

# SAFETY DATA SHEET



Revision date: 16-Jan-2014

Version: 2.0

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

### Product Identifier

**Material Name:** Campylobacter Fetus Bacterin

**Trade Name:** Vibrin (R)

**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:** Liquid solution in multiple-dose vials

### 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:** Not classified in accordance with international standards for workplace safety.

### Other Hazards

#### Short Term:

May cause eye and skin irritation. May cause allergic reaction. 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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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

| Ingredient            | CAS Number | EU EINECS/ELINCS List | EU Classification                                 | GHS Classification  | %    |
|-----------------------|------------|-----------------------|---|---|------|
| Aluminum monostearate | 7047-84-9  | 230-325-5             | Not Listed  | Not Listed  | *    |
| Formaldehyde          | 50-00-0    | 200-001-8             | T; R23/24/25<br>C; R34<br>Carc. Cat.3; R40<br>R43 | Acute Tox. 3 (H301)<br>Skin Corr. 1B (H314)<br>Skin Sens. 1 (H317)<br>Carc. 2 (H351)<br>Acute Tox. 3 (H331) | <0.1 |

| Ingredient          | CAS Number   | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---------------------|--------------|-----------------------|-------------------|--------------------|---|
| Campylobacter fetus | NOT ASSIGNED | Not Listed            | Not Listed        | Not Listed         | * |
| Safflower oil       | 8001-23-8    | 232-276-5             | Not Listed        | Not Listed         | * |
| Methylparaben       | 99-76-3      | 202-785-7             | Not Listed        | Not Listed         | * |
| Butylparaben        | 94-26-8      | 202-318-7             | Not Listed        | Not Listed         | * |
| Propylparaben       | 94-13-3      | 202-307-7             | Not Listed        | Not Listed         | * |

**Additional Information:** \* 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:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash skin with soap and water. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

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

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

**Medical Conditions Aggravated by Exposure:** None known

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

**Notes to Physician:** 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**

**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. 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 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**

Keep away from heat, sparks, and flame. Use with adequate ventilation. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Prevent environmental releases. Use appropriate personal protective equipment. 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.

**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.

**Aluminum monostearate**

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

Sweden OEL - TWAs 5 mg/m<sup>3</sup>

**Formaldehyde**

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Exposure Controls

|                                       |  |
|---------------------------------------|--|
| <b>Engineering Controls:</b>          | Engineering controls should be used as the primary means to control exposures. Exposure monitoring may be necessary to determine requirements. |
| <b>Personal Protective Equipment:</b> | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).                        |
| <b>Hands:</b>                         | Wear impervious gloves if skin contact is possible.  |
| <b>Eyes:</b>                          | Safety glasses or goggles  |

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Skin:** Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

**Respiratory protection:** In the event of a spill where the applicable Occupational Exposure Limit (OEL) may be exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

|   |  |                          |                    |
|---|--|--------------------------|--------------------|
| <b>Physical State:</b>                                      | Liquid solution in multiple-dose vials | <b>Color:</b>            | No data available. |
| <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>Solubility:</b>  | Soluble: Water (based on components)   |                          |                    |
| <b>pH:</b>  | 7.0 +/- 1.5                            |                          |                    |
| <b>Melting/Freezing Point (°C):</b>                         | No data available                      |                          |                    |
| <b>Boiling Point (°C):</b>                                  | >100                                   |                          |                    |
| <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>                                | Expected to be negligible              |                          |                    |
| <b>Vapor Density (g/ml):</b>                                | No data available                      |                          |                    |
| <b>Relative Density:</b>                                    | No data available                      |                          |                    |
| <b>Specific Gravity:</b>                                    | 1.0 +/-0.2                             |                          |                    |
| <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>                           |  | Non-flammable            |                    |
| <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

|   |   |
|---|---|
| <b>Reactivity:</b>                        | No data available   |
| <b>Chemical Stability:</b>                | Stable  |
| <b>Possibility of Hazardous Reactions</b> |   |
| <b>Oxidizing Properties:</b>              | No data available   |
| <b>Conditions to Avoid:</b>               | Store at 2°-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. |
| <b>Incompatible Materials:</b>            | This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.  |
| <b>Hazardous Decomposition Products:</b>  | None expected under normal conditions.  |

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### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

##### General Information:

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

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

###### Propylparaben

Mouse Oral LD 50 6332 mg/kg  
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

###### Formaldehyde

Rat Oral LD50 800 mg/kg

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

###### Safflower oil

Eye Irritation Rabbit Mild

###### Formaldehyde

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Moderate Severe

##### Skin Irritation / Sensitization

This product contains formaldehyde which is considered to be a skin sensitizer.

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

###### Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system  
4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

###### Formaldehyde

90 Day(s) Dog Inhalation Not Specified Lungs  
90 Day(s) Rat Inhalation Not Specified Lungs  
90 Day(s) Monkey Inhalation Not Specified Lungs  
9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

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

###### Formaldehyde

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

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

###### Formaldehyde

*In Vitro* Bacterial Mutagenicity (Ames) Bacteria Positive  
*In Vitro* Chromosome Aberration Rodent Positive  
*In Vitro* Sister Chromatid Exchange Rodent Positive  
*In Vivo* Chromosome Aberration Not specified Positive

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### 11. TOXICOLOGICAL INFORMATION

#### 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:** No known carcinogens are present at greater than 0.1%

##### Formaldehyde

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

### 12. ECOLOGICAL INFORMATION

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

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

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

##### 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.

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### 15. REGULATORY INFORMATION

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

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

None required

**Campylobacter fetus**

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

**Safflower oil**

|   |            |
|---|------------|
| CERCLA/SARA 313 Emission reporting          | Not Listed |
| California Proposition 65                   | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present    |
| Australia (AICS):                           | Present    |
| EU EINECS/ELINCS List                       | 232-276-5  |

**Methylparaben**

|   |            |
|---|------------|
| CERCLA/SARA 313 Emission reporting          | Not Listed |
| California Proposition 65                   | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present    |
| Australia (AICS):                           | Present    |
| EU EINECS/ELINCS List                       | 202-785-7  |

**Butylparaben**

|   |            |
|---|------------|
| CERCLA/SARA 313 Emission reporting          | Not Listed |
| California Proposition 65                   | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present    |
| Australia (AICS):                           | Present    |
| EU EINECS/ELINCS List                       | 202-318-7  |

**Propylparaben**

|   |            |
|---|------------|
| CERCLA/SARA 313 Emission reporting          | Not Listed |
| California Proposition 65                   | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present    |
| Australia (AICS):                           | Present    |
| EU EINECS/ELINCS List                       | 202-307-7  |

**Aluminum monostearate**

|   |            |
|---|------------|
| CERCLA/SARA 313 Emission reporting          | Not Listed |
| California Proposition 65                   | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present    |
| Australia (AICS):                           | Present    |



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### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List 230-325-5

#### Formaldehyde

|  |                                    |
|--|------------------------------------|
| CERCLA/SARA 313 Emission reporting                                 | 0.1 %                              |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities:  | 100 lb                             |
|  | 45.4 kg                            |
| CERCLA/SARA - Section 302 Extremely Hazardous TPQs                 | 500 lb                             |
| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | 100 lb                             |
| California Proposition 65  | carcinogen initial date 1/1/88 gas |
| OSHA - Specifically Regulated Chemicals                            | 2 ppm                              |
|  | 0.5 ppm                            |
|  | 0.75 ppm                           |
| Inventory - United States TSCA - Sect. 8(b)                        | Present                            |
| Australia (AICS):  | Present                            |
| Standard for the Uniform Scheduling for Drugs and Poisons:         | Schedule 2                         |
|  | Schedule 6                         |
| EU EINECS/ELINCS List  | 200-001-8                          |

### 16. OTHER INFORMATION

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

H301 - Toxic if swallowed  
H314 - Causes severe skin burns and eye damage  
H317 - May cause an allergic skin reaction  
H351 - Suspected of causing cancer  
H331 - Toxic if inhaled

C - Corrosive  
T - Toxic  
Carcinogenic: Category 3

R23 - Toxic by inhalation.  
R24 - Toxic in contact with skin.  
R25 - Toxic if swallowed.  
R34 - Causes burns.  
R40 - Limited evidence of a carcinogenic effect  
R43 - May cause sensitization by skin contact.

**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 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

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

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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**