

SAFETY DATA SHEET



Revision date: 21-Nov-2013

Version: 2.0

Page 1 of 7

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

Trade Name: Bovi-Shield GOLD 5
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 liquid vaccine

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:

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.

SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus
Revision date: 21-Nov-2013

Page 2 of 7

Version: 2.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|------------|------------|-----------------------|-------------------|--------------------|---|
| 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 | * |
| 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

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 |

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: | Not known |
|---------------------------------------|-----------|

SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified Live Virus
Revision date: 21-Nov-2013

Page 3 of 7

Version: 2.0

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions. Dust can form an explosive mixture in air.

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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

Avoid contact with eyes, skin and clothing. Avoid breathing dust, vapor or mist. Minimize dust generation and accumulation. Keep away from heat, sparks, and flame. Avoid accidental injection. When handling, use appropriate personal protective equipment (see Section 8).

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging. Keep container tightly closed when not in use.
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.

Gentamicin

Bulgaria OEL - TWA 0.1 mg/m³

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/m³ to < 1000ug/m³)

Exposure Controls

SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus
Revision date: 21-Nov-2013

Page 4 of 7

Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---------------------------------------|--|
| Engineering Controls: | 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. Keep airborne contamination levels below the exposure limits listed above in this section. |
| Personal Protective Equipment: | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). |
| Hands: | Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations. |
| Eyes: | Wear safety glasses or goggles if eye contact is possible. |
| Skin: | Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. |
| Respiratory protection: | 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

| | | | |
|---|--|--------------------------|--------------------|
| Physical State: | Freeze-dried preparation plus liquid vaccine | Color: | No data available. |
| Odor: | No data available. | Odor Threshold: | No data available. |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
| Solvent Solubility: | No data available | | |
| Water Solubility: | No data available | | |
| Solubility: | Soluble: Water (based on components) | | |
| pH: | 7.0 +/- 1.5 | | |
| Melting/Freezing Point (°C): | No data available | | |
| Boiling Point (°C): | >100 | | |
| Partition Coefficient: (Method, pH, Endpoint, Value) | No data available | | |
| Decomposition Temperature (°C): | No data available. | | |
| 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 | |

SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus
Revision date: 21-Nov-2013

Page 5 of 7

Version: 2.0

10. STABILITY AND REACTIVITY

| | |
|--|--|
| 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:

Toxicological properties of the formulation have not been investigated. The antigens included in this product are non-infectious. All have been prepared from modified 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)

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)

Gentamicin

Eye Irritation Rabbit Non-irritating

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.

SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus
Revision date: 21-Nov-2013

Page 6 of 7

Version: 2.0

12. ECOLOGICAL INFORMATION

| | |
|---------------------------------------|--|
| Environmental Overview: | The environmental characteristics of this material have not been fully evaluated. 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. |
|---------------------------------|---|

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.

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.

Bovine Parainfluenza3

SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus
Revision date: 21-Nov-2013

Page 7 of 7

Version: 2.0

15. REGULATORY INFORMATION

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

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 |
| 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

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 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