# SAFETY DATA SHEET



1. Identification

**Product identifier** Bovi-Shield® GOLD FP® 5 VL5

Other means of identification

**Synonyms** Bovi-Shield GOLD FP 5 VL5 \* Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3-Respiratory

Syncytial Virus Vaccine, Modified Live Virus-Campylobacter Fetus-Leptospira

Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pom

ona Bacterin

Recommended use Veterinary vaccine Recommended restrictions Not for human use Manufacturer/Importer/Supplier/Distributor information

Company Name (US) Zoetis Inc.

10 Sylvan Way

Parsippany, New Jersey 07054 (USA)

**Rocky Mountain Poison** 

and Drug Center

1-866-531-8896

**Product Support/Technical** 

Services

1-800-366-5288

**Emergency telephone** 

numbers

CHEMTREC (24 hours): 1-800-424-9300

International CHEMTREC (24 hours): +1-703-527-3887

Company Name (EU) Zoetis Belgium S.A.

> Mercuriusstraat 20 1930 Zaventem

Belgium

**Emergency telephone** 

number

International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards Not classified. Not classified. **Health hazards Environmental hazards** Not classified. Not classified. **OSHA** defined hazards

Label elements

None. Hazard symbol Signal word None.

The mixture does not meet the criteria for classification. **Hazard statement** 

**Precautionary statement** 

Prevention Observe good industrial hygiene practices.

Wash hands after handling. Response

Store away from incompatible materials. Storage

Dispose of waste and residues in accordance with local authority requirements. **Disposal** 

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an

allergic reaction may occur. Contains formaldehyde. May produce an allergic reaction.

3. Composition/information on ingredients

**Mixtures** 

Chemical name	Common name and synonyms	CAS number	%
Aluminum hydroxide gel		21645-51-2	1-3
Formaldehyde		50-00-0	<0.1
Bovine Parainfluenza3		NOT ASSIGNED	*
Bovine Respiratory Syncytial Virus		NOT ASSIGNED	*
Bovine Rhinotrachetitis		NOT ASSIGNED	*
Bovine Virus Diarrhea		NOT ASSIGNED	*
Campylobacter fetus		NOT ASSIGNED	*
Gentamicin		1403-66-3	##
Leptospira canicola		NOT ASSIGNED	*
Leptospira grippotyphosa		NOT ASSIGNED	*
Leptospira hardjo		NOT ASSIGNED	*
Leptospira icterohaemorrhagiae		NOT ASSIGNED	*
Leptospira pomona		NOT ASSIGNED	*
Thimerosal		54-64-8	##

**Composition comments** 

\* Non-hazardous Ingredients

## Trace

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been

withheld as a trade secret.

### 4. First-aid measures

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

**Skin contact** Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove

contact lenses, if present and easy to do.

Ingestion Rinse mouth. Call a physician or poison control center immediately. Only induce vomiting at the

instruction of medical personnel. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and

symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.

Indication of immediate medical attention and special treatment needed

Treat symptomatically.

**General information** 

For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from

the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

Use water spray to cool unopened containers.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

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

**Environmental precautions** 

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

7. Handling and storage

Precautions for safe handling

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

Conditions for safe storage, including any incompatibilities

Store away from direct sunlight. @ 2 - 7°C (36 - 45°F). Do not freeze. Store in original tightly closed container. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS).

# 8. Exposure controls/personal protection

#### Occupational exposure limits

Components	Туре	Value	
Formaldehyde (CAS 50-00-0)	STEL	2 ppm	
,	TWA	0.75 ppm	
US. OSHA Table Z-2 (29 CFR 1910.1000	)		
Components	Туре	Value	
Thimerosal (CAS 54-64-8)	Ceiling	0.04 mg/m3	
	TWA	0.01 mg/m3	
US. OSHA Table Z-3 (29 CFR 1910.1000	)		
Components	Туре	Value	Form
Aluminum hydroxide gel (CAS 21645-51-2)	TWA	5 mg/m3	Respirable fraction.
,		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction
US. ACGIH Threshold Limit Values			
Components	Туре	Value	Form
Aluminum hydroxide gel (CAS 21645-51-2)	TWA	1 mg/m3	Respirable fraction.
	Ceiling	0.3 ppm	
	Ceiling STEL	0.3 ppm 0.03 mg/m3	
50-00-0)	· ·	• •	
Formaldehyde (CAS 50-00-0) Thimerosal (CAS 54-64-8)  US. NIOSH: Pocket Guide to Chemical I	STEL TWA	0.03 mg/m3	
50-00-0) Thimerosal (CAS 54-64-8)  US. NIOSH: Pocket Guide to Chemical I	STEL TWA	0.03 mg/m3	
50-00-0) Thimerosal (CAS 54-64-8)  US. NIOSH: Pocket Guide to Chemical I Components  Formaldehyde (CAS	STEL TWA Hazards	0.03 mg/m3 0.01 mg/m3	
50-00-0) Thimerosal (CAS 54-64-8)	STEL TWA Hazards Type	0.03 mg/m3 0.01 mg/m3 <b>Value</b>	
50-00-0) Thimerosal (CAS 54-64-8)  US. NIOSH: Pocket Guide to Chemical I Components  Formaldehyde (CAS	STEL TWA Hazards Type Ceiling	0.03 mg/m3 0.01 mg/m3 <b>Value</b> 0.1 ppm	

**Biological limit values** 

No biological exposure limits noted for the ingredient(s).

**Exposure guidelines** 

US - California OELs: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

**US - Tennessee OELs: Skin designation** 

Thimerosal (CAS 54-64-8)

Can be absorbed through the skin.

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

Thimerosal (CAS 54-64-8)

Can be absorbed through the skin.

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

Thimerosal (CAS 54-64-8)

Can be absorbed through the skin.

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

Appropriate engineering

controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

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

Skin protection

**Hand protection** Wear impervious gloves if skin contact is possible.

Other Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable

coveralls, etc.) in both production and laboratory areas.

Respiratory protection No personal respiratory protective equipment normally required. In case of insufficient ventilation,

wear suitable respiratory equipment. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved

respirator must be worn.

Thermal hazards Not applicable.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective

equipment to remove contaminants.

9. Physical and chemical properties

**Appearance** Freeze-dried preparation plus liquid bacterin

Physical state Solid, Liquid.
Form Solid. Liquid.
Color Not available.
Odor threshold Not available.

**pH** 6-8

Melting point/freezing point Not available.

Initial boiling point and boiling

range

> 212 °F (> 100 °C)

Flash point

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

(%)

Explosive limit - lower (%) Not available.
Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) 100 %

Partition coefficient (n-octanol/water)

Not available.

Not available. Auto-ignition temperature **Decomposition temperature** Not available. **Viscosity** Not available.

Other information

Not explosive. **Explosive properties** Oxidizing properties Not oxidizing. Specific gravity 0.8 - 1.2

# 10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

**Chemical stability** Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Sunlight. High temperatures. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.

Strong oxidizing agents. This material can be denatured or inactivated by a variety of organic Incompatible materials

solvents, salts or heavy metals.

Hazardous decomposition

products

No hazardous decomposition products are known.

### 11. Toxicological information

# Information on likely routes of exposure

Inhalation No adverse effects due to inhalation are expected. Prolonged skin contact may cause temporary irritation. Skin contact Formaldehyde

Species: Rabbit

Severity: Moderate Severe

Eye contact Direct contact with eyes may cause temporary irritation.

Thimerosal Species: Rabbit

Severity: Mild

Gentamicin Species: Rabbit

Severity: Non-irritating

Formaldehyde Species: Rabbit

Severity: Severe

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur

# Information on toxicological effects

Expected to be a low hazard for usual industrial or commercial handling by trained personnel. **Acute toxicity** 

Components Species **Test Results** 

Aluminum hydroxide gel (CAS 21645-51-2)

Acute

Other

LD50 Rat 150 mg/kg

with acute exposures in sensitized patients.

Formaldehyde (CAS 50-00-0)

**Acute** 

Inhalation

LC50 Rat 0.48 mg/l, 4 Hours

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Components	Species		Test Results
Oral			
LD50	Rat		800 mg/kg
			100 mg/kg
<u>Chronic</u>			
Inhalation			
LOAEL	Mouse		15 ppm, 2 years Tumors
	Rat		15 ppm, 9 days Respiratory system
			6 ppm, 2 years Tumors
Gentamicin (CAS 1403-66-3)			
<u>Acute</u>			
Intramuscular			
LD50	Mouse		167 mg/kg
	Rat		463 mg/kg
Oral			
LD50	Rat		6600 mg/kg
Subcutaneous			
LD50	Rat		710 mg/kg
Thimerosal (CAS 54-64-8)			
<u>Acute</u>			
Oral			
LD50	Mouse		91 mg/kg
	Rat		75 mg/kg
Subcutaneous			
LD50	Rat		98 mg/kg
Skin corrosion/irritation	Prolonged skin contact may c	ause temporary irritation	on.
Serious eye damage/eye	Direct contact with eyes may cause temporary irritation.		
irritation			
Eye Contact		Occasion Dalabili	
Thimerosal		Species: Rabbit Severity: Mild	
		•	
Gentamicin		Species: Rabbit	22
		Severity: Non-irritatir	ig
Formaldehyde		Species: Rabbit	
		Severity: Severe	
Respiratory or skin sensitization	•		
ACGIH sensitization	•		
FORMALDEHYDE (CAS	50-00-0)	Dermal sensitization	
		Respiratory sensitiza	
Respiratory sensitization	Not a respiratory sensitizer.		
Skin sensitization	This product contains formaldehyde and merthiolate which are considered to be skin sensitizers. This product is not expected to cause skin sensitization.		
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.		
Mutagenicity			
Formaldehyde		In Vitro Bacterial Mut Result: Positive Species: Bacteria	tagenicity (Ames)

In Vitro Chromosome Aberration Result: Positive Species: Rodent

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Mutagenicity

Carcinogenicity

Formaldehyde In Vitro Sister Chromatid Exchange

Result: Positive Species: Rodent

In Vivo Chromosome Aberration

Result: Positive Species: Not specified

carcinogens are present at gi

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. No known

carcinogens are present at greater than 0.1%.

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0) 1 Carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Formaldehyde (CAS 50-00-0)

Cancer

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

Formaldehyde (CAS 50-00-0) Known To Be Human Carcinogen.

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

**Developmental effects** 

Formaldehyde 185 mg/kg/day Embryo / Fetal Development, Not teratogenic

Maternal toxicity Species: Mouse Organ: Oral

40 ppm Embryo / Fetal Development, Not Teratogenic

Maternal Toxicity Species: Rat Organ: Inhalation

Gentamicin 75 mg/kg/day Embryo / Fetal Development, Developmental

toxicity

Result: LOAEL Species: Rat Organ: Intramuscular

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

**Aspiration hazard** Not an aspiration hazard.

**Further information** Allergic reactions are possible. The antigens included in this product are non-infectious. All have

been prepared from modified or inactivated preparations of microorganisms.

12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Avoid release to the environment.

Components Species Test Results

Formaldehyde (CAS 50-00-0)

Aquatic

Crustacea EC50 Water flea (Daphnia pulex) 4.3 - 7.8 mg/l, 48 hours

Fish LC50 Striped bass (Morone saxatilis) 10.302 - 16.743 mg/l, 96 hours

**Persistence and degradability** No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

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### 13. Disposal considerations

**Disposal instructions**Avoid release to the environment. Do not discharge into drains, water courses or onto the ground.

in accordance with local/regional/national/international regulations.

Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. 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). Dispose of contents/container

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

None known. This product contains trace quantities of mercury, releases to the environment

should be avoided.

Disposal instructions).

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

# 14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

**IMDG** 

Not regulated as dangerous goods.

Transport in bulk according to

Not established.

Annex II of MARPOL 73/78 and

the IBC Code

### 15. Regulatory information

**US federal regulations**This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard

Communication Standard, 29 CFR 1910.1200.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Formaldehyde (CAS 50-00-0) Listed.

SARA 304 Emergency release notification

Formaldehyde (CAS 50-00-0) 100 LBS OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Formaldehyde (CAS 50-00-0) Cancer

Skin sensitization

Respiratory sensitization

Eye irritation Skin irritation

respiratory tract irritation

Acute toxicity Flammability

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)	
Formaldehyde	50-00-0	100	500			-

SARA 311/312 Hazardous No

chemical

SARA 313 (TRI reporting)

Not regulated.

#### Other federal regulations

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

Formaldehyde (CAS 50-00-0) Thimerosal (CAS 54-64-8)

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

Formaldehyde (CAS 50-00-0)

Safe Drinking Water Act

(SDWA)

**US state regulations** 

Not regulated.

WARNING: This product contains a chemical known to the State of California to cause cancer and

birth defects or other reproductive harm.

### US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Formaldehyde (CAS 50-00-0) Listed: January 1, 1988

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

Thimerosal (CAS 54-64-8) Listed: July 1, 1990

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

Formaldehyde (CAS 50-00-0)

#### **International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

<sup>\*</sup>A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

04-02-2017 Issue date

Version #

United States & Puerto Rico

Disclaimer Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while

it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently

available.

**Revision information** This document has undergone significant changes and should be reviewed in its entirety.

Toxic Substances Control Act (TSCA) Inventory

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No