

MATERIAL SAFETY DATA SHEET



Revision date: 12-Aug-2013

Version: 2.0

Page 1 of 10

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Mannheimia Haemolytica Toxoid

Trade Name: BOVI-SHIELD GOLD ONE SHOT
Compound Number: 4X41.20
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

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.

MATERIAL SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus, Mannheimia Haemolytica Toxoid
Revision date: 12-Aug-2013

Page 2 of 10

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 | ## |
| Formaldehyde | 50-00-0 | 200-001-8 | T; R23/24/25 C; R34 Carc.Cat.3; R40 R43 | Carc.2 (H351) Acute Tox.3 (H331) Acute Tox.3 (H311) Acute Tox.3 (H301) Skin Corr. 1B (H314) Skin Sens. 1 (H317) | <0.1 |

| 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 | * |
| Mannheimia haemolytica | Not Assigned | Not Listed | Not Listed | Not Listed | * |

Additional Information:

Trace

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation:

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions

None known

Aggravated by Exposure:

MATERIAL SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus, Mannheimia Haemolytica Toxoid
Revision date: 12-Aug-2013

Page 3 of 10

Version: 2.0

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: Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing dust, vapor or mist.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

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

Formaldehyde

MATERIAL SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus, Mannheimia Haemolytica Toxoid
Revision date: 12-Aug-2013

Page 4 of 10

Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|---|
| ACGIH Ceiling Threshold Limit: | 0.3 ppm |
| ACGIH - Sensitizer Designation | Sensitizer |
| Australia STEL | 2 ppm |
| | 2.5 mg/m ³ |
| Australia TWA | 1 ppm |
| | 1.2 mg/m ³ |
| Austria OEL - MAKs | 0.5 ppm |
| | 0.6 mg/m ³ |
| Bulgaria OEL - TWA | 1.0 mg/m ³ |
| Czech Republic OEL - TWA | 0.5 mg/m ³ |
| Estonia OEL - TWA | 0.5 ppm |
| | 0.6 mg/m ³ |
| Finland OEL - TWA | 0.3 ppm |
| | 0.37 mg/m ³ |
| France OEL - TWA | 0.5 ppm |
| Germany (DFG) - MAK | 0.3 ppm |
| | 0.37 mg/m ³ no irritation should occur during mixed exposure |
| Greece OEL - TWA | 2 ppm |
| | 2.5 mg/m ³ |
| Hungary OEL - TWA | 0.6 mg/m ³ |
| Ireland OEL - TWAs | 2 ppm |
| | 2.5 mg/m ³ |
| Japan - OELs - Ceilings | 0.2 ppm |
| | 0.24 mg/m ³ |
| Latvia OEL - TWA | 0.5 mg/m ³ |
| Lithuania OEL - TWA | 0.5 ppm |
| | 0.6 mg/m ³ |
| Netherlands OEL - TWA | 0.15 mg/m ³ |
| Vietnam OEL - TWAs | 0.5 mg/m ³ |
| OSHA - Final PELs - TWAs: | 0.75 ppm |
| OSHA - Specifically Regulated Chemicals | 2 ppm |
| | 0.5 ppm |
| | 0.75 ppm |
| Poland OEL - TWA | 0.5 mg/m ³ |
| Romania OEL - TWA | 1 ppm |
| | 1.20 mg/m ³ |
| Slovakia OEL - TWA | 0.3 ppm |
| | 0.37 mg/m ³ |
| Slovenia OEL - TWA | 0.5 ppm |
| | 0.62 mg/m ³ |
| Sweden OEL - TWAs | 0.3 ppm |
| | 0.37 mg/m ³ |
| Switzerland OEL - TWAs | 0.3 ppm |
| | 0.37 mg/m ³ |

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

MATERIAL SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus, Mannheimia Haemolytica Toxoid
Revision date: 12-Aug-2013

Page 5 of 10

Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands: Wear impervious gloves if skin contact is possible.
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: Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk.

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 under normal conditions of use. |
| Possibility of Hazardous Reactions | |
| 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: | No data available |

MATERIAL SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus, Mannheimia Haemolytica Toxoid
Revision date: 12-Aug-2013

Page 6 of 10

Version: 2.0

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

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 167mg/kg
Rat IM LD50 463mg/kg

Formaldehyde

Rat Oral LD50 100 mg/kg
Rat Inhalation LC50/4h 0.48mg/L
Mouse Inhalation LC50/4h 0.414mg/L
Rabbit Dermal LD50 270mg/kg

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

Gentamicin

Eye Irritation Rabbit Non-irritating

Formaldehyde

Skin Irritation Rabbit Severe
Eye Irritation Rabbit Severe
Skin Sensitization - Beuhler Guinea Pig Positive
Skin Sensitization - GPMT Guinea Pig Positive

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Formaldehyde

90 Day(s) Rat Inhalation 1.6 ppm NOAEL Lungs
13 Week(s) Rat Inhalation 0.0012 mg/L NOAEL Lungs, Respiratory system
4 Week(s) Rat Oral 25 mg/kg NOAEL Gastrointestinal system
13 Week(s) Mouse Inhalation 0.002 mg/L NOAEL Lungs, Respiratory system

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

Formaldehyde

Embryo / Fetal Development Rat Inhalation 40 ppm NOAEL Not Teratogenic, Maternal Toxicity
Embryo / Fetal Development Mouse Oral 185 mg/kg NOAEL Not Teratogenic, Maternal Toxicity

MATERIAL SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus, Mannheimia Haemolytica Toxoid
Revision date: 12-Aug-2013

Page 7 of 10

Version: 2.0

11. TOXICOLOGICAL INFORMATION

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Formaldehyde

In Vitro Bacterial Mutagenicity (Ames) Bacteria Positive
In Vitro Chromosome Aberration Rat Positive
In Vitro Sister Chromatid Exchange Rat Positive
In Vivo Chromosome Aberration Rat Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors
2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

Carcinogen Status:

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

Formaldehyde

IARC: Group 1 (Carcinogenic to Humans)
NTP: Known Human Carcinogen
OSHA: Listed

12. ECOLOGICAL INFORMATION

Environmental Overview:

The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Formaldehyde

Oncorhynchus mykiss (Rainbow Trout) EPA LC50 96 Hours 118 ppm
Daphnia magna (Water Flea) OECD EC50 24 Hours 42 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

MATERIAL SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus, Mannheimia Haemolytica Toxoid
Revision date: 12-Aug-2013

Page 8 of 10

Version: 2.0

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.

Formaldehyde

RCRA - U Series Wastes

Listed

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

| | |
|------------------------------------|------------|
| 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 |

MATERIAL SAFETY DATA SHEET

Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus, Mannheimia Haemolytica Toxoid
Revision date: 12-Aug-2013

Page 9 of 10

Version: 2.0

15. REGULATORY INFORMATION

| | |
|--|-------------------------------------|
| 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): Standard for the Uniform Scheduling for Drugs and Poisons: | Present Schedule 4 |
| EU EINECS/ELINCS List | 215-765-8 |
| Mannheimia haemolytica | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |
| Formaldehyde | |
| CERCLA/SARA 313 Emission reporting | 0.1 % |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 100 lb 45.4 kg |
| CERCLA/SARA - Section 302 Extremely Hazardous TPQs | 500 lb |
| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | 100 lb |
| California Proposition 65 | carcinogen initial date 1/1/88 gas |
| OSHA - Specifically Regulated Chemicals | 2 ppm 0.5 ppm 0.75 ppm |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons: | Present Schedule 2 Schedule 6 |
| EU EINECS/ELINCS List | 200-001-8 |

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, dermal-Cat.3; H311 - Toxic in contact with skin
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer

MATERIAL SAFETY DATA SHEET

**Material Name: Bovine Rhinotracheitis-Virus Diarrhea-
Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified
Live Virus, Mannheimia Haemolytica Toxoid**
Revision date: 12-Aug-2013

Page 10 of 10

Version: 2.0

T - Toxic
C - Corrosive
Carcinogenic: Category 3
Xi - Irritant

R34 - Causes burns.
R43 - May cause sensitization by skin contact.
R40 - Limited evidence of a carcinogenic effect
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

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.

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