWA	0.1 mg/m <sup>3</sup>
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The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### Gentamicin

Zoetis OEB	OEB 2 (control exposure to the range of 100ug/m <sup>3</sup> to < 1000ug/m <sup>3</sup> )
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#### Exposure Controls

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or aerosols.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Wear impervious gloves if skin contact is possible.
<b>Eyes:</b>	Safety glasses or goggles
<b>Skin:</b>	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection:</b>	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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid solution in multiple-dose vials	<b>Color:</b>	No data available.
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>Solubility:</b>	Soluble: Water (based on components)		
<b>pH:</b>	7.0 +/- 1.5		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	>100		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	No data available		
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	Expected to be negligible		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Specific Gravity:</b>	1.0 +/-0.2		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>	No data available		
<b>Flammability (Solids):</b>	No data available		
<b>Flash Point (Liquid) (°C):</b>	No data available		
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available		
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available		
<b>Polymerization:</b>	Will not occur		

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Store at 2°-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
<b>Incompatible Materials:</b>	This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
<b>Hazardous Decomposition Products:</b>	None expected under normal conditions.

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**General Information:** Toxicological properties of the formulation have not been investigated. The information included in this section describes the potential hazards of the individual ingredients. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms.

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### 11. TOXICOLOGICAL INFORMATION

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### **Merthiolate (as mercury)**

Rat Oral LD50 75 mg/kg

Rat Subcutaneous LD50 98mg/kg

##### **Gentamicin**

Rat Oral LD50 6600 mg/kg

Rat Subcutaneous LD50 710mg/kg

Mouse IM LD50 167 mg/kg

Rat IM LD50 463 mg/kg

##### **Formaldehyde**

Rat Oral LD50 800 mg/kg

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Merthiolate (as mercury)**

Eye Irritation Rabbit Mild

##### **Gentamicin**

Eye Irritation Rabbit Non-irritating

##### **Formaldehyde**

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

**Skin Irritation / Sensitization** This product contains formaldehyde and merthiolate which are considered to be skin sensitizers.

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### **Formaldehyde**

90 Day(s) Dog Inhalation Not Specified Lungs

90 Day(s) Rat Inhalation Not Specified Lungs

90 Day(s) Monkey Inhalation Not Specified Lungs

9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Gentamicin**

Embryo / Fetal Development Rat Intramuscular 75 mg/kg/day LOAEL Developmental toxicity

##### **Formaldehyde**

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

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



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### 11. TOXICOLOGICAL INFORMATION

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Formaldehyde

*In Vitro* Bacterial Mutagenicity (Ames) Bacteria Positive  
*In Vitro* Chromosome Aberration Rodent Positive  
*In Vitro* Sister Chromatid Exchange Rodent Positive  
*In Vivo* Chromosome Aberration Not specified Positive

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors  
2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

**Carcinogen Status:** No known carcinogens are present at greater than 0.1%

##### Formaldehyde

**IARC:** Group 1 (Carcinogenic to Humans)  
**NTP:** Known Human Carcinogen  
**OSHA:** Listed

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. This product contains trace quantities of mercury, releases to the environment should be avoided.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and 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).

##### Formaldehyde

**RCRA - U Series Wastes** Listed

## SAFETY DATA SHEET

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### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

#### Aluminum hydroxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	244-492-7

#### Bovine Parainfluenza3

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Campylobacter fetus

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Leptospira canicola

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Leptospira grippytypphosa

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

# SAFETY DATA SHEET

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## 15. REGULATORY INFORMATION

### Leptospira hardjo

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

### Leptospira icterohaemorrhagiae

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

### Leptospira pomona

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

### Bovine Respiratory Syncytial Virus

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

### Bovine Rhinotracheitis

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

### Bovine Virus Diarrhea

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

### Formaldehyde

CERCLA/SARA 313 Emission reporting	0.1 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	45.4 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	100 lb
OSHA - Specifically Regulated Chemicals	carcinogen initial date 1/1/88 gas
	2 ppm
	0.5 ppm
	0.75 ppm
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS/ELINCS List	Schedule 6
	200-001-8

### Merthiolate (as mercury)

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CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-210-4

#### Gentamicin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	215-765-8

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H301 - Toxic if swallowed  
H314 - Causes severe skin burns and eye damage  
H317 - May cause an allergic skin reaction  
H351 - Suspected of causing cancer  
H331 - Toxic if inhaled  
H330 - Fatal if inhaled  
H310 - Fatal in contact with skin  
H300 - Fatal if swallowed  
H373 - May cause damage to organs through prolonged or repeated exposure  
H400 - Very toxic to aquatic life  
H410 - Very toxic to aquatic life with long lasting effects

C - Corrosive  
Carcinogenic: Category 3  
N - Dangerous for the environment  
T - Toxic  
T+ - Very toxic

R23 - Toxic by inhalation.  
R24 - Toxic in contact with skin.  
R25 - Toxic if swallowed.  
R34 - Causes burns.  
R40 - Limited evidence of a carcinogenic effect

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.  
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

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**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material 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.

**End of Safety Data Sheet**

# SAFETY DATA SHEET



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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified Live Virus-Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin

**Trade Name:** Bovi-Shield GOLD FP 5 VL5  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary Vaccine

### Details of the Supplier of the Safety Data Sheet

**Zoetis Inc.**  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison Control Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

**Zoetis Belgium S.A.**  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

**Appearance:** Liquid solution in multiple-dose vials

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Signal Word:** Not Classified  
**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

### Other Hazards

**Short Term:** May cause eye irritation. May cause skin irritation. May cause allergic reaction. In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.  
**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## SAFETY DATA SHEET

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Formaldehyde	50-00-0	200-001-8	T; R23/24/25 C; R34 Carc.Cat.3; R40 R43	Acute Tox. 3 (H301) Skin Corr. 1B (H314) Skin Sens. 1 (H317) Carc. 2 (H351) Acute Tox. 3 (H331)	<0.1
Merthiolate (as mercury)	54-64-8	200-210-4	T+; R26/27/28 R33 N; R50/53	Acute Tox. 2 (H330) Acute Tox. 2 (H310) Acute Tox. 1 (H300) STOT RE 2 (H373) Aq. Acute 1 (H400) Aq. Chronic 1 (H410)	##
Gentamicin	1403-66-3	215-765-8	Not Listed	Not Listed	##

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Aluminum hydroxide	21645-51-2	244-492-7	Not Listed	Not Listed	*
Bovine Parainfluenza3	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Campylobacter fetus	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Leptospira canicola	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Leptospira grippytyphosa	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Leptospira hardjo	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Leptospira icterohaemorrhagiae	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Leptospira pomona	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Bovine Respiratory Syncytial Virus	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Bovine Rhinotracheitis	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Bovine Virus Diarrhea	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*

#### Additional Information:

\* Proprietary

## Trace

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

**For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16**

## SAFETY DATA SHEET

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### 4. FIRST AID MEASURES

#### Description of First Aid Measures

<b>Eye Contact:</b>	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
<b>Skin Contact:</b>	Wash skin with soap and water. If irritation occurs or persists, get medical attention.
<b>Ingestion:</b>	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Inhalation:</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
<b>Medical Conditions Aggravated by Exposure:</b>	None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

<b>Notes to Physician:</b>	None
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### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Additional Consideration for Large Spills:</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.



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### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Keep away from heat, sparks, and flame. Avoid breathing vapor or mist. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Prevent environmental releases. Use appropriate personal protective equipment. Avoid accidental injection.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store under refrigeration in closed container.

**Storage Temperature:** 2-7°C

**Incompatible Materials:** This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Aluminum hydroxide

ACGIH Threshold Limit Value (TWA)	1 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup>
	1.5 mg/m <sup>3</sup>
Latvia OEL - TWA	6 mg/m <sup>3</sup>
Lithuania OEL - TWA	6 mg/m <sup>3</sup>
Poland OEL - TWA	2.5 mg/m <sup>3</sup>
	1.2 mg/m <sup>3</sup>
Slovakia OEL - TWA	1.5 mg/m <sup>3</sup>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>

#### Formaldehyde

ACGIH Ceiling Threshold Limit:	0.3 ppm
ACGIH - Sensitizer Designation	Sensitizer
Australia STEL	2 ppm
	2.5 mg/m <sup>3</sup>
Australia TWA	1 ppm
	1.2 mg/m <sup>3</sup>
Austria OEL - MAKs	0.5 ppm
	0.6 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.5 mg/m <sup>3</sup>
Estonia OEL - TWA	0.5 ppm
	0.6 mg/m <sup>3</sup>
Finland OEL - TWA	0.3 ppm
	0.37 mg/m <sup>3</sup>
France OEL - TWA	0.5 ppm
Germany (DFG) - MAK	0.3 ppm
	0.37 mg/m <sup>3</sup> no irritation should occur during mixed exposure
Greece OEL - TWA	2 ppm
	2.5 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hungary OEL - TWA	0.6 mg/m <sup>3</sup>
Ireland OEL - TWAs	2 ppm
	2.5 mg/m <sup>3</sup>
Japan - OELs - Ceilings	0.2 ppm
	0.24 mg/m <sup>3</sup>
Latvia OEL - TWA	0.5 mg/m <sup>3</sup>
Lithuania OEL - TWA	0.5 ppm
	0.6 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.15 mg/m <sup>3</sup>
Vietnam OEL - TWAs	0.5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	0.75 ppm
OSHA - Specifically Regulated Chemicals	2 ppm
	0.5 ppm
	0.75 ppm
Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Romania OEL - TWA	1 ppm
	1.20 mg/m <sup>3</sup>
Slovakia OEL - TWA	0.3 ppm
	0.37 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.5 ppm
	0.62 mg/m <sup>3</sup>
Sweden OEL - TWAs	0.3 ppm
	0.37 mg/m <sup>3</sup>
Switzerland OEL - TWAs	0.3 ppm
	0.37 mg/m <sup>3</sup>

#### Gentamicin

Bulgaria OEL - TWA	0.1 mg/m <sup>3</sup>
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The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### Gentamicin

Zoetis OEB	OEB 2 (control exposure to the range of 100ug/m <sup>3</sup> to < 1000ug/m <sup>3</sup> )
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#### Exposure Controls

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or aerosols.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Wear impervious gloves if skin contact is possible.
<b>Eyes:</b>	Safety glasses or goggles
<b>Skin:</b>	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection:</b>	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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid solution in multiple-dose vials	<b>Color:</b>	No data available.
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>Solubility:</b>	Soluble: Water (based on components)		
<b>pH:</b>	7.0 +/- 1.5		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	>100		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	No data available		
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	Expected to be negligible		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Specific Gravity:</b>	1.0 +/-0.2		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>	No data available		
<b>Flammability (Solids):</b>	No data available		
<b>Flash Point (Liquid) (°C):</b>	No data available		
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available		
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available		
<b>Polymerization:</b>	Will not occur		

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Store at 2°-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
<b>Incompatible Materials:</b>	This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
<b>Hazardous Decomposition Products:</b>	None expected under normal conditions.

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

<b>General Information:</b>	Toxicological properties of the formulation have not been investigated. The information included in this section describes the potential hazards of the individual ingredients. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms.
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## SAFETY DATA SHEET

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### 11. TOXICOLOGICAL INFORMATION

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### **Merthiolate (as mercury)**

Rat Oral LD50 75 mg/kg

Rat Subcutaneous LD50 98mg/kg

##### **Gentamicin**

Rat Oral LD50 6600 mg/kg

Rat Subcutaneous LD50 710mg/kg

Mouse IM LD50 167 mg/kg

Rat IM LD50 463 mg/kg

##### **Formaldehyde**

Rat Oral LD50 800 mg/kg

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Merthiolate (as mercury)**

Eye Irritation Rabbit Mild

##### **Gentamicin**

Eye Irritation Rabbit Non-irritating

##### **Formaldehyde**

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

##### **Skin Irritation / Sensitization**

This product contains formaldehyde and merthiolate which are considered to be skin sensitizers.

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### **Formaldehyde**

90 Day(s) Dog Inhalation Not Specified Lungs

90 Day(s) Rat Inhalation Not Specified Lungs

90 Day(s) Monkey Inhalation Not Specified Lungs

9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Gentamicin**

Embryo / Fetal Development Rat Intramuscular 75 mg/kg/day LOAEL Developmental toxicity

##### **Formaldehyde**

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

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

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### 11. TOXICOLOGICAL INFORMATION

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Formaldehyde

*In Vitro* Bacterial Mutagenicity (Ames) Bacteria Positive  
*In Vitro* Chromosome Aberration Rodent Positive  
*In Vitro* Sister Chromatid Exchange Rodent Positive  
*In Vivo* Chromosome Aberration Not specified Positive

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors  
2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

**Carcinogen Status:** No known carcinogens are present at greater than 0.1%

##### Formaldehyde

**IARC:** Group 1 (Carcinogenic to Humans)  
**NTP:** Known Human Carcinogen  
**OSHA:** Listed

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. This product contains trace quantities of mercury, releases to the environment should be avoided.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and 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).

##### Formaldehyde

**RCRA - U Series Wastes** Listed

## SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-  
Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified  
Live Virus-Campylobacter Fetus-Leptospira Canicola-  
Grippytypphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin  
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### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Canada - WHMIS: Classifications

##### **WHMIS hazard class:**

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

#### **Aluminum hydroxide**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	244-492-7

#### **Bovine Parainfluenza3**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### **Campylobacter fetus**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### **Leptospira canicola**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### **Leptospira grippytypphosa**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

## SAFETY DATA SHEET

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### 15. REGULATORY INFORMATION

#### Leptospira hardjo

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Leptospira icterohaemorrhagiae

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Leptospira pomona

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Bovine Respiratory Syncytial Virus

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Bovine Rhinotracheitis

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Bovine Virus Diarrhea

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Formaldehyde

CERCLA/SARA 313 Emission reporting	0.1 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	45.4 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	100 lb
OSHA - Specifically Regulated Chemicals	carcinogen initial date 1/1/88 gas
	2 ppm
	0.5 ppm
	0.75 ppm
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS/ELINCS List	Schedule 6
	200-001-8

#### Merthiolate (as mercury)

## SAFETY DATA SHEET

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### 15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-210-4

#### Gentamicin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	215-765-8

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H301 - Toxic if swallowed  
H314 - Causes severe skin burns and eye damage  
H317 - May cause an allergic skin reaction  
H351 - Suspected of causing cancer  
H331 - Toxic if inhaled  
H330 - Fatal if inhaled  
H310 - Fatal in contact with skin  
H300 - Fatal if swallowed  
H373 - May cause damage to organs through prolonged or repeated exposure  
H400 - Very toxic to aquatic life  
H410 - Very toxic to aquatic life with long lasting effects

C - Corrosive  
Carcinogenic: Category 3  
N - Dangerous for the environment  
T - Toxic  
T+ - Very toxic

R23 - Toxic by inhalation.  
R24 - Toxic in contact with skin.  
R25 - Toxic if swallowed.  
R34 - Causes burns.  
R40 - Limited evidence of a carcinogenic effect

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.



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**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

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**End of Safety Data Sheet**