

# SAFETY DATA SHEET



Revision date: 21-Apr-2014

Version: 2.0

Page 1 of 7

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

### Product Identifier

**Material Name:** INFORCE 3

**Trade Name:**

INFORCE 3

**Synonyms:**

Bovine Rhinotracheitis-Parainfluenza3-Respiratory Syncytial Virus Vaccine, Modified Live Virus

**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:** White to off-white freeze-dried plug

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Signal Word:** Not Classified

**Hazard Statements:** Non-hazardous in accordance with international standards for workplace safety.

### Other Hazards

#### Short Term:

In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

#### Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

### Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## SAFETY DATA SHEET

Material Name: INFORCE 3  
Revision date: 21-Apr-2014

Page 2 of 7  
Version: 2.0

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Gentamicin	1403-66-3	215-765-8	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Bovine Respiratory Syncytial Virus	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Bovine Parainfluenza3	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Bovine Rhinotracheitis	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*

#### Additional Information:

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

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion:</b>	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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
<b>Medical Conditions Aggravated by Exposure:</b>	None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

<b>Notes to Physician:</b>	None
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### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

## SAFETY DATA SHEET

Material Name: **INFORCE 3**  
Revision date: **21-Apr-2014**

Page **3** of **7**  
Version: **2.0**

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

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

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store under refrigeration in closed container.  
**Storage Temperature:** 2-7°C  
**Incompatible Materials:** This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals. As a precautionary measure, keep away from strong oxidizers

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Gentamicin

**Bulgaria OEL - TWA** 0.1 mg/m<sup>3</sup>

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/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

#### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

## SAFETY DATA SHEET

Material Name: INFORCE 3  
Revision date: 21-Apr-2014

Page 4 of 7  
Version: 2.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hands:** Wear impervious gloves if skin contact is possible.  
**Eyes:** Safety glasses or goggles  
**Skin:** Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.  
**Respiratory protection:** 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Freeze-dried plug	<b>Color:</b>	White to off-white
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>			
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>		No data available	
<b>Flammability (Solids):</b>		No data available	
<b>Flash Point (Liquid) (°C):</b>		No data available	
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Polymerization:</b>		Will not occur	

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**

**Oxidizing Properties:** No data available  
    **Conditions to Avoid:** Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals. As a precautionary measure, keep away from strong oxidizers

**Hazardous Decomposition Products:** None expected under normal conditions.

## SAFETY DATA SHEET

Material Name: INFORCE 3  
Revision date: 21-Apr-2014

Page 5 of 7  
Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

##### General Information:

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 killed or inactivated preparations of microorganisms. Toxicological properties of the formulation have not been investigated.

##### Acute Toxicity: (Species, Route, End Point, Dose)

###### Gentamicin

Rat Oral LD50 6600 mg/kg  
Rat Subcutaneous LD50 710mg/kg  
Mouse IM LD50 167 mg/kg  
Rat IM LD50 463 mg/kg

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

###### Gentamicin

Eye Irritation Rabbit Non-irritating

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

###### Gentamicin

Embryo / Fetal Development Rat Intramuscular 75 mg/kg/day LOAEL Developmental toxicity

##### Reproductive Effects

Not considered to be a reproductive hazard.

##### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### 12. ECOLOGICAL INFORMATION

##### Environmental Overview:

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

##### Toxicity:

No data available

##### Persistence and Degradability:

No data available

##### Bio-accumulative Potential:

No data available

##### Mobility in Soil:

No data available

## SAFETY DATA SHEET

Material Name: INFORCE 3  
Revision date: 21-Apr-2014

Page 6 of 7  
Version: 2.0

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

**Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture**

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

**Bovine Respiratory Syncytial Virus**

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

EU EINECS/ELINCS List Not Listed

**Bovine Parainfluenza3**

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

EU EINECS/ELINCS List Not Listed

**Bovine Rhinotracheitis**

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

EU EINECS/ELINCS List Not Listed

**Gentamicin**

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 developmental toxicity initial date 10/1/92

Australia (AICS): Present

## SAFETY DATA SHEET

Material Name: INFORCE 3  
Revision date: 21-Apr-2014

Page 7 of 7  
Version: 2.0

### 15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	215-765-8

### 16. OTHER INFORMATION

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

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.

**End of Safety Data Sheet**