

SAFETY DATA SHEET



Revision date: 03-Feb-2014

Version: 1.0

Page 1 of 10

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

Product Identifier

Material Name: Bovine Virus Diarrhea Vaccine, Modified Live Virus, Mannheimia Haemolytica Toxoid

Trade Name: ONE SHOT BVD

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 sterile diluent

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.

SAFETY DATA SHEET

Material Name: Bovine Virus Diarrhea Vaccine, Modified Live
 Virus, Mannheimia Haemolytica Toxoid
 Revision date: 03-Feb-2014

Page 2 of 10

Version: 1.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Formaldehyde	50-00-0	200-001-8	T; R23/24/25 C; R34 Carc. Cat.3; R40 R43	Acute Tox. 3 (H301) Skin Corr. 1B (H314) Skin Sens. 1 (H317) Carc. 1A (H350) Acute Tox. 3 (H331)	<0.1
Gentamicin	1403-66-3	215-765-8	Not Listed	Not Listed	##

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
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:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

None

SAFETY DATA SHEET

Material Name: Bovine Virus Diarrhea Vaccine, Modified Live
Virus, Mannheimia Haemolytica Toxoid
Revision date: 03-Feb-2014

Page 3 of 10

Version: 1.0

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 spill with absorbent material. 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. Avoid accidental injection. When handling, use proper personal protective equipment as specified in Section 8. Releases to the environment should be avoided.

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.

Formaldehyde

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

SAFETY DATA SHEET

Material Name: Bovine Virus Diarrhea Vaccine, Modified Live
Virus, Mannheimia Haemolytica Toxoid
Revision date: 03-Feb-2014

Page 4 of 10

Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
Gentamicin	
Bulgaria OEL - TWA	0.1 mg/m ³

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 Virus Diarrhea Vaccine, Modified Live
Virus, Mannheimia Haemolytica Toxoid
Revision date: 03-Feb-2014

Page 5 of 10

Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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).
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

SAFETY DATA SHEET

Material Name: Bovine Virus Diarrhea Vaccine, Modified Live
Virus, Mannheimia Haemolytica Toxoid
Revision date: 03-Feb-2014

Page 6 of 10

Version: 1.0

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

Toxicological properties of the formulation have not been investigated. The information included in this section describes the potential hazards of the individual ingredients. The antigens included in this product are non-infectious. All have been prepared from modified or inactivated preparations of microorganisms.

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

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))

SAFETY DATA SHEET

Material Name: Bovine Virus Diarrhea Vaccine, Modified Live
Virus, Mannheimia Haemolytica Toxoid
Revision date: 03-Feb-2014

Page 7 of 10

Version: 1.0

11. TOXICOLOGICAL INFORMATION

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

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

SAFETY DATA SHEET

Material Name: Bovine Virus Diarrhea Vaccine, Modified Live
Virus, Mannheimia Haemolytica Toxoid
Revision date: 03-Feb-2014

Page 8 of 10

Version: 1.0

12. ECOLOGICAL INFORMATION

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

Toxicity:

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

Formaldehyde

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	EPA	LC50	96 Hours	118 ppm
<i>Daphnia magna</i> (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

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

SAFETY DATA SHEET

Material Name: Bovine Virus Diarrhea Vaccine, Modified Live
Virus, Mannheimia Haemolytica Toxoid
Revision date: 03-Feb-2014

Page 9 of 10

Version: 1.0

15. REGULATORY INFORMATION

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.

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):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 6
EU EINECS/ELINCS List	200-001-8

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

Bovine Virus Diarrhea

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

Mannheimia haemolytica

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

16. OTHER INFORMATION

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

SAFETY DATA SHEET

**Material Name: Bovine Virus Diarrhea Vaccine, Modified Live
Virus, Mannheimia Haemolytica Toxoid**
Revision date: 03-Feb-2014

Page 10 of 10

Version: 1.0

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
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.1A; H350 - May cause cancer

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: New data sheet.

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