

SAFETY DATA SHEETS

This SDS packet was issued with item:

078914598

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078914599

SAFETY DATA SHEET



Revision date: 03-Feb-2014

Version: 1.0

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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: VMIPRecords@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.

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SAFETY DATA SHEET

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

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

Exposure:

None known

Medical Conditions

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

None

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SAFETY DATA SHEET

Material Name: Bovine Virus Diarrhea Vaccine, Modified Live
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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
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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
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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

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

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Material Name: Bovine Virus Diarrhea Vaccine, Modified Live
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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 NOEL Lungs
13 Week(s) Rat Inhalation 0.0012 mg/L NOEL Lungs, Respiratory system
4 Week(s) Rat Oral 25 mg/kg NOEL Gastrointestinal system
13 Week(s) Mouse Inhalation 0.002 mg/L NOEL Lungs, Respiratory system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

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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

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

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

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SAFETY DATA SHEET

Material Name: Bovine Virus Diarrhea Vaccine, Modified Live
Virus, Mannheimia Haemolytica Toxoid
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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
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	45.4 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	100 lb
OSHA - Specifically Regulated Chemicals	carcinogen initial date 1/1/88 gas
	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
EU EINECS/ELINCS List	Schedule 6
	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

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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

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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

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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
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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

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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

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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

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

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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
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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
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	45.4 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	100 lb
OSHA - Specifically Regulated Chemicals	carcinogen initial date 1/1/88 gas
	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
EU EINECS/ELINCS List	Schedule 6
	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

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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

SAFETY DATA SHEET



1. Identification

Product identifier	ONE SHOT® BVD
Other means of identification	
Synonyms	ONE SHOT BVD * Bovine Virus Diarrhea Vaccine, Modified Live Virus, Mannheimia Haemolytica Toxoid
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.

3. Composition/information on ingredients

Mixtures			
Chemical name	Common name and synonyms	CAS number	%
Formaldehyde		50-00-0	<0.1

Chemical name	Common name and synonyms	CAS number	%
Bovine Virus Diarrhea		NOT ASSIGNED	
Gentamicin		1403-66-3	##
Mannheimia haemolytica		Not Assigned	

Composition comments

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. For breathing difficulties, oxygen may be necessary.

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.

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. Symptoms may be delayed.

General information

IF exposed or concerned: Get medical advice/attention. 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

Move containers from fire area if you can do so without risk.

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. 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.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid accidental injection. Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapor. 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. Refrigeration recommended. @ 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

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 Specifically Regulated Substances (29 CFR 1910.1001-1050)

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

US. ACGIH Threshold Limit Values

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	0.3 ppm
	TWA	0.1 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm
	TWA	0.016 ppm

Biological limit values

No biological exposure limits noted for the ingredient(s).

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. 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 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. In case of insufficient ventilation, wear suitable respiratory equipment. 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.

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 sterile diluent

Physical state

Solid, Liquid.

Form

Solid, Liquid.

Color

Not available.

Odor	Not available.
Odor threshold	Not available.
pH	6.5 - 7.5
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 applicable.
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	Negligible
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble
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. Keep away from heat, sparks, flame and all other sources of ignition. Protect from sunlight. 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. May include products of carbon, nitrogen.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Prolonged skin contact may cause temporary irritation.
Formaldehyde	Species: Rabbit Severity: Moderate to Severe
Eye contact	Direct contact with eyes may cause temporary irritation.
Gentamicin	Species: Rabbit Severity: Non-irritating

Eye contact
Formaldehyde

Species: Rabbit
Severity: Severe

Ingestion

Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes 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.

Information on toxicological effects

Acute toxicity

Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components

Species

Test Results

Formaldehyde (CAS 50-00-0)

Acute

Dermal

LD50

Rabbit

270 mg/kg

Inhalation

LC50

Mouse

0.414 mg/L, 4 hours

Rat

0.48 mg/L, 4 hours

Oral

LD50

Rat

100 mg/kg

Chronic

Inhalation

LOAEL

Mouse

15 ppm, 2 years Tumors

Rat

15 ppm, 90 days Respiratory system

6 ppm, 2 years Tumors

Gentamicin (CAS 1403-66-3)

Acute

Intramuscular

LD50

Mouse

167 mg/kg

Rat

463 mg/kg

Oral

LD50

Rat

6600 mg/kg

Subcutaneous

LD50

Rat

710 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

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

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

Skin sensitization

Due to partial or complete lack of data the classification is not possible. This product contains formaldehyde which is considered to be a skin sensitizer. This product is not expected to cause skin sensitization.

Skin sensitization
Formaldehyde

Species: Guinea Pig
Severity: Positive

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

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. 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.

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

The antigens included in this product are non-infectious. All have been prepared from modified or inactivated preparations of microorganisms.

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
Formaldehyde (CAS 50-00-0)	EC50	Daphnia magna (Water Flea)	42 mg/L, 24 Hours
	LC50	Oncorhynchus mykiss (Rainbow Trout)	118 ppm, 96 Hours
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 for this product. 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 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. 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	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
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

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)

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.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Formaldehyde (CAS 50-00-0)

Listed: January 1, 1988

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
 01-16-2018

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.

SAFETY DATA SHEET



1. Identification

Product identifier	ONE SHOT® BVD
Other means of identification	
Synonyms	ONE SHOT BVD * Bovine Virus Diarrhea Vaccine, Modified Live Virus, Mannheimia Haemolytica Toxoid
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.

3. Composition/information on ingredients

Mixtures			
Chemical name	Common name and synonyms	CAS number	%
Formaldehyde		50-00-0	<0.1

Material name: ONE SHOT® BVD

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Chemical name	Common name and synonyms	CAS number	%
Bovine Virus Diarrhea		NOT ASSIGNED	
Gentamicin		1403-66-3	##
Mannheimia haemolytica		Not Assigned	
Composition comments	## 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. For breathing difficulties, oxygen may be necessary.		
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.		
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. Symptoms may be delayed.		
General information	IF exposed or concerned: Get medical advice/attention. 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	Move containers from fire area if you can do so without risk.		
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. 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.		
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.		

7. Handling and storage

Precautions for safe handling

Avoid accidental injection. Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapor. 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. Refrigeration recommended. @ 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

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 Specifically Regulated Substances (29 CFR 1910.1001-1050)

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

US. ACGIH Threshold Limit Values

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	0.3 ppm
	TWA	0.1 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm
	TWA	0.016 ppm

Biological limit values

No biological exposure limits noted for the ingredient(s).

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. 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 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. In case of insufficient ventilation, wear suitable respiratory equipment. 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.

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 sterile diluent

Physical state

Solid, Liquid.

Form

Solid, Liquid.

Color

Not available.

Odor	Not available.
Odor threshold	Not available.
pH	6.5 - 7.5
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 applicable.
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	Negligible
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble
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. Keep away from heat, sparks, flame and all other sources of ignition. Protect from sunlight. 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. May include products of carbon, nitrogen.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Prolonged skin contact may cause temporary irritation.
Formaldehyde	Species: Rabbit Severity: Moderate to Severe
Eye contact	Direct contact with eyes may cause temporary irritation.
Gentamicin	Species: Rabbit Severity: Non-irritating

Eye contact
Formaldehyde

Species: Rabbit
Severity: Severe

Ingestion

Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes 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.

Information on toxicological effects

Acute toxicity

Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components

Species

Test Results

Formaldehyde (CAS 50-00-0)

Acute

Dermal

LD50

Rabbit

270 mg/kg

Inhalation

LC50

Mouse

0.414 mg/L, 4 hours

Rat

0.48 mg/L, 4 hours

Oral

LD50

Rat

100 mg/kg

Chronic

Inhalation

LOAEL

Mouse

15 ppm, 2 years Tumors

Rat

15 ppm, 90 days Respiratory system

6 ppm, 2 years Tumors

Gentamicin (CAS 1403-66-3)

Acute

Intramuscular

LD50

Mouse

167 mg/kg

Rat

463 mg/kg

Oral

LD50

Rat

6600 mg/kg

Subcutaneous

LD50

Rat

710 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

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

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

Skin sensitization

Due to partial or complete lack of data the classification is not possible. This product contains formaldehyde which is considered to be a skin sensitizer. This product is not expected to cause skin sensitization.

Skin sensitization
Formaldehyde

Species: Guinea Pig
Severity: Positive

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

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. 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.

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

The antigens included in this product are non-infectious. All have been prepared from modified or inactivated preparations of microorganisms.

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
Formaldehyde (CAS 50-00-0)		
	EC50	Daphnia magna (Water Flea) 42 mg/L, 24 Hours
	LC50	Oncorhynchus mykiss (Rainbow Trout) 118 ppm, 96 Hours
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 for this product. 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 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. 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	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
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

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)

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.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Formaldehyde (CAS 50-00-0)

Listed: January 1, 1988

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)

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