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

**Product Identifier**

<table>
<thead>
<tr>
<th>Material Name:</th>
<th>Escherichia Coli Bacterial Extract</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name:</td>
<td>Escherichia Coli Bacterial Extract</td>
</tr>
<tr>
<td>Synonyms:</td>
<td>USDA veterinary biologic product code 264E.01</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

**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 and Drug Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

**Emergency telephone number:** CHEMTREC (24 hours): 1-800-424-9300

**Contact E-Mail:** VMIPSrecrds@zoetis.com

**Zoetis Belgium S.A.**

Mercuriusstraat 20
1930 Zaventem
Belgium

**Emergency telephone number:** International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

**Appearance:** Liquid solution

**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:** May cause eye and skin irritation. May cause allergic skin reaction. 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. 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>200-001-8</td>
<td>T; R23/24/25C; R34</td>
<td>Skin Corr. 1B</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Carc. Cat. 3; R40</td>
<td>Skin Sens. 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R43</td>
<td>Carc. 1A (H350)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 3 (H301)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Corr. 1B (H314)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Sens. 1 (H317)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Carc. 1A (H350)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 3 (H331)</td>
<td></td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Surfactant</td>
<td>NOT APPLICABLE</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Emulsigen</td>
<td>Proprietary</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>25</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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

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: Formation of toxic gases is possible during heating or fire.
Products: 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
When handling, use proper personal protective equipment as specified in Section 8. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid accidental injection. Wash thoroughly after handling. Releases to the environment should be avoided.

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.

Formaldehyde
ACGIH Ceiling Threshold Limit: 0.3 ppm
ACGIH - Sensitizer Designation: Sensitizer

ZT00757
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
<th>OEL - STEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>2 ppm</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>2.5 mg/m³</td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>0.5 ppm</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td></td>
<td>1.2 mg/m³</td>
<td>1.2 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1.0 mg/m³</td>
<td>1.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>0.5 mg/m³</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>0.5 ppm</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td></td>
<td>0.6 mg/m³</td>
<td>0.6 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>0.3 ppm</td>
<td>0.3 ppm</td>
</tr>
<tr>
<td></td>
<td>0.37 mg/m³</td>
<td>0.37 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>0.5 ppm</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>0.3 ppm</td>
<td>0.3 ppm</td>
</tr>
<tr>
<td></td>
<td>0.37 mg/m³ no irritation should occur during mixed exposure</td>
<td>0.37 mg/m³ no irritation should occur during mixed exposure</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>2 ppm</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>2.5 mg/m³</td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>0.6 mg/m³</td>
<td>0.6 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>2 ppm</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>2.5 mg/m³</td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>0.2 ppm</td>
<td>0.2 ppm</td>
</tr>
<tr>
<td></td>
<td>0.24 mg/m³</td>
<td>0.24 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>0.5 ppm</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td></td>
<td>0.6 mg/m³</td>
<td>0.6 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>0.5 ppm</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td></td>
<td>0.6 mg/m³</td>
<td>0.6 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>0.75 ppm</td>
<td>0.75 ppm</td>
</tr>
<tr>
<td></td>
<td>0.6 mg/m³</td>
<td>0.6 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs</td>
<td>2 ppm</td>
<td>2 ppm</td>
</tr>
<tr>
<td>OSHA - Specifically Regulated Chemicals</td>
<td>0.5 ppm</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td></td>
<td>0.75 ppm</td>
<td>0.75 ppm</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>0.5 ppm</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>1 ppm</td>
<td>1 ppm</td>
</tr>
<tr>
<td></td>
<td>1.20 mg/m³</td>
<td>1.20 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>0.3 ppm</td>
<td>0.3 ppm</td>
</tr>
<tr>
<td></td>
<td>0.37 mg/m³</td>
<td>0.37 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>0.5 ppm</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td></td>
<td>0.62 mg/m³</td>
<td>0.62 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>0.3 ppm</td>
<td>0.3 ppm</td>
</tr>
<tr>
<td></td>
<td>0.37 mg/m³</td>
<td>0.37 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>0.3 ppm</td>
<td>0.3 ppm</td>
</tr>
<tr>
<td></td>
<td>0.37 mg/m³</td>
<td>0.37 mg/m³</td>
</tr>
</tbody>
</table>

### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**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:** Safety glasses or goggles

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

**Respiratory protection:** If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid solution
Color: No data available.
Odor: 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

Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): Non-flammable
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
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
Hazardous Decomposition Products: None expected under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. Routes of exposure: eye contact, skin contact
11. TOXICOLOGICAL INFORMATION

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

Formaldehyde
Rat  Oral  LD50  800 mg/kg

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

Formaldehyde
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Moderate Severe
Skin Sensitization  Positive

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

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
90 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

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

ZTO0757
12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. 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.

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.

U.S. DOT Reportable Quantity (RQ), 49 CFR 172.101 Appendix A:

Formaldehyde

CERCLA/SARA Hazardous Substances and their Reportable Quantities:

- 100 lb
- 45.4 kg

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications
SAFETY DATA SHEET

Material Name: Escherichia Coli Bacterial Extract
Revision date: 26-May-2015
Page 8 of 9
Version: 2.5

15. REGULATORY INFORMATION

WHMIS hazard class:
Non-controlled
This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

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

Formaldehyde
- CERCLA/SARA 313 Emission reporting: 0.1 %
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - CERCLA/SARA - Section 302 Extremely Hazardous TPQs: 45.4 kg
  - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs: 500 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
- EU EINECS/ELINCS List: 200-001-8

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

Emulsigen
- 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

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

ZT00757
T - Toxic
C - Corrosive
Carcinogenic: Category 3

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

Data Sources: The data contained in this SDS 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 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