This SDS packet was issued with item:

078912889

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

078404023 078422773 078426047

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).

078912814 078912856



Revision date: 25-Sep-2009 Version: 1.5 Page 1 of 8

IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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

Technical Services Phone: 1-800-366-5288

Emergency telephone number:

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

Emergency telephone number:

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

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

Trade Name: Ultrabac 7 - Somubac

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.

EU Indication of danger: Irrita

EU Hazard Symbols:



EU Risk Phrases:

Australian Hazard Classification

(NOHSC):

Note:

R43 - May cause sensitization by skin contact. Hazardous Substance. Non-Dangerous Goods.

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 Name: Clostridium Chauvoei-Septicum-Novyi- Page 2 of 8

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 25-Sep-2009 Version: 1.5

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Formaldehyde	50-00-0	200-001-8	C;R34	0.1 - 1.0%
			Carc. Cat.3;R40	
			R43	
			T;R23/24/25	

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Clostridium perfringens type C	NOT ASSIGNED	Not listed	Not Listed	*
Aluminum hydroxide gel	21645-51-2	244-492-7	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	>90%
Clostridium chauvoei	NOT ASSIGNED	Not listed	Not Listed	*
Haemophilus somnus	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	*

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.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Hazardous Combustion Products: Not known

Fire Fighting Procedures: Dike and collect water used to fight fire.

Fire / Explosion Hazards: Not applicable

Material Name: Clostridium Chauvoei-Septicum-Novyi-Page 3 of 8

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 25-Sep-2009 Version: 1.5

Additional Information: This product is a nonflammable aqueous solution. This material is not expected to

support combustion.

6. ACCIDENTAL RELEASE MEASURES

Personnel involved in clean-up should wear appropriate personal protective equipment (see **Health and Safety Precautions:**

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

Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing **General Handling:**

vapor or mist. Use appropriate personal protective equipment.

Store under refrigeration in closed container. **Storage Conditions:**

Storage Temperature:

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Aluminum hydroxide gel

ACGIH Threshold Limit Value (TWA) 1 mg/m³ TWA

Austria OEL - MAKs Listed **Bulgaria OEL - TWA** Listed Czech Republic OEL - TWA Listed

Germany (DFG) - MAK 1.5 mg/m³ MAK

4 mg/m³ MAK

Latvia OEL - TWA Listed Lithuania OEL - TWA Listed Poland OEL - TWA Listed

Formaldehyde

0.3 ppm **ACGIH Ceiling Threshold Limit: ACGIH - Sensitizer Designation** Listed **Australia STEL**

2 ppm 2.5 mg/m³

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

Material Name: Clostridium Chauvoei-Septicum-Novyi-Page 4 of 8

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 25-Sep-2009 Version: 1.5

EXPOSURE CONTROLS / PERSONAL PROTECTION

0.3 ppm MAK Germany (DFG) - MAK

0.37 mg/m³ MAK

Greece OEL - TWA Listed **Hungary OEL - TWA** Listed **Ireland OEL - TWAs** Listed Japan - OELs - Ceilings 0.2 ppm 0.24 mg/m³

Listed Listed

Latvia OEL - TWA Lithuania OEL - TWA Listed **Netherlands OEL - TWA OSHA - Final PELS - TWAs:** 0.75 ppm

0.5 ppm-Action Level **OSHA - Specifically Regulated Chemicals**

0.75 ppm-TWA 2 ppm-STEL

Poland OEL - TWA Listed 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.

Refer to specific Member State legislation for requirements under Community environmental **Environmental Exposure Controls:**

legislation.

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:

Eves: Safety glasses or goggles

Skin: Wear protective clothing when working with large quantities. Wash hands and arms thoroughly

after handling this material.

In the event of a spill where the applicable Occupational Exposure Limit (OEL) may be Respiratory protection:

exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures

below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

No data available. **Physical State:** Liquid Solution in multiple-dose vials Color:

Molecular Formula: Mixture Molecular Weight: Mixture

Soluble: Water (based on components) Solubility:

7.0 +/- 1.5 pH: >100 **Boiling Point (°C):**

Expected to be negligible Vapor Pressure (kPa):

Specific Gravity: 1.0 + / - 0.2

Non-flammable Flash Point (Liquid) (°C): Polymerization: Will not occur

Material Name: Clostridium Chauvoei-Septicum-Novyi- Page 5 of 8

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 25-Sep-2009 Version: 1.5

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do

not freeze.

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

metals.

Hazardous Decomposition Products: None expected under normal conditions.

11. TOXICOLOGICAL INFORMATION

General Information: The antigens included in this product are non-infectious. All have been prepared from killed or

inactivated preparations of microorganisms. The primary hazards are due to the formaldehyde

content.

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

Formaldehyde

Rat Oral LD50 800 mg/kg

Aluminum hydroxide gel

Rat Intraperitoneal LD50 150 mg/kg

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

Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

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

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

7423.00

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))

Material Name: Clostridium Chauvoei-Septicum-Novyi- Page 6 of 8

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 25-Sep-2009 Version: 1.5

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

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

specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental

releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xi EU Indication of danger: Irritant

EU Risk Phrases:

R43 - May cause sensitization by skin contact.

EU Safety Phrases:

S24 - Avoid contact with skin.S37 - Wear suitable gloves.

OSHA Label:

Material Name: Clostridium Chauvoei-Septicum-Novyi- Page 7 of 8

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 25-Sep-2009 Version: 1.5

15. REGULATORY INFORMATION

WARNING

May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Aluminum hydroxide gel

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

Australia (AICS):

EU EINECS/ELINCS List

244-492-7

Water, purified

Inventory - United States TSCA - Sect. 8(b)ListedAustralia (AICS):ListedREACH - Annex IV - Exemptions from thePresent

obligations of Register:

EU EINECS/ELINCS List 231-791-2

Formaldehyde

CERCLA/SARA 313 Emission reporting 0.1% de minimis concentration

CERCLA/SARA Hazardous Substances
and their Reportable Quantities:
45.4 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous
500 lb TPQ

TPQs

CERCLA/SARA - Section 302 Extremely Hazardous 100 lb

Substances EPCRA RQs

California Proposition 65 carcinogen, initial date 1/1/88 (gas)

OSHA - Specifically Regulated Chemicals 0.5 ppm-Action Level

0.75 ppm-TWA 2 ppm-STEL

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

Australia (AICS):

Standard for the Uniform Scheduling
for Drugs and Poisons:

EU EINECS/ELINCS List

Listed

Schedule 2

Schedule 6

200-001-8

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R34 - Causes burns.

R40 - Limited evidence of a carcinogenic effect

R43 - May cause sensitization by skin contact.

R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

•

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

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 25-Sep-2009 Version: 1.5

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information.

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

Ingredients. Updated Section 4 - First Aid Measures. Updated Section 13 - Disposal

Considerations.

Prepared by: Toxicology and Hazard Communication

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



Version: 2.0 Revision date: 22-Apr-2014 Page 1 of 11

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

Product Identifier

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

Somnus Bacterin-Toxoid

Ultrabac 7 - Somubac **Trade Name:**

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:

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: VMIPSrecords@zoetis.com 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:

EU Risk Phrases:

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

Label Elements

Signal Word: Danger

Hazard Statements: H317 - May cause an allergic skin reaction

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H350 - May cause cancer

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

Bacterin-Toxoid

Revision date: 22-Apr-2014 Version: 2.0

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 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.

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)	0.1-1.0%

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

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 22-Apr-2014 Version: 2.0

Ingredient	CAS Number	EU	EU Classification	GHS	%
		EINECS/ELINCS		Classification	
		List			
Haemophilus somnus	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	*

Additional Information: * Proprietary

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.

Advice for Fire-Fighters

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

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

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 22-Apr-2014 Version: 2.0

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. 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.

Aluminum hydroxide gel

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

Formaldehyde

ACGIH Ceiling Threshold Limit:

ACGIH - Sensitizer Designation

Australia STEL

2 ppm
2.5 mg/m³

Australia TWA

1 ppm
1.2 mg/m³

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

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 22-Apr-2014 Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

France OEL - TWA 0.5 ppm Germany (DFG) - MAK 0.3 ppm

0.37 mg/m³ no irritation should occur during mixed exposure

Greece OEL - TWA2 ppm
2.5 mg/m³

 Hungary OEL - TWA
 0.6 mg/m³

 Ireland OEL - TWAs
 2 ppm

 2.5 mg/m³

Japan - OELs - Ceilings 0.2 ppm 0.24 mg/m³

 Latvia OEL - TWA
 0.5 mg/m³

 Lithuania OEL - TWA
 0.5 ppm

 0.6 mg/m³
 0.6 mg/m³

Netherlands OEL - TWA 0.15 mg/m³
Vietnam OEL - TWAs 0.5 mg/m³
OSHA - Final PELS - TWAs: 0.75 ppm
OSHA - Specifically Regulated Chemicals 2 ppm

0.5 ppm 0.75 ppm 0.5 mg/m³

 Poland OEL - TWA
 0.5 mg/m³

 Romania OEL - TWA
 1 ppm

 1.20 mg/m³

 Slovenia OEL - TWA
 0.5 ppm

 0.62 mg/m³
 0.3 ppm

 0.37 mg/m³
 0.37 mg/m³

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

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

Equipment: 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.

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

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 22-Apr-2014 Version: 2.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:Liquid Solution in multiple-dose vialsColor:No data available.Odor:No data available.Odor Threshold:No data available.

Molecular Formula: Mixture 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

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 availableRelative Density:No data availableSpecific Gravity:1.0 +/-0.2

Viscosity: No data available

Flammablity:

Autoignition Temperature (Solid) (°C):

Flammability (Solids):

Flash Point (Liquid) (°C):

Upper Explosive Limits (Liquid) (% by Vol.):

Lower Explosive Limits (Liquid) (% by Vol.):

Polymerization:

No data available
No data available
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 No data available

Products:

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.

Material Name: Clostridium Chauvoei-Septicum-Novyi- Page 7 of 11

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 22-Apr-2014 Version: 2.0

11. TOXICOLOGICAL INFORMATION

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

Formaldehyde

Rat Oral LD50 800 mg/kg

Aluminum hydroxide gel

Rat 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) 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

7423.00

IARC: Group 1 (Carcinogenic to Humans)

Page 8 of 11

Material Name: Clostridium Chauvoei-Septicum-Novyi-

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 22-Apr-2014 Version: 2.0

11. TOXICOLOGICAL INFORMATION

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.

15. REGULATORY INFORMATION

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

Page 9 of 11

Material Name: Clostridium Chauvoei-Septicum-Novyi-

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 22-Apr-2014 Version: 2.0

15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A Class D, Division 2, Subdivision B



Haemophilus somnus

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

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 Listed

Present

244-492-7

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

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

Australia (AICS):

Standard for the Uniform Scheduling
for Drugs and Poisons:

EU EINECS/ELINCS List

O.75 ppm
Present
Schedule 2
Schedule 2
Schedule 6
200-001-8

Clostridium sordellii

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Clostridium novyi

CERCLA/SARA 313 Emission reporting

California Proposition 65

Not Listed

EU EINECS/ELINCS List

Not Listed

Material Name: Clostridium Chauvoei-Septicum-Novyi- Page 10 of 11

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 22-Apr-2014 Version: 2.0

15. REGULATORY INFORMATION

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

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

H331 - Toxic if inhaled

H350 - May cause cancer

T - Toxic C - Corrosive

Carcinogenic: Category 3

R34 - Causes burns.

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

R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

Data Sources: 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.

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

Sordelli-Perfringens Types C&D Haemophilus Somnus

Bacterin-Toxoid

Revision date: 22-Apr-2014 Version: 2.0

Prepared by: Toxicology and Hazard Communication Zoetis Global Risk Management

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End of Safety Data Sheet