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

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288

Pfizer Ltd,
Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Contact E-Mail: pfizer-MSDS@pfizer.com

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

Trade Name: One Shot Ultra 7
Chemical Family: Mixture
Intended Use: Veterinary Vaccine

2. HAZARDS IDENTIFICATION

Appearance: Freeze-dried preparation
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

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. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

EU Indication of danger: Irritant

EU Hazard Symbols: Xi

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

Hazardous

<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</td>
<td>0.1 - &lt;1.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Carc. Cat.3;R40</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R43</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>T;R23/24/25</td>
<td></td>
</tr>
<tr>
<td>Aluminum potassium sulfate</td>
<td>7784-24-9</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: 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.

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: Fine particles (such as dust and mists) may fuel fires/explosions.
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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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. Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing.

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>Requirement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Ceiling Threshold 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></td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>1 ppm</td>
</tr>
<tr>
<td></td>
<td>1.2 mg/m³</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></td>
<td>0.37 mg/m³ MAK</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></td>
<td>0.24 mg/m³</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></td>
<td>0.75 ppm-TWA</td>
</tr>
<tr>
<td></td>
<td>2 ppm-STEEL</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.

9. PHYSICAL AND CHEMICAL PROPERTIES

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- **Physical State:** Freeze-dried preparation
- **Color:** No data available.
- **Molecular Formula:** Mixture
- **Molecular Weight:** Mixture

Polymerization:Will not occur

10. STABILITY AND REACTIVITY

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- **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

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- **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
11. TOXICOLOGICAL INFORMATION

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

Formaldehyde
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Moderate Severe

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)

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))

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.  See below

Formaldehyde
IARC:  Group 1
NTP:  Listed
OSHA:  Present

12. ECOLOGICAL INFORMATION

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

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:
WARNING
May cause allergic skin reaction.

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

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

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

Aluminum potassium sulfate

- Australia (AICS): Listed

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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

Data Sources:
Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision:
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 11 - Toxicology Information. 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