

SAFETY DATA SHEET



1. Identification

Product identifier	CattleMaster GOLD FP 5 L5
Other means of identification	
Synonyms	CattleMaster® GOLD FP® 5 L5 * Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified Live & Killed Virus-Leptospira Canicola-Grippotyphosa-Hardjo-Ichtherohaemorrhagiae-Po mona Bacterin * Bovishield GOLD FP 5 L5
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 & Drug Safety	1-866-531-8896
Product Support/Technical Services	1-888-963-8471
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. Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium
Telephone	+32 10 808080
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPRecords@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. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Amphigen (liquid paraffin+lecithin)		8042-47-5	5-30
Quil-A saponin		66594-14-7	1-10
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	*
Merthiolate (as mercury)		54-64-8	##

Composition comments

Trace

* Non-hazardous Ingredients

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

In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.

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. If swallowed, do NOT induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

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. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

Indication of immediate medical attention and special treatment needed

Treat symptomatically. Where parenteral oil-adjuvanted vaccine exposure has occurred, the patient should be promptly evaluated for the development of vasospasm and/or compartment syndrome.

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

Foam. Dry chemicals. 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. Material will burn in a fire.

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

Cool containers exposed to heat with water spray and remove container, if no risk is involved.

Specific methods

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

General fire hazards

Combustible. Material will burn in a fire.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Remove sources of ignition. Wear personal protective equipment

Large Spills: Stop the flow of material, if this is without risk. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Clean contaminated surface thoroughly.

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

Conditions for safe storage, including any incompatibilities

Do not freeze. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. Keep away from heat, sparks and open flame. Store in original tightly closed container. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS). Store away from direct sunlight.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

US. OSHA Table Z-1 Permissible Exposure Limits (PEL) for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Amphigen (liquid paraffin+lecithin) (CAS 8042-47-5)	PEL	5 mg/m3	Mist.

US. OSHA Table Z-2 Permissible Exposure Limits (PEL) (29 CFR 1910.1000)

Components	Type	Value
Merthiolate (as mercury) (CAS 54-64-8)	Ceiling	0.04 mg/m3
	TWA	0.01 mg/m3

US. ACGIH Threshold Limit Values (TLV)

Components	Type	Value	Form
Amphigen (liquid paraffin+lecithin) (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m3	

NIOSH. Immediately Dangerous to Life or Health (IDLH) Values, as amended

Components	Type	Value
Amphigen (liquid paraffin+lecithin) (CAS 8042-47-5)	IDLH	2500 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards Recommended Exposure Limits (REL)

Components	Type	Value	Form
Amphigen (liquid paraffin+lecithin) (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m3	

US. NIOSH: Pocket Guide to Chemical Hazards Recommended Exposure Limits (REL)

Components	Type	Value	Form
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	TWA	0.01 mg/m3	
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Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines

US - Tennessee OELs: Skin designation

Merthiolate (as mercury) (CAS 54-64-8) Can be absorbed through the skin.

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

Merthiolate (as mercury) (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 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. General ventilation normally adequate. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section.

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 appropriate chemical resistant gloves.

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. 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. 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. Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

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 + Liquid solution.

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 Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable. Not available.

Upper/lower flammability or explosive limits

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)	Not available.
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	Keep away from heat, sparks and open flame. Sunlight. High temperatures. Contact with incompatible materials. 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	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Prolonged inhalation may be harmful.
Skin contact	Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.
Amphigen (liquid paraffin+lecithin)	Species: Rabbit Severity: Non-irritating

Eye contact	Direct contact with eyes may cause temporary irritation.
Merthiolate (as mercury)	Species: Rabbit Severity: Mild
Amphigen (liquid paraffin+lecithin)	Species: Rabbit Severity: Non-irritating
Gentamicin	Species: Rabbit Severity: Non-irritating

Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
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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. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.
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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. Allergic reactions are possible. May be harmful if swallowed.
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Components	Species	Test Results
Amphigen (liquid paraffin+lecithin) (CAS 8042-47-5)		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg
<u>Chronic</u>		
Oral		
NOAEL	Rat	1800 mg/kg/day, 90 days Liver
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
Merthiolate (as mercury) (CAS 54-64-8)		
<u>Acute</u>		
Oral		
LD50	Rat	75 mg/kg
Subcutaneous		
LD50	Rat	98 mg/kg
Quil-A saponin (CAS 66594-14-7)		
<u>Acute</u>		
Intravenous		
LD50	Rat	670 ug/kg
Skin corrosion/irritation	Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye Contact		
Merthiolate (as mercury)	Species: Rabbit Severity: Mild	
Amphigen (liquid paraffin+lecithin)	Species: Rabbit Severity: Non-irritating	
Gentamicin	Species: Rabbit Severity: Non-irritating	
Respiratory or skin sensitization		
Respiratory sensitization	Due to partial or complete lack of data the classification is not possible. In the event of accidental injection, an allergic reaction may occur.	
Skin sensitization	Due to partial or complete lack of data the classification is not possible. In the event of accidental injection, an allergic reaction may occur. This product contains merthiolate which is considered to be a skin sensitizer.	
Skin sensitization		
Amphigen (liquid paraffin+lecithin)	Species: Guinea Pig Severity: Negative	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Amphigen (liquid paraffin+lecithin)	In Vitro Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella	

Mutagenicity
Amphigen (liquid paraffin+lecithin)

In Vitro Mammalian Cell Mutagenicity
Result: Negative
Species: Mouse Lymphoma

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Amphigen (liquid paraffin+lecithin) (CAS 8042-47-5) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Due to partial or complete lack of data the classification is not possible. This product is not expected to cause reproductive or developmental effects.

Developmental effects

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 Due to partial or complete lack of data the classification is not possible.

Chronic effects Prolonged inhalation may be harmful.

Further information The antigens included in this product are non-infectious. All have been prepared from modified or inactivated preparations of microorganisms. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

12. Ecological information

Ecotoxicity Based on available data, the classification criteria are not met for hazardous to the aquatic environment. 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
Amphigen (liquid paraffin+lecithin) (CAS 8042-47-5)		
Aquatic		
Fish	LC50	Lepomis macrochirus (Bluegill Sunfish) > 10000 mg/L, 96 Hours
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulative potential	Not expected to bioaccumulate.	
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. Dispose of contents/container in accordance with local/regional/national/international regulations. 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).

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.
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.

Toxic Substances Control Act (TSCA) One or more components of the mixture are not on the TSCA 8(b) inventory or are designated "inactive".

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

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

Merthiolate (as mercury) (CAS 54-64-8)

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

Not regulated.

Safe Drinking Water Act (SDWA) Contains component(s) regulated under the Safe Drinking Water Act.

US state regulations

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

Amphigen (liquid paraffin+lecithin) (CAS 8042-47-5)

California Proposition 65



WARNING: This product can expose you to Merthiolate (as mercury), which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Developmental toxin

Merthiolate (as mercury) (CAS 54-64-8)

Listed: July 1, 1990

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No

Country(s) or region	Inventory name	On inventory (yes/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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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	03-12-2018
Revision date	01-25-2024
Version #	02
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.