

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



MATERIAL SAFETY DATA SHEET

Revision date: 28-Feb-2011

Version: 2.0

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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.
Hazardous Substance. Non-Hazardous Substance.

Australian Hazard Classification (NOHSC):

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.

MATERIAL SAFETY DATA SHEET

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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

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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 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

MATERIAL SAFETY DATA SHEET

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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):	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.
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Acute Toxicity: (Species, Route, End Point, Dose)

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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 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.

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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)	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
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	45.4 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb TPQ
California Proposition 65	100 lb
OSHA - Specifically Regulated Chemicals	carcinogen, initial date 1/1/88 (gas)
	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
EU EINECS/ELINCS List	Schedule 6
	200-001-8

Trade reg. no.

Australia (AICS):	Listed
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16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-sordellii-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 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

SAFETY DATA SHEET



Revision date: 17-Mar-2014

Version: 3.0

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

Product Identifier

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

Trade Name: UltraChoice 7
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary Vaccine

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

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

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

2. HAZARDS IDENTIFICATION

Appearance: Liquid solution in multiple-dose vials

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1
Carcinogenicity: Category 1A

EU Classification:

EU Indication of danger: Irritant
Carcinogenic: Category 3

EU Symbol: T Xi
EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect
R43 - May cause sensitization by skin contact.

Label Elements

Signal Word: Danger
Hazard Statements: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
H350 - May cause cancer

SAFETY DATA SHEET

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

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P284 - Wear respiratory protection
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

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.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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	GHS Classification	%
Formaldehyde	50-00-0	200-001-8	T; R23/24/25 C; R34 Carc.Cat.3; R40 R43	Acute Tox. 3 (H301) Skin Corr. 1B (H314) Skin Sens. 1 (H317) Carc. 1A (H350) Acute Tox. 3 (H331)	0.1-1.0%
Saponin	8047-15-2	232-462-6	Not Listed	Not Listed	##

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

Additional Information:

* Proprietary

Trace

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions

None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

None

5. FIRE-FIGHTING MEASURES

Extinguishing Media:

Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products:

Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards:

Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling

Use with adequate ventilation. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Prevent environmental releases. Use appropriate personal protective equipment. Avoid accidental injection.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store under refrigeration in closed container.

Storage Temperature: 2-7°C

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Formaldehyde

ACGIH Ceiling Threshold Limit:	0.3 ppm
ACGIH - Sensitizer Designation	Sensitizer
Australia STEL	2 ppm
	2.5 mg/m ³
Australia TWA	1 ppm
	1.2 mg/m ³
Austria OEL - MAKs	0.5 ppm
	0.6 mg/m ³
Bulgaria OEL - TWA	1.0 mg/m ³
Czech Republic OEL - TWA	0.5 mg/m ³
Estonia OEL - TWA	0.5 ppm
	0.6 mg/m ³
Finland OEL - TWA	0.3 ppm
	0.37 mg/m ³
France OEL - TWA	0.5 ppm
Germany (DFG) - MAK	0.3 ppm
	0.37 mg/m ³ no irritation should occur during mixed exposure
Greece OEL - TWA	2 ppm
	2.5 mg/m ³
Hungary OEL - TWA	0.6 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ireland OEL - TWAs	2 ppm 2.5 mg/m ³
Japan - OELs - Ceilings	0.2 ppm 0.24 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
Lithuania OEL - TWA	0.5 ppm 0.6 mg/m ³
Netherlands OEL - TWA	0.15 mg/m ³
Vietnam OEL - TWAs	0.5 mg/m ³
OSHA - Final PELs - TWAs:	0.75 ppm
OSHA - Specifically Regulated Chemicals	2 ppm 0.5 ppm 0.75 ppm
Poland OEL - TWA	0.5 mg/m ³
Romania OEL - TWA	1 ppm 1.20 mg/m ³
Slovakia OEL - TWA	0.3 ppm 0.37 mg/m ³
Slovenia OEL - TWA	0.5 ppm 0.62 mg/m ³
Sweden OEL - TWAs	0.3 ppm 0.37 mg/m ³
Switzerland OEL -TWAs	0.3 ppm 0.37 mg/m ³

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

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:

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection:

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:

Liquid Solution in multiple-dose vials

Odor:

No data available.

Molecular Formula:

Mixture

Color:

No data available.

Odor Threshold:

No data available.

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

No data available

Solubility:

Soluble: Water (based on components)

pH:

7.0 +/- 1.5

Melting/Freezing Point (°C):

No data available

Boiling Point (°C):

>100

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9. PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): Expected to be negligible

Vapor Density (g/ml): No data available

Relative Density: No data available

Specific Gravity: 1.0 +/-0.2

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): Non-flammable

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been fully investigated. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Formaldehyde

Rat Oral LD50 800 mg/kg

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

Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

Skin Sensitization Positive

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11. TOXICOLOGICAL INFORMATION

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
90 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: See below

Formaldehyde

IARC: Group 1 (Carcinogenic to Humans)
NTP: Known Human Carcinogen
OSHA: Listed

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12. ECOLOGICAL INFORMATION

Environmental Overview:	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

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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Formaldehyde	
RCRA - U Series Wastes	Listed

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

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15. REGULATORY INFORMATION



Formaldehyde

CERCLA/SARA 313 Emission reporting	0.1 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	45.4 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	100 lb
OSHA - Specifically Regulated Chemicals	carcinogen initial date 1/1/88 gas
	2 ppm
	0.5 ppm
	0.75 ppm
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS/ELINCS List	Schedule 6
	200-001-8

Saponin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	232-462-6

Clostridium sordellii

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Clostridium novyi

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Clostridium chauvoei

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Clostridium perfringens type D

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Clostridium septicum

CERCLA/SARA 313 Emission reporting	Not Listed
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15. REGULATORY INFORMATION

California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Clostridium perfringens type C	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Water, purified	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H301 - Toxic if swallowed
H314 - Causes severe skin burns and eye damage
H317 - May cause an allergic skin reaction
H350 - May cause cancer
H331 - Toxic if inhaled

T - Toxic
Carcinogenic: Category 3
C - Corrosive

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: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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End of Safety Data Sheet