This SDS packet was issued with item:

078912890

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

078403544 078403783

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078912809 078912850



Revision date: 07-Dec-2006 Version: 1.4 Page 1 of 7

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

Pfizer Animal Health
Pfizer Inc
State 42nd Street
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: Emergency telephone number:

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D Bacterin-Toxoid

Trade Name: Ultrabac (R) 8
Chemical Family: Mixture

Intended Use: Veterinary Vaccine

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Formaldehyde	50-00-0	200-001-8	0.1 - 1.0%

Ingredient	CAS Number	EU EINECS List	%
Clostridium perfringens type C	NOT ASSIGNED	Not listed	*
Aluminum hydroxide gel	21645-51-2	244-492-7	*
Water, purified	7732-18-5	231-791-2	>90%
Clostridium chauvoei	NOT ASSIGNED	Not listed	*
Clostridium haemolyticum	NOT ASSIGNED	Not listed	*
Clostridium septicum	NOT ASSIGNED	Not listed	*
Clostridium sordellii	NOT ASSIGNED	Not listed	*
Clostridium perfringens type D	NOT ASSIGNED	Not listed	*
Clostridium novyi	NOT ASSIGNED	Not listed	*

Additional Information: * Proprietary

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

safety.

3. HAZARDS IDENTIFICATION

Appearance: Liquid solution in multiple-dose vials

Signal Word: WARNING

Statement of Hazard: Contains formaldehyde: potential cancer hazard

May cause sensitization of the skin and respiratory system

May cause eye, skin and respiratory tract irritation.

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

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

Page 2 of 7

removed to the nearest emergency room and the appropriate therapy instituted.

EU Indication of danger: Irritan

EU Hazard Symbols:



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.

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: 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 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.

Material Name: Clostridium Chauvoei-Septicum- Page 3 of 7

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

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

Formaldehyde

OSHA - Final PELS - TWAs: = 0.75 ppm TWA
OSHA - Specifically Regulated Chemicals = 0.5 ppm Action Level

= 0.75 ppm TWA

= 2 ppm STEL Irritant and potential cancer hazard - see 29 CFR

1910.1048

ACGIH Ceiling Threshold Limit: = 0.3 ppm Ceiling
ACGIH - Sensitizer Designation Sensitizer

Australia STEL= 2 ppm STEL= 2.5 mg/m³ STELAustralia TWA= 1 ppm TWA

= 1 ppm TWA = 1.2 mg/m³ TWA

See exposure limits for component (s) listed above. The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Exposure

monitoring may be necessary to determine requirements.

Personal Protective Equipment:

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

Material Name: Clostridium Chauvoei-Septicum- Page 4 of 7

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

10. STABILITY AND REACTIVITY

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.

Polymerization: Will not occur

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. 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

Aluminum hydroxide gel

Rat Intraperitoneal LD50 150 mg/kg

Inhalation Acute Toxicity

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

components.

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

Subchronic Effects 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

Page 5 of 7

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

Embryo / Fetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

Reproductive Effects Not considered to be a reproductive hazard.

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 Tumors2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

Carcinogen Status: Contains formaldehyde: potential cancer hazard. See below

Formaldehyde

IARC: Group 1

NTP: Reasonably Anticipated To Be A Carcinogen

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

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

Formaldehyde

RCRA - U Series Wastes waste number U122

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Material Name: Clostridium Chauvoei-Septicum-Page 6 of 7 Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

15. REGULATORY INFORMATION

EU Symbol: 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

Contains formaldehyde: potential cancer hazard

May cause sensitization of the skin and respiratory system May cause eye, skin and respiratory tract irritation.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Aluminum hydroxide gel

Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present **EU EINECS List** 244-492-7

Formaldehyde

CERCLA/SARA 313 Emission reporting = 0.1 % de minimis concentration

CERCLA/SARA Hazardous Substances = 100 lb final RQ and their Reportable Quantities: = 45.4 kg final RQ

CERCLA/SARA - Section 302 Extremely Hazardous = 500 lb TPQ

CERCLA/SARA - Section 302 Extremely Hazardous

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 Irritant and potential cancer hazard - see 29 CFR

1910.1048 Present

Present

= 100 lb EPCRA RQ

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Standard for the Uniform Scheduling Schedule 2 for Drugs and Poisons: Schedule 6 **EU EINECS List** 200-001-8

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

Water, purified

Inventory - United States TSCA - Sect. 8(b)PresentAustralia (AICS):PresentEU EINECS List231-791-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard

Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated

Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication

Pfizer Global Environment, Health, and Safety

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet



Revision date: 07-Dec-2006 Version: 1.4 Page 1 of 7

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

Pfizer Animal Health
Pfizer Inc
Street
Pfizer Ltd,
Kent
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: Emergency telephone number:

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D Bacterin-Toxoid

Trade Name: Ultrabac (R) 8 Chemical Family: Mixture

Intended Use: Veterinary Vaccine

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Formaldehyde	50-00-0	200-001-8	0.1 - 1.0%

Ingredient	CAS Number	EU EINECS List	%
Clostridium perfringens type C	NOT ASSIGNED	Not listed	*
Aluminum hydroxide gel	21645-51-2	244-492-7	*
Water, purified	7732-18-5	231-791-2	>90%
Clostridium chauvoei	NOT ASSIGNED	Not listed	*
Clostridium haemolyticum	NOT ASSIGNED	Not listed	*
Clostridium septicum	NOT ASSIGNED	Not listed	*
Clostridium sordellii	NOT ASSIGNED	Not listed	*
Clostridium perfringens type D	NOT ASSIGNED	Not listed	*
Clostridium novyi	NOT ASSIGNED	Not listed	*

Additional Information: * Proprietary

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

safety.

3. HAZARDS IDENTIFICATION

Appearance: Liquid solution in multiple-dose vials

Signal Word: WARNING

Statement of Hazard: Contains formaldehyde: potential cancer hazard

May cause sensitization of the skin and respiratory system

May cause eye, skin and respiratory tract irritation.

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

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

Page 2 of 7

removed to the nearest emergency room and the appropriate therapy instituted.

EU Indication of danger: Irritani

EU Hazard Symbols:



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.

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: 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 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.

Material Name: Clostridium Chauvoei-Septicum- Page 3 of 7

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

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

Formaldehyde

OSHA - Final PELS - TWAs: = 0.75 ppm TWA
OSHA - Specifically Regulated Chemicals = 0.5 ppm Action Level

= 0.75 ppm TWA

= 2 ppm STEL Irritant and potential cancer hazard - see 29 CFR

1910.1048

ACGIH Ceiling Threshold Limit: = 0.3 ppm Ceiling
ACGIH - Sensitizer Designation Sensitizer

Australia STEL = 2 ppm STEL = 2.5 mg/m³ STEL Australia TWA = 1 ppm TWA

= 1 ppm TWA = 1.2 mg/m³ TWA

See exposure limits for component (s) listed above. The exposure limit(s) listed for solid components are only relevant if dust or

mist may be generated.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Exposure

monitoring may be necessary to determine requirements.

Personal Protective Equipment:

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

Material Name: Clostridium Chauvoei-Septicum- Page 4 of 7

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

10. STABILITY AND REACTIVITY

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.

Polymerization: Will not occur

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. 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

Aluminum hydroxide gel

Rat Intraperitoneal LD50 150 mg/kg

Inhalation Acute ToxicityNot determined for this mixture. However, irritation may occur based on effects of individual

components.

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

Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

Skin Irritation / SensitizationThis 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

Subchronic EffectsRats 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

Page 5 of 7

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

Embryo / Fetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

Reproductive Effects Not considered to be a reproductive hazard.

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 Tumors2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

Carcinogen Status: Contains formaldehyde: potential cancer hazard. See below

Formaldehyde

IARC: Group 1

NTP: Reasonably Anticipated To Be A Carcinogen

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

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

Formaldehyde

RCRA - U Series Wastes waste number U122

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Material Name: Clostridium Chauvoei-Septicum-Page 6 of 7 Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

15. REGULATORY INFORMATION

EU Symbol: 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

Contains formaldehyde: potential cancer hazard May cause sensitization of the skin and respiratory system May cause eye, skin and respiratory tract irritation.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Aluminum hydroxide gel

Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present **EU EINECS List** 244-492-7

Formaldehyde

= 0.1 % de minimis concentration **CERCLA/SARA 313 Emission reporting**

CERCLA/SARA Hazardous Substances = 100 lb final RQ and their Reportable Quantities: = 45.4 kg final RQ = 500 lb TPQ

CERCLA/SARA - Section 302 Extremely Hazardous

CERCLA/SARA - Section 302 Extremely Hazardous

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 Irritant and potential cancer hazard - see 29 CFR

1910.1048 Present

Present

= 100 lb EPCRA RQ

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS): Standard for the Uniform Scheduling

Schedule 2 for Drugs and Poisons: Schedule 6 **EU EINECS List** 200-001-8

Obtained by Global Safety Management, 1-813-435-5161 - www.GSMSDS.com Obtained by Global Safety Management, www.GSMSDS.com, 877-683-7460

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

Water, purified

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

Present
231-791-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard

Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated

Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication

Pfizer Global Environment, Health, and Safety

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet



Revision date: 17-Mar-2014 Version: 3.0 Page 1 of 11

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

Product Identifier

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Trade Name: Ultrabac 8
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

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

EU Classification:

EU Indication of danger: Irritant

Carcinogenic: Category 3

EU Symbol: Xi

EU Risk Phrases:

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

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

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

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

Page 2 of 11

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 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.

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	%
Aluminum hydroxide gel	21645-51-2	244-492-7	Not Listed	Not Listed	##
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

7160.00

Material Name: Clostridium Chauvoei-SepticumHaemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

Ingredient	CAS Number	EU	EU Classification	GHS	%
		EINECS/ELINCS		Classification	
		List			
Clostridium haemolyticum	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
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 For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Exposure: 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

Formation of toxic gases is possible during heating or fire.

Products:

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

Material Name: Clostridium Chauvoei-Septicum- Page 4 of 11

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

Advice for Fire-Fighters

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

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 / Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill

Collecting: area thoroughly.

Additional Consideration for Non-essential personnel should be evacuated from affected area. Report emergency

Large Spills: 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. Releases to the environment should be avoided. Use appropriate personal protective equipment. Avoid accidental injection.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy

metals.

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.

Aluminum hydroxide gel

 ACGIH Threshold Limit Value (TWA)
 1 mg/m³

 Austria OEL - MAKs
 5 mg/m³

 Germany (DFG) - MAK
 4 mg/m³

 Latvia OEL - TWA
 6 mg/m³

 Lithuania OEL - TWA
 6 mg/m³

 Poland OEL - TWA
 2.5 mg/m³

 Slovakia OEL - TWA
 1.5 mg/m³

Slovakia OEL - TWA 1.5 mg/m³
Switzerland OEL -TWAs 3 mg/m³

Formaldehyde

ACGIH Ceiling Threshold Limit: 0.3 ppm
ACGIH - Sensitizer Designation Sensitizer

Material Name: Clostridium Chauvoei-Septicum-Page 5 of 11

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

8. EXPOSURE CONTROLS	/ PERSONAL PROTECTION

8. EXPOSURE CONTROLS	S / PERSONAL PROTECTION
Australia STEL	2 ppm
	2.5 mg/m ³
Australia TWA	1 ppm
	1.2 mg/m ³
Austria OEL - MAKs	0.5 ppm
D 051 514	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
Finland OFL TIMA	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
Germany (DFG) - MAK	0.37 mg/m³ no irritation should occur during mixed exposure
Greece OEL - TWA	2 ppm
Gleece OLL - IWA	2.5 mg/m ³
Hungary OEL - TWA	0.6 mg/m ³
Ireland OEL - TWAs	2 ppm
	2.5 mg/m ³
Japan - OELs - Ceilings	0.2 ppm
3	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	0.37 mg/m ³
Slovenia OEL - TWA	0.5 ppm
Sweden OEL TWAs	0.62 mg/m ³
Sweden OEL - TWAs	0.3 ppm 0.37 mg/m ³
Switzerland OEL -TWAs	0.3 ppm
SWILZERIANU UEL -I WAS	0.37 mg/m ³
	0.07 mg/m

Exposure Controls

Engineering controls should be used as the primary means to control exposures. General **Engineering Controls:**

room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne

contamination levels below the exposure limits listed above in this section.

Personal Protective

Equipment:

Refer to applicable national standards and regulations in the selection and use of personal

protective equipment (PPE).

Wear impervious gloves if skin contact is possible. Hands:

Safety glasses or goggles Eyes:

7160.00

Material Name: Clostridium Chauvoei-Septicum-Page 6 of 11

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 No data available. Color: Odor: No data available. **Odor Threshold:** No data available.

Mixture Mixture Molecular Formula: **Molecular Weight:**

Solvent Solubility: No data available Water Solubility: No data available

Solubility: Soluble: Water (based on components)

7.0 + / - 1.5:Ha Melting/Freezing Point (°C): No data available

Boiling Point (°C): >100

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 (q/ml): No data available No data available **Relative Density: Specific Gravity:** 1.0 + / - 0.2Viscosity: No data available

Flammablity:

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

Will not occur Polymerization:

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: 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:

7160.00

No data available

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

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.

Page 7 of 11

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

Formaldehyde

Rat Oral LD50 800 mg/kg

Aluminum hydroxide gel

Para-periosteal LD50 150 mg/kg

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

Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

Skin Sensitization Positive

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Formaldehyde

90 Day(s) Inhalation Not Specified Dog Lungs Lungs 90 Day(s) Rat Inhalation Not Specified 90 Day(s) Monkey Inhalation Not Specified Lungs

90 Day(s) Inhalation 15 ppm LOAEL Rat 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 Not Teratogenic, Maternal Toxicity Rat Inhalation 40 ppm

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Formaldehyde

In Vitro Bacterial Mutagenicity (Ames) Bacteria Positive

In Vitro Chromosome Aberration Rodent Positive

Positive In Vitro Sister Chromatid Exchange Rodent

In Vivo Chromosome Aberration Not specified Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Formaldehyde

7160.00

Material Name: Clostridium Chauvoei-Septicum- Page 8 of 11

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

11. TOXICOLOGICAL INFORMATION

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

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.

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.

Material Name: Clostridium Chauvoei-Septicum-Page 9 of 11 Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

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



Aluminum hydroxide ael

CERCLA/SARA 313 Emission reporting Not Listed Not Listed **California Proposition 65** Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present **EU EINECS/ELINCS List** 244-492-7

Clostridium haemolyticum

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

Formaldehyde

CERCLA/SARA 313 Emission reporting 0.1 % **CERCLA/SARA Hazardous Substances** 100 lb and their Reportable Quantities: 45.4 kg **CERCLA/SARA - Section 302 Extremely Hazardous** 500 lb

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 2 ppm

0.5 ppm 0.75 ppm Present

Inventory - United States TSCA - Sect. 8(b) Australia (AICS): Present Standard for the Uniform Scheduling Schedule 2 for Drugs and Poisons: Schedule 6 **EU EINECS/ELINCS List** 200-001-8

Clostridium sordellii

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

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

15. REGULATORY INFORMATION

Clostridium novyi

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Clostridium chauvoei

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Clostridium perfringens type D

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Clostridium septicum

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Clostridium perfringens type C

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Water, purified

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the

Not Listed

Not Listed

Present

Present

obligations of Register:

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

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

R40 - Limited evidence of a carcinogenic effect

R43 - May cause sensitization by skin contact.

R34 - Causes burns.

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 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 -

Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication

Zoetis Global Risk Management

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.

End of Safety Data Sheet

7160.00



Revision date: 17-Mar-2014 Version: 3.0 Page 1 of 11

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

Product Identifier

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Trade Name: Ultrabac 8
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

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

EU Classification:

EU Indication of danger: Irritant

Carcinogenic: Category 3

EU Symbol: Xi

EU Risk Phrases:

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

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

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

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

Page 2 of 11

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 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.

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	EU Classification	GHS Classification	%
		List			
Aluminum hydroxide gel	21645-51-2	244-492-7	Not Listed	Not Listed	##
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

7400.00

Material Name: Clostridium Chauvoei-Septicum- Page 3 of 11

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

Ingredient	CAS Number	EU	EU Classification	GHS	%
		EINECS/ELINCS		Classification	
		List			
Clostridium haemolyticum	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
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 For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Exposure: Identification and/or Section 11 - Toxicological Information.

Aggravated by Exposure:

Medical Conditions None known

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 Formation of toxic gases is possible during heating or fire.

Products:

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

Material Name: Clostridium Chauvoei-Septicum- Page 4 of 11

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

Advice for Fire-Fighters

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

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 / Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill

Collecting: area thoroughly.

Additional Consideration for Non-essential personnel should be evacuated from affected area. Report emergency

Large Spills: 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. Releases to the environment should be avoided. Use appropriate personal protective equipment. Avoid accidental injection.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy

metals.

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.

Aluminum hydroxide gel

Switzerland OEL -TWAs

ACGIH Threshold Limit Value (TWA) 1 mg/m^3 5 mg/m³ Austria OEL - MAKs Germany (DFG) - MAK 4 ma/m³ 1.5 mg/m^3 Latvia OEL - TWA 6 mg/m³ 6 mg/m³ Lithuania OEL - TWA 2.5 mg/m³ **Poland OEL - TWA** 1.2 mg/m³ Slovakia OEL - TWA 1.5 mg/m³

Formaldehyde

ACGIH Ceiling Threshold Limit: 0.3 ppm
ACGIH - Sensitizer Designation Sensitizer

3 mg/m³

Material Name: Clostridium Chauvoei-Septicum-Page 5 of 11

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION				
Australia STEL	2 ppm			
, taos ana 0122	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			
Form OF LINE	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			
Greece OEL - TWA	2.5 mg/m ³			
Hungary OEL - TWA	0.6 mg/m ³			
Ireland OEL - TWAs	2 ppm			
	2.5 mg/m ³			
Japan - OELs - Ceilings	0.2 ppm			
	0.24 mg/m³			
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			
Dala JOSI TWA	0.75 ppm			
Poland OEL - TWA	0.5 mg/m ³			
Romania OEL - TWA	1 ppm 1.20 mg/m³			
Slovakia OEL - TWA	0.3 ppm			
SIOVANIA CEL - I WA	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			
	0.07			

Exposure Controls

Engineering controls should be used as the primary means to control exposures. General **Engineering Controls:**

0.37 mg/m³

room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne

contamination levels below the exposure limits listed above in this section.

Personal Protective

Equipment:

Refer to applicable national standards and regulations in the selection and use of personal

protective equipment (PPE).

Wear impervious gloves if skin contact is possible. Hands:

Safety glasses or goggles Eyes:

Material Name: Clostridium Chauvoei-Septicum-Page 6 of 11

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 No data available. Color: Odor: No data available. **Odor Threshold:** No data available.

Mixture **Molecular Weight:** Mixture Molecular Formula:

Solvent Solubility: No data available Water Solubility: No data available

Solubility: Soluble: Water (based on components)

7.0 + / - 1.5:Ha Melting/Freezing Point (°C): No data available

Boiling Point (°C): >100

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 (q/ml): No data available **Relative Density:** No data available **Specific Gravity:** 1.0 + / - 0.2Viscosity: No data available

Flammablity:

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

Will not occur Polymerization:

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: 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:

No data available

Material Name: Clostridium Chauvoei-Septicum-

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

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.

Page 7 of 11

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

Formaldehyde

Rat Oral LD50 800 mg/kg

Aluminum hydroxide gel

Para-periosteal LD50 150 mg/kg

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

Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

Skin Sensitization Positive

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Formaldehyde

90 Day(s) Inhalation Not Specified Dog Lungs Lungs 90 Day(s) Rat Inhalation Not Specified 90 Day(s) Inhalation Not Specified Monkey

Lungs

90 Day(s) Inhalation 15 ppm LOAEL Rat 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 Not Teratogenic, Maternal Toxicity Rat Inhalation 40 ppm

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

7160.00

Material Name: Clostridium Chauvoei-Septicum- Page 8 of 11

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

11. TOXICOLOGICAL INFORMATION

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

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.

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.

Material Name: Clostridium Chauvoei-SepticumPage 9 of 11

Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

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



Aluminum hydroxide gel

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not

Clostridium haemolyticum

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Formaldehyde

CERCLA/SARA 313 Emission reporting 0.1 %
CERCLA/SARA Hazardous Substances 100 lb
and their Reportable Quantities: 45.4 kg
CERCLA/SARA - Section 302 Extremely Hazardous 500 lb

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 2 ppm 0.5 ppm

0.75 ppm Present

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Standard for the Uniform Scheduling
for Drugs and Poisons:

EU EINECS/ELINCS List

Present
Schedule 2
Schedule 6
200-001-8

Clostridium sordellii

CERCLA/SARA 313 Emission reporting

California Proposition 65

Not Listed

EU EINECS/ELINCS List

Not Listed

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

15. REGULATORY INFORMATION

Clostridium novyi

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Clostridium chauvoei

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Clostridium perfringens type D

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Clostridium septicum

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Clostridium perfringens type C

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Water, purified

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the obligations of Register:

Not Listed

Not Listed

Present

Present

obligations of Register.

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

Material Name: Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordelli-Perfringens Types C&D

Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 3.0

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

R34 - Causes burns.

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 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 -

Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication

Zoetis Global Risk Management

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.

End of Safety Data Sheet