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

Product Identifier
- **Material Name:** Rabies Vaccine, Killed Virus
- **Trade Name:** DEFENSOR® 1; DEFENSOR® 3
- **Chemical Family:** Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
- **Intended Use:** Veterinary Vaccine

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:** 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.
### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

<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>Merthiolate (as mercury)</td>
<td>54-64-8</td>
<td>200-210-4</td>
<td>T+; R26/27/28</td>
<td>Acute Tox. 2</td>
<td>##</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R33 N; R50/53</td>
<td>Acute Tox. 2</td>
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<td>Acute Tox. 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT RE 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aq. Acute 1</td>
<td></td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>215-765-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>##</td>
</tr>
</tbody>
</table>

**Additional Information:**

* Proprietary

## Trace

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
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. 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 hydroxide gel
- **ACGIH Threshold Limit Value (TWA):** 1 mg/m³
- **Austria OEL - MAKs:** 5 mg/m³
- **Germany (DFG) - MAK:** 4 mg/m³
- **Latvia OEL - TWA:** 6 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithuania</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Poland</td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1.2 mg/m³</td>
</tr>
<tr>
<td>Slovakia</td>
<td>1.5 mg/m³</td>
</tr>
<tr>
<td>Switzerland</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>0.1 mg/m³</td>
</tr>
</tbody>
</table>

Gentamicin

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poland</td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1.2 mg/m³</td>
</tr>
</tbody>
</table>

Zoetis OEB

OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

**Exposure Controls**

**Engineering Controls:**

Engineering controls should be used as the primary means to control exposures. Exposure monitoring may be necessary to determine requirements.

**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 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

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

**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): No data available
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.

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

Merthiolate (as mercury)
Rat Oral LD50 75 mg/kg
Rat Subcutaneous LD50 98mg/kg

Aluminum hydroxide gel
Rat Para-periosteal LD50 150 mg/kg

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)

Merthiolate (as mercury)
Eye Irritation Rabbit Mild

Gentamicin
Eye Irritation Rabbit Non-irritating
11. TOXICOLOGICAL INFORMATION

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

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

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. This product contains trace quantities of mercury and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP).

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

0408B
15. REGULATORY INFORMATION

Canada - WHMIS: Classifications
WHMIS hazard class: Non-controlled
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.

Aluminum hydroxide gel
- 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: 244-492-7

Rabies virus, killed
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Merthiolate (as mercury)
- 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: 200-210-4

Gentamicin
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: 215-765-8

16. OTHER INFORMATION

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

H330 - Fatal if inhaled
H310 - Fatal in contact with skin
H300 - Fatal if swallowed
H373 - May cause damage to organs through prolonged or repeated exposure
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects

R33 - Danger of cumulative effects.
R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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