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

Product Identifier

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D Bacterin-Toxoid

Trade Name: Ultrabac 8
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

Classifcation of the Substance or Mixture

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1
Carcinogenicity: Category 1A

EU Classification:

EU Indication of danger: Irritant
Carcinogenic: Category 3

EU Symbol: Xi
EU Risk Phrases:
R43 - May cause sensitization by skin contact.
R40 - Limited evidence of a carcinogenic effect

Label Elements

Signal Word: Danger
Hazard Statements:
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
H350 - May cause cancer
Precautionary Statements:

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P284 - Wear respiratory protection
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P308 + P313 - IF exposed or concerned: Get medical advice/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

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):


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>Hazardous</th>
<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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<tbody>
<tr>
<td></td>
<td>Aluminum hydroxide gel</td>
<td>21645-51-2</td>
<td>244-492-7</td>
<td>Not Listed</td>
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<tr>
<td></td>
<td>Formaldehyde</td>
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<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>0.1-1</td>
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</table>
4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek 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.
SAFETY DATA SHEET

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
Use with adequate ventilation. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Releases to the environment should be avoided. Use appropriate personal protective equipment. Avoid accidental injection.

Conditions for Safe Storage, Including any Incompatibilities
- **Storage Conditions:** Store as directed by product packaging.
- **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:** 1.5 mg/m³
- **Lithuania OEL - TWA:** 6 mg/m³
- **Poland OEL - TWA:** 2.5 mg/m³
- **Slovakia OEL - TWA:** 1.2 mg/m³
- **Switzerland OEL -TWAs:** 1.5 mg/m³

Formaldehyde
- **ACGIH Ceiling Threshold Limit:** 0.3 ppm
- **ACGIH - Sensitizer Designation:** Sensitizer
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
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<tr>
<th>Country</th>
<th>STEL</th>
<th>TWA</th>
<th>OEL - MAKs</th>
<th>OEL - TWA</th>
<th>Belgium - Ceilings</th>
<th>Czech Republic OEL - TWA</th>
<th>LGI</th>
<th>France - OEL - TWA</th>
<th>Germany (DFG) - MAK</th>
<th>Greece OEL - TWA</th>
<th>Hungary OEL - TWA</th>
<th>Ireland OEL - TWA</th>
<th>Japan - OELs - Ceilings</th>
<th>Latvia OEL - TWA</th>
<th>Lithuania OEL - TWA</th>
<th>Netherlands OEL - TWA</th>
<th>Vietnam OEL - TWAs</th>
<th>OSHA - Final PELS - TWAs</th>
<th>OSHA - Specifically Regulated Chemicals</th>
<th>Poland OEL - TWA</th>
<th>Romania OEL - TWA</th>
<th>Slovakia OEL - TWA</th>
<th>Slovenia OEL - TWA</th>
<th>Sweden OEL - TWA</th>
<th>Switzerland OEL - TWA</th>
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<td>Germany (DFG) - MAK</td>
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<td>no irritation should occur during mixed exposure</td>
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<td>Ireland OEL - TWAs</td>
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<td>Latvia OEL - TWA</td>
<td>0.5 mg/m³</td>
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<td>Lithuania OEL - TWA</td>
<td>0.5 ppm</td>
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<td>Netherlands OEL - TWA</td>
<td>0.15 mg/m³</td>
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<td>Vietnam OEL - TWAs</td>
<td>0.5 mg/m³</td>
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<td>OSHA - Specifically Regulated Chemicals</td>
<td>2 ppm</td>
<td>0.5 ppm</td>
<td>0.75 ppm</td>
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<td>Poland OEL - TWA</td>
<td>0.5 mg/m³</td>
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<td>1 ppm</td>
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#### Exposure Controls

**Engineering Controls:**

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**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
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 in multiple-dose vials
Color: No data available.

Odor: No data available.
Odor Threshold: 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)
P H: 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

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 under normal conditions of use.

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: No data available
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)

Formaldehyde
Rat  Oral  LD50  800 mg/kg

Aluminum hydroxide gel
Rat  Para-periosteal  LD50  150 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
11. TOXICOLOGICAL INFORMATION

2 Year(s)  Rat  Inhalation  6 ppm  LOAEL  Tumors
2 Year(s)  Mouse  Inhalation  15 ppm  LOAEL  Tumors

Carcinogen Status: See below

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.
15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications

WHMIS hazard class:
- Class D, Division 2, Subdivision A
- Class D, Division 2, Subdivision B

Aluminum hydroxide gel

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<tr>
<th>Regulation</th>
<th>Reporting/Quantity</th>
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</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
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<tr>
<td>California Proposition 65</td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<tr>
<td>Australia (AICS):</td>
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<td>EU EINECS/ELINCS List</td>
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Clostridium haemolyticum

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<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
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<tr>
<td>EU EINECS/ELINCS List</td>
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Formaldehyde

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<tr>
<td>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</td>
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<tr>
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<tr>
<td>CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs</td>
<td>100 lb</td>
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<tr>
<td>California Proposition 65</td>
<td>carcinogen initial date 1/1/88 gas</td>
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<tr>
<td>OSHA - Specifically Regulated Chemicals</td>
<td>2 ppm, 0.5 ppm, 0.75 ppm</td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<tr>
<td>Australia (AICS):</td>
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<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 2, Schedule 6</td>
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<td>EU EINECS/ELINCS List</td>
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Clostridium sordellii

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<td>California Proposition 65</td>
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</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

Clostridium novyi
  CERCLA/SARA 313 Emission reporting Not Listed
  California Proposition 65 Not Listed
  EU EINECS/ELINCS List Not Listed

Clostridium chauvoei
  CERCLA/SARA 313 Emission reporting Not Listed
  California Proposition 65 Not Listed
  EU EINECS/ELINCS List Not Listed

Clostridium perfringens type D
  CERCLA/SARA 313 Emission reporting Not Listed
  California Proposition 65 Not Listed
  EU EINECS/ELINCS List Not Listed

Clostridium septicum
  CERCLA/SARA 313 Emission reporting Not Listed
  California Proposition 65 Not Listed
  EU EINECS/ELINCS List Not Listed

Clostridium perfringens type C
  CERCLA/SARA 313 Emission reporting Not Listed
  California Proposition 65 Not Listed
  EU EINECS/ELINCS List Not Listed

Water, purified
  CERCLA/SARA 313 Emission reporting Not Listed
  California Proposition 65 Not Listed
  Inventory - United States TSCA - Sect. 8(b) Present
  Australia (AICS): Present
  REACH - Annex IV - Exemptions from the obligations of Register: Present
  EU EINECS/ELINCS List 231-791-2

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
H350 - May cause cancer
H331 - Toxic if inhaled

T - Toxic
Carcinogenic: Category 3
C - Corrosive
R40 - Limited evidence of a carcinogenic effect
R43 - May cause sensitization by skin contact.
R34 - Causes burns.
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

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 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory 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