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

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

Trade Name: Ultrabac 7 - Somubac
Chemical Family: Mixture
Intended Use: Veterinary Vaccine

2. HAZARDS IDENTIFICATION

Appearance: Liquid solution in multiple-dose vials
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:

Short Term: May cause eye and skin irritation. May cause allergic skin 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.

EU Indication of danger: 

Irritant

EU Hazard Symbols: Xi

EU Risk Phrases:

R43 - May cause sensitization by skin contact.

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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>200-001-8</td>
<td>C;R34 Carc. Cat.3;R40 R43 T;R23/24/25</td>
<td>0.1 - 1.0%</td>
</tr>
<tr>
<td>Clostridium perfringens type C</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Aluminum hydroxide gel</td>
<td>21645-51-2</td>
<td>244-492-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>Clostridium chauvoei</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Haemophilus somnus</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Clostridium sordelli</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Clostridium septicum</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Clostridium perfringens type D</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Clostridium novyi</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Hazardous Combustion Products: Not known

Fire Fighting Procedures: Dike and collect water used to fight fire.

Fire / Explosion Hazards: Not applicable
Additional Information:

This product is a nonflammable aqueous solution. This material is not expected to support combustion.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

Measures for Environmental Protections:
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

General Handling:
Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment.

Storage Conditions:
Store under refrigeration in closed container.

Storage Temperature:
2-7°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Aluminum hydroxide gel
ACGIH Threshold Limit Value (TWA)
Austria OEL - MAKs Listed
Bulgaria OEL - TWA Listed
Czech Republic OEL - TWA Listed
Germany (DFG) - MAK 1.5 mg/m³ MAK
4 mg/m³ MAK
Latvia OEL - TWA Listed
Lithuania OEL - TWA Listed
Poland OEL - TWA Listed

Formaldehyde
ACGIH Ceiling Threshold Limit: 0.3 ppm
ACGIH - Sensitizer Designation Listed
Australia STEL 2 ppm
2.5 mg/m³
Australia TWA 1 ppm
1.2 mg/m³
Austria OEL - MAKs Listed
Bulgaria OEL - TWA Listed
Czech Republic OEL - TWA Listed
Estonia OEL - TWA Listed
Finland OEL - TWA Listed
France OEL - TWA Listed
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Standard</th>
<th>Level</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany (DFG) - MAK</td>
<td></td>
<td>0.3 ppm MAK</td>
<td>0.37 mg/m³ MAK</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>Listed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>Listed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>Listed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td></td>
<td>0.2 ppm</td>
<td>0.24 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>Listed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>Listed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>Listed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs</td>
<td></td>
<td>0.75 ppm</td>
<td></td>
</tr>
<tr>
<td>OSHA - Specifically Regulated Chemicals</td>
<td></td>
<td>0.5 ppm-Action Level</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.75 ppm-TWA</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 ppm- STEL</td>
<td></td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>Listed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>Listed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>Listed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>Listed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

See exposure limits for component(s) listed above.

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

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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: Wear protective clothing when working with large quantities. Wash hands and arms thoroughly after handling this material.

Respiratory protection: In the event of a spill where the applicable Occupational Exposure Limit (OEL) may be exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Liquid Solution in multiple-dose vials</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble: Water (based on components)</td>
</tr>
<tr>
<td>pH</td>
<td>7.0 +/- 1.5</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
<td>Expected to be negligible</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.0 +/-0.2</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C)</td>
<td>Non-flammable</td>
</tr>
<tr>
<td>Polymerization</td>
<td>Will not occur</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

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

General Information: The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The primary hazards are due to the formaldehyde content.

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

Formaldehyde
Rat Oral LD50 800 mg/kg

Aluminum hydroxide gel
Rat Intraperitoneal LD50 150 mg/kg

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

Formaldehyde
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate Severe

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
9 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))
11. TOXICOLOGICAL INFORMATION

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

Carcinogen Status:  Contains formaldehyde: potential cancer hazard.

Formaldehyde
  IARC:  Group 1
  NTP:  Listed
  OSHA:  Present

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:  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

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol:  Xi
EU Indication of danger:  Irritant
EU Risk Phrases:  R43 - May cause sensitization by skin contact.
EU Safety Phrases:  S24 - Avoid contact with skin.
                    S37 - Wear suitable gloves.

OSHA Label:
15. REGULATORY INFORMATION

WARNING
May cause allergic skin reaction.

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

Aluminum hydroxide gel
- Inventory - United States TSCA - Sect. 8(b): Listed
- Australia (AICS): Listed
- EU EINECS/ELINCS List: 244-492-7

Water, purified
- Inventory - United States TSCA - Sect. 8(b): Listed
- Australia (AICS): Listed
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 231-791-2

Formaldehyde
- CERCLA/SARA 313 Emission reporting: 0.1% de minimis concentration
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - 100 lb final RQ
  - 45.4 kg final RQ
- CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs:
  - 500 lb TPQ
- 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:
  - 0.5 ppm-Action Level
  - 0.75 ppm-TWA
  - 2 ppm-STEEL

16. OTHER INFORMATION

Text of R phrases mentioned in Section 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.
MATERIAL SAFETY DATA SHEET

Material Name: Clostridium Chauvoei-Septicum-Novyi-Sordelli-Perfringens Types C&D Haemophilus Somnus Bacterin-Toxoid
Revision date: 25-Sep-2009

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet