SAFETY DATA SHEETS

This SDS packet was issued with item:

078912819

N/A

MATERIAL SAFETY DATA SHEET

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
Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

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:

Xi

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

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Hazardous Substance.

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

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Saponin	8047-15-2	232-462-6	Not Listed	*
Formaldehyde	50-00-0	200-001-8	C;R34 Carc. Cat.3;R40 R43 T;R23/24/25	0.1 - 1.0%
Trade reg. no.	Proprietary	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Clostridium perfringens type C	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium chauvoei	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium sordellii	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium septicum	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium perfringens type D	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium novyi	NOT ASSIGNED	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	>90%

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

ACGIH Ceiling Threshold Limit:	0.3 ppm
ACGIH - Sensitizer Designation	Listed
Australia STEL	2 ppm 2.5 mg/m^3
Australia TWA	1 ppm 1.2 mg/m^3
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 0.37 mg/m^3 MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Japan - OELs - Ceilings	0.2 ppm 0.24 mg/m^3
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELS - TWAs:	0.75 ppm
OSHA - Specifically Regulated Chemicals	0.5 ppm-Action Level 0.75 ppm-TWA 2 ppm-STEL
Poland OEL - TWA	Listed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Sweden OEL - TWAs	Listed

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

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
Rat Oral LD50 800 mg/kg

Inhalation Acute Toxicity Not determined for this mixture. However, irritation may occur based on effects of individual components.

Ingestion Acute Toxicity See Acute toxicity table.

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

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.

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))

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

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