

# SAFETY DATA SHEET



Revision date: 26-May-2015

Version: 2.5

Page 1 of 9

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

### Product Identifier

**Material Name:** Escherichia Coli Bacterial Extract

**Trade Name:** Escherichia Coli Bacterial Extract  
**Synonyms:** USDA veterinary biologic product code 264E.01  
**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 and Drug Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
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**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  
**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.

## SAFETY DATA SHEET

Material Name: Escherichia Coli Bacterial Extract  
Revision date: 26-May-2015

Page 2 of 9  
Version: 2.5

**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

#### 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

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Escherichia coli	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Surfactant	NOT APPLICABLE	Not Listed	Not Listed	Not Listed	*
Emulsigen	Proprietary	Not Listed	Not Listed	Not Listed	25

**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

## SAFETY DATA SHEET

Material Name: Escherichia Coli Bacterial Extract  
Revision date: 26-May-2015

Page 3 of 9  
Version: 2.5

### 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 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

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

## SAFETY DATA SHEET

Material Name: Escherichia Coli Bacterial Extract  
Revision date: 26-May-2015

Page 4 of 9  
Version: 2.5

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia STEL	2 ppm 2.5 mg/m <sup>3</sup>
Australia TWA	1 ppm 1.2 mg/m <sup>3</sup>
Austria OEL - MAKs	0.5 ppm 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 0.6 mg/m <sup>3</sup>
Finland OEL - TWA	0.3 ppm 0.37 mg/m <sup>3</sup>
France OEL - TWA	0.5 ppm
Germany (DFG) - MAK	0.3 ppm 0.37 mg/m <sup>3</sup> no irritation should occur during mixed exposure
Greece OEL - TWA	2 ppm 2.5 mg/m <sup>3</sup>
Hungary OEL - TWA	0.6 mg/m <sup>3</sup>
Ireland OEL - TWAs	2 ppm 2.5 mg/m <sup>3</sup>
Japan - OELs - Ceilings	0.2 ppm 0.24 mg/m <sup>3</sup>
Latvia OEL - TWA	0.5 mg/m <sup>3</sup>
Lithuania OEL - TWA	0.5 ppm 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 0.5 ppm 0.75 ppm
Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Romania OEL - TWA	1 ppm 1.20 mg/m <sup>3</sup>
Slovakia OEL - TWA	0.3 ppm 0.37 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.5 ppm 0.62 mg/m <sup>3</sup>
Sweden OEL - TWAs	0.3 ppm 0.37 mg/m <sup>3</sup>
Switzerland OEL -TWAs	0.3 ppm 0.37 mg/m <sup>3</sup>

#### Exposure Controls

**Engineering Controls:**  
**Personal Protective Equipment:**

Engineering controls should be used as the primary means to control exposures. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:**  
**Eyes:**  
**Skin:**

Wear impervious gloves if skin contact is possible.  
Safety glasses or goggles  
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.

## SAFETY DATA SHEET

Material Name: Escherichia Coli Bacterial Extract  
Revision date: 26-May-2015

Page 5 of 9  
Version: 2.5

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid solution	<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.

### 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

## SAFETY DATA SHEET

Material Name: Escherichia Coli Bacterial Extract  
Revision date: 26-May-2015

Page 6 of 9  
Version: 2.5

### 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

## SAFETY DATA SHEET

Material Name: Escherichia Coli Bacterial Extract  
Revision date: 26-May-2015

Page 7 of 9  
Version: 2.5

### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	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.

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

<b>Formaldehyde</b> CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb 45.4 kg
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### 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**

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

**Formaldehyde**

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

**Surfactant**

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

**Emulsigen**

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



## SAFETY DATA SHEET

**Material Name: Escherichia Coli Bacterial Extract**  
**Revision date: 26-May-2015**

**Page 9 of 9**  
**Version: 2.5**

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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**