## **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

078912858

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078912822 078912891



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

Pfizer Animal Health
Pfizer Inc
Street
CT13 9NJ
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Pfizer Ltd,
Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Technical Services Phone: 1-800-366-5288

**Emergency telephone number:** 

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



(NOHSC):

**EU Risk Phrases:** 

R43 - May cause sensitization by skin contact.

Australian Hazard Classification 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.

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

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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### **Hazardous**

Ingredient	CAS Number	<b>EU EINECS/ELINCS List</b>	<b>EU Classification</b>	%
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	<b>EU EINECS/ELINCS List</b>	<b>EU Classification</b>	%
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

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

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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

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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/m³ Australia TWA 1 nnm

Australia TWA 1 ppm 1.2 mg/m³

Austria OEL - MAKs

Bulgaria OEL - TWA

Czech Republic OEL - TWA

Estonia OEL - TWA

Listed
Finland OEL - TWA

Listed
France OEL - TWA

Listed

**Germany (DFG) - MAK**0.3 ppm MAK
0.37 mg/m³ MAK

Greece OEL - TWA

Hungary OEL - TWA

Ireland OEL - TWAs

Japan - OELs - Ceilings

0.2 ppm
0.24 mg/m³

Latvia OEL - TWAListedLithuania OEL - TWAListedNetherlands OEL - TWAListedOSHA - 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

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Material Name: Clostridium chauvoei-septicum-novyi- Page 4 of 8

sordellii-perfringens Types C&D Bacterin-Toxoid

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## 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):

Polymerization:

Non-flammable
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)

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

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## 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))

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## 11. TOXICOLOGICAL INFORMATION

Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors2 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.

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## 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.

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

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## 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)

Australia (AICS):

REACH - Annex IV - Exemptions from the

Listed

Present

obligations of Register: 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:
45.4 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous
500 lb TPQ

**TPQs** 

CERCLA/SARA - Section 302 Extremely Hazardous 100 lb

Substances EPCRA RQs

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
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

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

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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

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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** 

7410.02

## SAFETY DATA SHEET



1. Identification

Product identifier Clostridium chauvoei-septicum-haemolyticum-novyi-sordellii-perfringens Types C&D

**Bacterin-Toxoid** 

Other means of identification

Synonyms UltraChoice® 8 \* UltraChoice™ 8

Recommended use Veterinary vaccine
Recommended restrictions Not for human use
Manufacturer/Importer/Supplier/Distributor information

Company Name (US) Zoetis Inc.

10 Sylvan Way

Parsippany, New Jersey 07054 (USA)

**Rocky Mountain Poison** 

and Drug Center

1-866-531-8896

**Product Support/Technical** 

Services

1-800-366-5288

Services

**Emergency telephone** 

numbers

CHEMTREC (24 hours): 1-800-424-9300

International CHEMTREC (24 hours): +1-703-527-3887

Company Name (EU) Zoetis Belgium S.A.

Mercuriusstraat 20 1930 Zaventem

Belgium

**Emergency telephone** 

number

International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Sensitization, respiratory Category 1A

Sensitization, skin Category 1A
Carcinogenicity Category 1A

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing

difficulties if inhaled. May cause cancer.

**Precautionary statement** 

**Prevention**Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing mist or vapor. Contaminated work clothing must not be allowed

and understood. Avoid breathing mist or vapor. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. In

case of inadequate ventilation wear respiratory protection.

**Response**If exposed or concerned: Get medical advice/attention. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. If inhaled: If breathing is difficult.

remove person to fresh air and keep comfortable for breathing. If experiencing respiratory

symptoms: Call a poison center/doctor. Wash contaminated clothing before reuse.

Storage Store locked up.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)

None known.

**Supplemental information** 

Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an

allergic reaction may occur.

## 3. Composition/information on ingredients

#### **Mixtures**

Chemical name	Common name and synonyms	CAS number	%
Water, purified		7732-18-5	>90
Aluminum potassium sulfate		7784-24-9	<5
Formaldehyde		50-00-0	0.2
Clostridium chauvoei		NOT ASSIGNED	*
Clostridium haemolyticum		NOT ASSIGNED	*
Clostridium novyi		NOT ASSIGNED	*
Clostridium perfringens type C		NOT ASSIGNED	*
Clostridium perfringens type D		NOT ASSIGNED	*
Clostridium septicum		NOT ASSIGNED	*
Clostridium sordellii		NOT ASSIGNED	*
Saponin		8047-15-2	##

Composition comments

## Trace

\* Non-hazardous Ingredients

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

#### 4. First-aid measures

Inhalation Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTER or

doctor/physician. For breathing difficulties, oxygen may be necessary.

Skin contact Remove contaminated clothing immediately and wash skin with soap and water. Get medical

attention if irritation develops and persists. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove

contact lenses, if present and easy to do.

**Ingestion** Rinse mouth. Call a physician immediately. Do not induce vomiting without advice from poison

control center. Never give anything by mouth to a victim who is unconscious or is having

convulsions.

Most important

symptoms/effects, acute and

delayed

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. May cause an allergic skin reaction. Dermatitis. Rash. Difficulty

in breathing.

Indication of immediate medical attention and special

treatment needed

**General information** 

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take

precautions to protect themselves. Wash contaminated clothing before reuse.

## 5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from

the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

Move containers from fire area if you can do so without risk.

equipment/instructions Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

#### Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Ventilate closed spaces before entering them. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

# Methods and materials for containment and cleaning up

Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Avoid release to the environment.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

## **Environmental precautions**

7. Handling and storage Precautions for safe handling

Do not handle until all safety precautions have been read and understood. Use with adequate ventilation. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Store in a cool, dry place out of direct sunlight. @ 2 - 7°C (36 - 45°F). Do not freeze. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

## Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

US. OSHA Specifica	lly Regulated Substances (	29 CFR 1910.1001-1050)

Components	Туре	Value	
Formaldehyde (CAS 50-00-0)	STEL	2 ppm	
,	TWA	0.75 ppm	
<b>US. ACGIH Threshold Limit Valu</b>	es		
Components	Туре	Value	Form
Aluminum potassium sulfate (CAS 7784-24-9)	TWA	1 mg/m3	Respirable fraction.
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	
US. NIOSH: Pocket Guide to Che	mical Hazards		
Components	Туре	Value	
Aluminum potassium sulfate (CAS 7784-24-9)	TWA	2 mg/m3	
Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm	
	TWA	0.016 ppm	

Biological limit values
Control banding approach

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Not available.

Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

Material name: Clostridium chauvoei-septicum-haemolyticum-novyi-sordellii-perfringens Types C&D Bacterin-Toxoid 336 Version #: 03 Revision date: 05-05-2017 Issue date: 03-12-2014

#### Individual protection measures, such as personal protective equipment

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended.

Skin protection

**Hand protection** Wear protective gloves. Wear impervious gloves if skin contact is possible.

Other Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable

coveralls, etc.) in both production and laboratory areas.

Respiratory protection No personal respiratory protective equipment normally required. In case of insufficient ventilation,

wear suitable respiratory equipment. If engineering controls do not maintain airborne

concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is

recommended as a precaution to minimize exposure.

Thermal hazards Not applicable.

General hygiene considerations

Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

## 9. Physical and chemical properties

Appearance Liquid Solution in multiple-dose vials

Physical stateLiquid.FormLiquid.

ColorNot available.OdorNot available.Odor thresholdNot available.

**pH** 6 - 8

Melting point/freezing point Not available.

Initial boiling point and boiling > 212 °F (> 100 °C)

range

Flash pointNon-flammableEvaporation rateNot available.Flammability (solid, gas)Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

(%)

Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Soluble

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

Specific gravity 0.8 - 1.2

#### 10. Stability and reactivity

**Reactivity**The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Protect from sunlight. Store at 2-7°C. Prolonged exposure to

higher temperatures may adversely affect potency. Do not freeze.

Incompatible materials Strong oxidizing agents. This material can be denatured or inactivated by a variety of organic

solvents, salts or heavy metals.

Hazardous decomposition

products

No hazardous decomposition products are known.

## 11. Toxicological information

## Information on likely routes of exposure

**Inhalation** May cause allergy or asthma symptoms or breathing difficulties if inhaled. Prolonged inhalation

may be harmful.

**Skin contact** May cause an allergic skin reaction.

Formaldehyde Species: Rabbit

Severity: Moderate to Severe

**Eye contact** Direct contact with eyes may cause temporary irritation.

Formaldehyde Species: Rabbit Severity: Severe

Deventy. Dever

**Ingestion** Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash.

Information on toxicological effects

**Acute toxicity** Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components Species Test Results

Formaldehyde (CAS 50-00-0)

**Acute** 

Dermal

LD50 Rabbit 270 mg/kg

Inhalation

LC50 Mouse 0.414 mg/L, 4 hours

Rat 0.48 mg/L, 4 hours

Oral

LD50 Rat 100 mg/kg

Chronic Inhalation

LOAEL Mouse 15 ppm, 2 years Tumors

Rat 15 ppm, 90 days Respiratory system

6 ppm, 2 years Tumors

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye Direct contact with eyes may cause temporary irritation.

irritation

Formaldehyde Species: Rabbit Severity: Severe

Respiratory or skin sensitization

**ACGIH** sensitization

**Eye Contact** 

FORMALDEHYDE (CAS 50-00-0) Dermal sensitization

Respiratory sensitization

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Skin sensitization** May cause an allergic skin reaction.

Skin sensitization

Formaldehyde Species: Guinea Pig Severity: Positive

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Mutagenicity

Formaldehyde In Vitro Bacterial Mutagenicity (Ames)

Result: Positive Species: Bacteria

In Vitro Chromosome Aberration

Result: Positive Species: Rodent

In Vitro Sister Chromatid Exchange

Result: Positive Species: Rodent

In Vivo Chromosome Aberration

Result: Positive Species: Not specified

Carcinogenicity May cause cancer.

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0) 1 Carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Formaldehyde (CAS 50-00-0)

Cancer

**US. National Toxicology Program (NTP) Report on Carcinogens** 

Formaldehyde (CAS 50-00-0) Known To Be Human Carcinogen.

**Reproductive toxicity**This product is not expected to cause reproductive or developmental effects.

**Developmental effects** 

Formaldehyde 185 mg/kg/day Embryo / Fetal Development, Not teratogenic

Maternal toxicity Species: Mouse Organ: Oral

40 ppm Embryo / Fetal Development, Not Teratogenic

Maternal Toxicity Species: Rat Organ: Inhalation

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

**Aspiration hazard** Not an aspiration hazard.

**Chronic effects** Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

**Further information** May cause allergic respiratory and skin reactions. In the event of accidental injection, an allergic

reaction may occur. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. Saponins have little toxicity for

humans when ingested but have hemolytic effects when injected intravenously.

12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Avoid release to the environment.

Components **Species Test Results** Formaldehyde (CAS 50-00-0) EC50 Daphnia magna (Water Flea) 42 mg/L, 24 Hours LC50 Oncorhynchus mykiss (Rainbow Trout) 118 ppm, 96 Hours Aquatic Crustacea EC50 Water flea (Daphnia pulex) 4.3 - 7.8 mg/l, 48 hours Fish LC50 10.302 - 16.743 mg/l, 96 hours Striped bass (Morone saxatilis)

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential No data available. No data available. Mobility in soil

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. **Disposal instructions** 

Do not allow this material to drain into sewers/water supplies. 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. Dispose of contents/container in

accordance with local/regional/national/international regulations.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Since emptied containers may retain product residue, follow label warnings even after container is Contaminated packaging

emptied.

## 14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

**IMDG** 

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and Not established.

the IBC Code

## 15. Regulatory information

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication **US federal regulations** 

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)** 

Formaldehyde (CAS 50-00-0) Listed.

SARA 304 Emergency release notification

Formaldehyde (CAS 50-00-0) 100 LBS OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Formaldehyde (CAS 50-00-0)

Skin sensitization Respiratory sensitization

Eye irritation Skin irritation

respiratory tract irritation

Acute toxicity

#### Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Chemical name CAS number Reportable Threshold quantity planning quantity (pounds) (pounds)	lower value	Threshold planning quantity, upper value (pounds)
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Formaldehyde 50-00-0 100 500

SARA 311/312 Hazardous No

chemical

SARA 313 (TRI reporting)

 Chemical name	CAS number	% by wt.
Formaldehyde	50-00-0	0.2

#### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Formaldehyde (CAS 50-00-0)

## Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Formaldehyde (CAS 50-00-0)

Safe Drinking Water Act

Not regulated.

(SDWA)

**US state regulations** WARNING: This product contains a chemical known to the State of California to cause cancer.

## US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Inventory name

Formaldehyde (CAS 50-00-0) Listed: January 1, 1988

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Formaldehyde (CAS 50-00-0)

## **International Inventories**

Country(s) or region

Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

<sup>\*</sup>A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

## 16. Other information, including date of preparation or last revision

 Issue date
 03-12-2014

 Revision date
 05-05-2017

Version # 03

On inventory (yes/no)\*

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**Disclaimer** Zoetis Inc. believes that the information contained in this 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. The information in the sheet was written based on the best knowledge and experience currently

available.

**Revision information** This document has undergone significant changes and should be reviewed in its entirety.