

# SAFETY DATA SHEET



Revision date: 04-Dec-2013

Version: 2.0

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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-Leptospira Canicola-Grippotyphosa-Hardjo-Ichtherohaemorrhagiae-Pomona Bacterin

**Trade Name:** Bovi-Shield GOLD® FPT™ 5L5  
**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:** Freeze-dried preparation plus a liquid adjuvanted preparation

### 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 allergic skin reaction . Dust irritating to respiratory tract. 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	%
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	*
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.

### 4. FIRST AID MEASURES

**Description of 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.

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

**Symptoms and Effects of Exposure:**

No data available

**Medical Conditions Aggravated by Exposure:**

None known

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

Notes to Physician: None

## 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** As for primary cause of fire.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Not known

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

## 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. Avoid generating airborne dust.

**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

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

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store under refrigeration in closed container. Keep container tightly closed when not in use.

**Storage Temperature:** 2-7°C (35 - 45°F)

**Incompatible Materials:** None known

**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>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>

**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 fumes.
<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>	Wear protective clothing when working with large quantities. Wash hands and arms thoroughly after handling this material.
<b>Respiratory protection:</b>	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Freeze-dried preparation plus Liquid	<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		

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**Vapor Pressure (kPa):** No data available  
**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):** Non-flammable  
**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:** Avoid prolonged exposure to higher temperatures and/or direct sunlight. Do not freeze.  
**Incompatible Materials:** None known  
**Hazardous Decomposition Products:** None known

## 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. Toxicological properties of the formulation have not been investigated.

### 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

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

#### Merthiolate (as mercury)

Eye Irritation Rabbit Mild

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### 11. TOXICOLOGICAL INFORMATION

#### Gentamicin

Eye Irritation Rabbit Non-irritating

**Skin Irritation / Sensitization** This product contains merthiolate which is considered to be a skin sensitizer.

#### 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

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### 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:**

Observe all local and national regulations when disposing of this material. 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).

### 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:

None required

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

##### Merthiolate (as mercury)

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

##### 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

##### Gentamicin

CERCLA/SARA 313 Emission reporting	Not Listed
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### 15. REGULATORY INFORMATION

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

H300 - Fatal if swallowed  
H310 - Fatal in contact with skin  
H330 - Fatal if inhaled  
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

R33 - Danger of cumulative effects.  
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 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology 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**