

1. Identification

Product identifier	Bovi-Shield GOLD® FP® 5 L5 HB
Other means of identification	
Synonyms	Bovi-Shield GOLD FP5 L5 HB * Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae- Pomona 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.
Health hazards	Not classified.
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.

Label elements

Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
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 Rhinotracheitis		NOT ASSIGNED	*
Bovine Virus Diarrhea		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 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

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

Unsuitable extinguishing media

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

Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

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

Fire fighting equipment/instructions

Use water spray to cool unopened containers.

Specific methods

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

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

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

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

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Avoid discharge into drains, water courses or onto the ground.

Environmental precautions**7. Handling and storage****Precautions for safe handling**

Avoid contact with eyes, skin, and clothing. Avoid breathing mist or 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****US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	2 ppm
	TWA	0.75 ppm

US. OSHA Table Z-2 (29 CFR 1910.1000)

Components	Type	Value
Thimerosal (CAS 54-64-8)	Ceiling	0.04 mg/m ³
	TWA	0.01 mg/m ³

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Aluminum hydroxide gel (CAS 21645-51-2)	TWA	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Aluminum hydroxide gel (CAS 21645-51-2)	TWA	1 mg/m ³	Respirable fraction.
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m ³	
	TWA	0.01 mg/m ³	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm
	TWA	0.016 ppm
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m ³
	TWA	0.01 mg/m ³

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.

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** 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** Not available.**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.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.
Specific gravity	0.8 - 1.2

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
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.
Incompatible materials	Strong oxidizing agents. This material can be denatured or inactivated by a variety of organic 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.
Skin contact	Prolonged skin contact may cause temporary irritation.
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
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Formaldehyde	Species: Rabbit Severity: Severe
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Ingestion	Expected to be a low ingestion hazard.
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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 with acute exposures in sensitized patients.
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Information on toxicological effects

Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
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Components	Species	Test Results
Aluminum hydroxide gel (CAS 21645-51-2)		
<u>Acute</u>		
Other		
LD50	Rat	150 mg/kg
Formaldehyde (CAS 50-00-0)		
<u>Acute</u>		
Inhalation		
LC50	Rat	0.48 mg/l, 4 Hours

Components	Species	Test Results
Oral LD50	Rat	800 mg/kg 100 mg/kg
<u>Chronic</u> Inhalation LOAEL	Mouse Rat	15 ppm, 2 years Tumors 15 ppm, 9 days Respiratory system 6 ppm, 2 years Tumors
Gentamicin (CAS 1403-66-3)		
<u>Acute</u> Intramuscular LD50	Mouse Rat	167 mg/kg 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 Rat	91 mg/kg 75 mg/kg
Subcutaneous LD50	Rat	98 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye Contact Thimerosal	Species: Rabbit Severity: Mild	
Gentamicin	Species: Rabbit Severity: Non-irritating	
Formaldehyde	Species: Rabbit Severity: Severe	
Respiratory or skin sensitization		
ACGIH sensitization FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization Respiratory sensitization	
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 Mutagenicity (Ames) Result: Positive Species: Bacteria In Vitro Chromosome Aberration Result: Positive Species: Rodent	

Mutagenicity
Formaldehyde

In Vitro Sister Chromatid Exchange
Result: Positive
Species: Rodent

In Vivo Chromosome Aberration
Result: Positive
Species: Not specified

Carcinogenicity

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

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.		

13. Disposal considerations

Disposal instructions	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. 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 in accordance with local/regional/national/international regulations.
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.
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: Disposal instructions).
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 Annex II of MARPOL 73/78 and the IBC Code Not established.

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 chemical No

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) Not regulated.

US state regulations

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
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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

Issue date 04-03-2017

Version # 01

Disclaimer

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

Revision information

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