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

Material Name: Clostridium chauvoei-septicum-novyi-sordellii-perfringens Types C&D Bacterin-Toxoid

Trade Name: UltraChoice 7
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. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

EU Indication of danger: Irritant

EU Hazard Symbols: X

EU Risk Phrases: R43 - May cause sensitization by skin contact.


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>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saponin</td>
<td>8047-15-2</td>
<td>232-462-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>200-001-8</td>
<td>C;R34 Carn. Cat.3;R40 R43 T;R23/24/25</td>
<td>0.1 - 1.0%</td>
</tr>
<tr>
<td>Trade reg. no.</td>
<td>Proprietary</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.

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
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.

Formaldehyde

<table>
<thead>
<tr>
<th>Source</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Ceiling Limit</td>
<td>0.3 ppm</td>
</tr>
<tr>
<td>ACGIH - Sensitizer Designation</td>
<td>Listed</td>
</tr>
<tr>
<td>Australia STEL</td>
<td>2 ppm</td>
</tr>
<tr>
<td>2.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>1 ppm</td>
</tr>
<tr>
<td>1.2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAK</td>
<td>Listed</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>0.3 ppm MAK</td>
</tr>
<tr>
<td>0.37 mg/m³ MAK</td>
<td></td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>Listed</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>0.2 ppm</td>
</tr>
<tr>
<td>0.24 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>0.75 ppm</td>
</tr>
<tr>
<td>OSHA - Specifically Regulated Chemicals</td>
<td>0.5 ppm-Action Level</td>
</tr>
<tr>
<td>0.75 ppm-TWA</td>
<td></td>
</tr>
<tr>
<td>2 ppm-STEL</td>
<td></td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>Listed</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

See exposure limits for component(s) listed above.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Physical State: Liquid Solution in multiple-dose vials
- Color: No data available.
- Molecular Formula: Mixture
- Molecular Weight: Mixture
- Solubility: Soluble: Water (based on components)
- pH: 7.0 +/- 1.5
- Boiling Point (°C): >100
- Vapor Pressure (kPa): Expected to be negligible
- Specific Gravity: 1.0 +/- 0.2
- Flash Point (Liquid) (°C): Non-flammable
- Polymerization: Will not occur

10. STABILITY AND REACTIVITY

- Chemical Stability: Stable
- 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)
11. TOXICOLOGICAL INFORMATION

Formaldehyde

<table>
<thead>
<tr>
<th>Inhalation Acute Toxicity</th>
<th>Not determined for this mixture. However, irritation may occur based on effects of individual components.</th>
</tr>
</thead>
</table>

Ingestion Acute Toxicity

<table>
<thead>
<tr>
<th>Ingestion Acute Toxicity</th>
<th>See Acute toxicity table.</th>
</tr>
</thead>
</table>

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

Skin Irritation / Sensitization

This product contains formaldehyde which is considered to be a skin sensitizer.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Rats exposed to 15 ppm formaldehyde vapor for six hours/day for up to nine days showed an acute cell degeneration, necrosis and inflammation in the nasal cavities. Inhalation exposure to formaldehyde for up to 90 days produced interstitial inflammation in the lungs of dogs, rats, monkeys, rabbits and guinea pigs.

Chronic Effects/Carcinogenicity

In rats, several inhalation studies have shown that formaldehyde induces squamous-cell carcinomas and necrosis of the nasal cavity. Formaldehyde also showed cocarcinogenic effects when inhaled, ingested, or applied to the skin of rodents.

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Reproductive Effects

Not considered to be a reproductive hazard. Intravenous injection of saponins in pregnant rabbits, goats, and cows has caused abortion. Intraperitoneal administration of saponin to pregnant rats produced complete litter resorption at 25 mg/kg/day.

Teratogenicity

Formaldehyde has been tested by inhalation, oral, and dermal routes and has not been shown to be teratogenic in animals. Intravenous injection of saponins in pregnant rabbits, goats, and cows has caused abortion. Intraperitoneal administration of saponin to pregnant rats produced complete litter resorption at 25 mg/kg/day. Lower doses of 5 and 15 mg/kg/day did not produce adverse effects on pregnancy except for pregnancy prolongation.

Mutagenicity

Formaldehyde has been reported to be active in many short-term tests, both in vitro and in vivo.

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Embryo / Fetal Development

Mouse Oral 185 mg/kg/day Not teratogenic, Maternal toxicity

Embryo / Fetal Development

Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Formaldehyde

In Vitro Bacterial Mutagenicity (Ames) Bacteria Positive

In Vitro Chromosome Aberration Rodent Positive

In Vivo Sister Chromatid Exchange Rodent Positive

In Vivo Chromosome Aberration Not specified Positive
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.

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

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.

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

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.
15. REGULATORY INFORMATION

OSHA Label:
WARNING
May cause allergic skin reaction.

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

Saponin
  Australia (AICS): Listed
  EU EINECS/ELINCS List 232-462-6

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
  TPQs 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-STEL
  Inventory - United States TSCA - Sect. 8(b): Listed
  Australia (AICS): Listed
  Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 2
  Schedule 6
  EU EINECS/ELINCS List 200-001-8

Trade reg. no.
  Australia (AICS): Listed

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.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

Pfizer 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