

# SAFETY DATA SHEET



Revision date: 30-Jan-2014

Version: 2.1

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

### Product Identifier

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

**Trade Name:** PregGuard GOLD(R) FP(TM) 10  
**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:** Non-hazardous in accordance with international standards for workplace safety.

### Other Hazards

#### Short Term:

May cause eye and 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.

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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	%
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 grippotyphosa	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 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

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

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### 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.

#### 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

**Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

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

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

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** 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

**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.

**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

#### Precautions for Safe Handling

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### 7. HANDLING AND STORAGE

Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. 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.

#### 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>
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>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>
<b>Gentamicin</b> Bulgaria OEL - TWA	0.1 mg/m <sup>3</sup>

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>)

#### Exposure Controls

**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:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**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:** 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.

### 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.		

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**Evaporation Rate (Gram/s):** No data available  
**Vapor Pressure (kPa):** Expected to be negligible  
**Vapor Density (g/ml):** No data available  
**Relative Density:** No data available  
**Specific Gravity:** 1.0 +/-0.2  
**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available  
**Flammability (Solids):** No data available  
**Flash Point (Liquid) (°C):** No data available  
**Upper Explosive Limits (Liquid) (% by Vol.):** No data available  
**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

**Polymerization:** Will not occur

## 10. STABILITY AND REACTIVITY

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

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

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

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### 11. TOXICOLOGICAL INFORMATION

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

##### **Reproductive Effects**

Not considered to be a reproductive hazard.

#### 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

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**Carcinogen Status:** None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

**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. Member State specific and Community specific provisions must be considered. 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. 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

### 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.



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### 15. REGULATORY INFORMATION

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

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**

Non-controlled

#### **Bovine Parainfluenza3**

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

#### **Campylobacter fetus**

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

#### **Leptospira canicola**

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

#### **Leptospira grippotyphosa**

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

#### **Leptospira hardjo**

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

#### **Leptospira icterohaemorrhagiae**

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

#### **Leptospira pomona**

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**15. REGULATORY INFORMATION**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Bovine Rhinotracheitis</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Formaldehyde</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	0.1 %
<b>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</b>	100 lb
<b>CERCLA/SARA - Section 302 Extremely Hazardous TPQs</b>	45.4 kg
<b>CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs</b>	500 lb
<b>CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs</b>	100 lb
<b>California Proposition 65</b>	carcinogen initial date 1/1/88 gas
<b>OSHA - Specifically Regulated Chemicals</b>	2 ppm
	0.5 ppm
	0.75 ppm
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 2
	Schedule 6
<b>EU EINECS/ELINCS List</b>	200-001-8
<b>Merthiolate (as mercury)</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	200-210-4
<b>Gentamicin</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>EU EINECS/ELINCS List</b>	215-765-8
<b>Bovine Virus Diarrhea</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EU EINECS/ELINCS List</b>	Not Listed

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### 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

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

R34 - Causes burns.  
R40 - Limited evidence of a carcinogenic effect  
R43 - May cause sensitization by skin contact.  
R33 - Danger of cumulative effects.  
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.  
R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.  
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**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 4 - First Aid Measures. 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 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

**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**