SAFETY DATA SHEET

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

Product Identifier

Material Name: Salmonella Newport Bacterial Extract
Trade Name: Salmonella Newport Bacterial Extract
Synonyms: USDA veterinary biologic product code 2811.00
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
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

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.

SAFETY DATA SHEET

Material Name: Salmonella Newport Bacterial Extract
Revision date: 28-May-2015

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>
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</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>200-001-8</td>
<td>T; R23/24/25 C; R34 Carc. Cat.3; R40 R43</td>
<td>Acute Tox. 3 (H301) Skin Corr. 1B (H314) Skin Sens. 1 (H317) Carc. 1A (H350) Acute Tox. 3 (H331)</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Polymyxin B</td>
<td>1404-26-8</td>
<td>215-768-4</td>
<td>Xn; R22 Xn; R42/43</td>
<td>Acute Tox. 4 (H302) Skin Sens. 1 (H317) Resp Sens. 1 (H334)</td>
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</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Salmonella enteritidis</td>
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<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>Surfactant</td>
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<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>
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</tbody>
</table>

Additional Information:
## Trace
* 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.
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.

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
Australia STEL 2 ppm
2.5 mg/m³
Australia TWA 1 ppm
1.2 mg/m³
Austria OEL - MAKs 0.5 ppm
0.6 mg/m³
Bulgaria OEL - TWA 1.0 mg/m³
Czech Republic OEL - TWA 0.5 mg/m³
Estonia OEL - TWA 0.5 ppm
0.6 mg/m³
Finland OEL - TWA 0.3 ppm
0.37 mg/m³
France OEL - TWA 0.5 ppm
Germany (DFG) - MAK 0.3 ppm
0.37 mg/m³ no irritation should occur during mixed exposure
Greece OEL - TWA 2 ppm
2.5 mg/m³
Hungary OEL - TWA 0.6 mg/m³
Ireland OEL - TWAs 2 ppm
2.5 mg/m³
Japan - OELs - Ceilings 0.2 ppm
0.24 mg/m³
Latvia OEL - TWA 0.5 mg/m³
Lithuania OEL - TWA 0.5 ppm
0.6 mg/m³
Netherlands OEL - TWA 0.15 mg/m³
Vietnam OEL - TWAs 0.5 mg/m³
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/m³
Romania OEL - TWA 1 ppm
1.20 mg/m³
Slovakia OEL - TWA 0.3 ppm
0.37 mg/m³
Slovenia OEL - TWA 0.5 ppm
0.62 mg/m³
Sweden OEL - TWAs 0.3 ppm
0.37 mg/m³
Switzerland OEL -TWAs 0.3 ppm
0.37 mg/m³

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.
SAFETY DATA SHEET

Material Name: Salmonella Newport Bacterial Extract
Revision date: 28-May-2015

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Polymyxin B
Zoetis OEB

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:
Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid solution
Odor: No data available
Molecular Formula: 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

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): 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

ZT00767
10. STABILITY AND REACTIVITY

- **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

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

- **Formaldehyde**
  - Rat Oral LD50 800 mg/kg

- **Polymyxin B**
  - Mouse Oral LD50 790 mg/kg
  - Mouse Para-periosteal LD50 3980ug/kg
  - Rat Subcutaneous LD50 50mg/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**
11. TOXICOLOGICAL INFORMATION

**Carcinogenicity:**

**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

**Polymyxin B**
- In Vitro: Negative
- In Vivo: Negative

**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

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.

**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:

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

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.

Salmonella enteritidis

| 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: | 100 lb | 45.4 kg |
| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | 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

Polymyxin B
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Regulation Type</th>
<th>Value</th>
</tr>
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</tbody>
</table>

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
- Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
- Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

T - Toxic
C - Corrosive
Carcinogenic: Category 3
Xn - Harmful

R34 - Causes burns.
R40 - Limited evidence of a carcinogenic effect
R43 - May cause sensitization by skin contact.
R22 - Harmful if swallowed.
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.
R42/43 - May cause sensitization by inhalation and skin contact.

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