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

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

| Trade Name: | One Shot Ultra 8 |
| 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 Carc. Cat.3;R40 R43 T;R23/24/25</td>
<td>0.1 - &lt;1.0%</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

ACGIH Ceiling Threshold Limit: 0.3 ppm
ACGIH - Sensitizer Designation: Listed
Australia STEL: 2 ppm
Australia STEL: 2.5 mg/m³
Australia TWA: 1 ppm
Australia TWA: 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
Germany (DFG) - MAK: 0.3 ppm MAK
Germany (DFG) - MAK: 0.37 mg/m³ MAK
Greece OEL - TWA: Listed
Hungary OEL - TWA: Listed
Ireland OEL - TWAs: Listed
Japan - OELs - Ceilings: 0.2 ppm
Japan - OELs - Ceilings: 0.24 mg/m³
Latvia OEL - TWA: Listed
Lithuania OEL - TWA: Listed
Netherlands OEL - TWA: Listed
OSHA - Final PELS - TWAs: 0.75 ppm
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

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

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

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))

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

Teratogenicity

Formaldehyde has been tested by inhalation, oral, and dermal routes and has not been shown to be teratogenic in animals.

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

Mutagenicity

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

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.
11. TOXICOLOGICAL INFORMATION

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

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

Material Name: Clostridium chauvoei-septicum-haemolyticum-novyi-sordelli-perfringens Types C&D-Pasteurella haemolytica Bacterin-Toxoid
15. REGULATORY INFORMATION

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

Formaldehyde
- CERCLA/SARA 313 Emission reporting: 0.1% de minimis concentration
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - Hazardous Substances: 100 lb final RQ
  - Reportable Quantities: 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):
- Australia (AICS): Listed
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 2
- 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.

Prepared by:
- Product Stewardship Hazard Communications
- Pfizer Global Environment, Health, and Safety Operations
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End of Safety Data Sheet