# This SDS packet was issued with item:

078912816

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

078421112 078422880 078425906

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).

078912857 078912888



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-Novyi-Sordelli-Perfringens Types C&D Bacterin-Toxoid

Trade Name: Ultrabac(R) 7
Chemical Family: Mixture

Intended Use: Veterinary Vaccine

# 2. COMPOSITION/INFORMATION ON INGREDIENTS

### **Hazardous**

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

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

**Additional Hazard Information:** 

Material Name: Clostridium Chauvoei-Septicum-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 skin 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:

**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: Not applicable

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

support combustion.

# 6. ACCIDENTAL RELEASE MEASURES

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

Section 8). Minimize exposure.

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill Measures for Cleaning / Collecting:

area thoroughly.

**Measures for Environmental** 

**Protections:** 

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

avoid environmental release.

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

Sordelli-Perfringens Types C&D Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

Additional Consideration for Large

Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

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

vapor or mist. Use appropriate personal protective equipment.

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

2-7°C Storage Temperature:

# 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/m<sup>3</sup> STEL = 1 ppm TWA

**Australia TWA**  $= 1.2 \text{ mg/m}^3 \text{ TWA}$ 

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.

**Personal Protective Equipment:** 

Hands: Wear impervious gloves if skin contact is possible.

Safety glasses or goggles Eyes:

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

1.0 +/-0.2 **Specific Gravity:** 

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

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

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.

#### 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.

**Ingestion Acute Toxicity** See Acute toxicity table.

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

Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

**Skin Irritation / Sensitization**This product contains formaldehyde which is considered to be a skin sensitizer.

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

### **Formaldehyde**

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

9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

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

Page 5 of 7

Material Name: Clostridium Chauvoei-Septicum-Novyi-

Sordelli-Perfringens Types C&D Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

**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

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: Contains formaldehyde: potential cancer hazard.

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-NovyiPage 6 of 7

Sordelli-Perfringens Types C&D Bacterin-Toxoid

Revision date: 07-Dec-2006 Version: 1.4

# 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:**

**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)

Australia (AICS):

Present

Present

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

**TPQs** 

CERCLA/SARA - Section 302 Extremely Hazardous = 100 lb EPCRA RQ

Substances EPCRA RQs
California Proposition 65

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

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present

Standard for the Uniform SchedulingSchedule 2for Drugs and Poisons:Schedule 6EU EINECS List200-001-8

Water, purified

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

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

Revision date: 07-Dec-2006 Version: 1.4

Australia (AICS): Present EU EINECS List 231-791-2

# **16. OTHER INFORMATION**

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures.

Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

Page 7 of 7

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: 2.0 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 Bacterin-Toxoid

Ultrabac 7 **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. Zoetis Belgium S.A. 100 Campus Drive, P.O. Box 651 Mercuriusstraat 20 Florham Park, New Jersey 07932 (USA) 1930 Zaventem **Belgium** 

Rocky Mountain Poison Control Center Phone: 1-866-531-8896 Product Support/Technical Services Phone: 1-800-366-5288

**Emergency telephone number: Emergency telephone number:** 

CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887 Contact E-Mail: VMIPSrecords@zoetis.com

# 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: Χi 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-Novyi-Sordelli-Perfringens Types C&D Bacterin-Toxoid

Revision date: 17-Mar-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 comfortable for breathing

Page 2 of 11

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:

Australian Hazard Classification (NOHSC):

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.

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

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

Sordelli-Perfringens Types C&D Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 2.0

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

Additional Information: \* Proprietary

## Trace

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

safety.

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

# 4. FIRST AID MEASURES

**Description of First Aid Measures** 

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention

immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek

medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not

induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of 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.

Page 4 of 11

Material Name: Clostridium Chauvoei-Septicum-Novyi-

Sordelli-Perfringens Types C&D Bacterin-Toxoid

Revision date: 17-Mar-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

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/m<sup>3</sup> **Austria OEL - MAKs** 5 mg/m<sup>3</sup> 4 mg/m<sup>3</sup> Germany (DFG) - MAK 1.5 mg/m<sup>3</sup> Latvia OEL - TWA 6 mg/m<sup>3</sup> 6 mg/m<sup>3</sup> Lithuania OEL - TWA Poland OEL - TWA 2.5 mg/m3 1.2 mg/m<sup>3</sup>  $1.5 \text{ mg/m}^{3}$ Slovakia OEL - TWA **Switzerland OEL -TWAs** 3 mg/m<sup>3</sup>

**Formaldehyde** 

ACGIH Ceiling Threshold Limit:

ACGIH - Sensitizer Designation

Australia STEL

2 ppm
2.5 mg/m³

Australia TWA

1 ppm

1.2 mg/m<sup>3</sup>

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

Sordelli-Perfringens Types C&D Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 2.0

# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs 0.5 ppm 0.6 mg/m<sup>3</sup> **Bulgaria OEL - TWA** 1.0 ma/m<sup>3</sup> Czech Republic OEL - TWA 0.5 mg/m<sup>3</sup> **Estonia OEL - TWA** 0.5 ppm 0.6 mg/m<sup>3</sup> **Finland OEL - TWA** 0.3 ppm 0.37 mg/m<sup>3</sup> France OEL - TWA 0.5 ppm Germany (DFG) - MAK 0.3 ppm 0.37 mg/m<sup>3</sup> no irritation should occur during mixed exposure **Greece OEL - TWA** 2 ppm 2.5 mg/m<sup>3</sup> **Hungary OEL - TWA** 0.6 mg/m<sup>3</sup> **Ireland OEL - TWAs** 2 ppm 2.5 mg/m<sup>3</sup> 0.2 ppm Japan - OELs - Ceilings 0.24 mg/m<sup>3</sup> Latvia OEL - TWA  $0.5 \text{ mg/m}^{3}$ Lithuania OEL - TWA 0.5 ppm  $0.6 \text{ mg/m}^{3}$ **Netherlands OEL - TWA** 0.15 mg/m<sup>3</sup> **Vietnam OEL - TWAs** 0.5 mg/m<sup>3</sup> 0.75 ppm **OSHA - Final PELS - TWAs: OSHA - Specifically Regulated Chemicals** 2 ppm 0.5 ppm 0.75 ppm **Poland OEL - TWA**  $0.5 \text{ mg/m}^{3}$ Romania OEL - TWA 1 ppm 1.20 mg/m<sup>3</sup>

Slovakia OEL - TWA 0.3 ppm 0.37 mg/m<sup>3</sup>

0.5 ppm Slovenia OEL - TWA 0.62 mg/m<sup>3</sup> Sweden OEL - TWAs 0.3 ppm 0.37 mg/m<sup>3</sup>

**Switzerland OEL -TWAs** 0.3 ppm 0.37 mg/m<sup>3</sup>

**Exposure Controls** 

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

monitoring may be necessary to determine requirements.

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

protective equipment (PPE). **Equipment:** 

Wear impervious gloves if skin contact is possible. Hands:

Eves: Safety glasses or goggles

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

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.

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

Sordelli-Perfringens Types C&D Bacterin-Toxoid

Revision date: 17-Mar-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 +/-0.2Viscosity: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: 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

# 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

Material Name: Clostridium Chauvoei-Septicum-Novyi-

Sordelli-Perfringens Types C&D Bacterin-Toxoid

Revision date: 17-Mar-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 Tumors2 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

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

Revision date: 17-Mar-2014 Version: 2.0

# 11. TOXICOLOGICAL INFORMATION

# 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

Page 8 of 11

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

Canada - WHMIS: Classifications

Page 9 of 11

Material Name: Clostridium Chauvoei-Septicum-Novyi-

Sordelli-Perfringens Types C&D Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 2.0

# 15. REGULATORY INFORMATION

### 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 Listed

Not Listed

Not Listed

Not Listed

Not Listed

Not Eisted

Not Listed

Not

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

**OSHA - Specifically Regulated Chemicals** 

California Proposition 65 carcinogen initial date 1/1/88 gas

2 ppm

0.5 ppm
0.75 ppm
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
Present
Standard for the Uniform Scheduling
Schedule 2

for Drugs and Poisons:Schedule 6EU EINECS/ELINCS List200-001-8

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

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

Not Listed
California Proposition 65

Not Listed

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

Sordelli-Perfringens Types C&D Bacterin-Toxoid

Revision date: 17-Mar-2014 Version: 2.0

# 15. REGULATORY INFORMATION

EU EINECS/ELINCS List 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
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

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 11 - Toxicology Information. Updated Section 15 -

Regulatory Information.

Page 11 of 11

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

Revision date: 17-Mar-2014 Version: 2.0

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** 



### 1. Identification

Product identifier Ultrabac 7 / Somubac

Other means of identification

Synonyms Ultrabac® 7/Somubac® \* ULTRABAC® 7/SOMUBAC® \* Clostridium

Chauvoei-Septicum-Novyi-Sordelli-Perfringens Types C&D Haemophilus Somnus Bacterin-Toxoid

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

Company Name (US) Zoetis Inc.

10 Sylvan Way

Parsippany, New Jersey 07054 (USA)

**Rocky Mountain Poison** 

and Drug Center

1-866-531-8896

**Product Support/Technical** 

**Services** 

1-800-366-5288

**Emergency telephone** 

numbers

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

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

Company Name (EU) Zoetis Belgium S.A.

Mercuriusstraat 20 1930 Zaventem

Belgium

**Emergency telephone** 

number

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

Contact E-Mail VMIPSrecords@zoetis.com

# 2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Skin corrosion/irritation Category 2

Serious eye damage/eye irritation

Category 2A

Sensitization, respiratory

Category 1A

Sensitization, skin

Category 1A

Germ cell mutagenicity

Category 2

Carcinogenicity

Category 1A

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May

cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of causing

genetic defects. May cause cancer.

Material name: Ultrabac 7 / Somubac

SDS US

**Precautionary statement** 

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Avoid breathing mist or vapor. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory

protection.

If exposed or concerned: Get medical advice/attention. If on skin: Wash with plenty of water. If Response

skin irritation or rash occurs: Get medical advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get

medical advice/attention. Take off contaminated clothing and wash before reuse.

Storage Store locked up.

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

Hazard(s) not otherwise classified (HNOC)

None known.

**Supplemental information** None.

# 3. Composition/information on ingredients

#### **Mixtures**

Chemical name	Common name and synonyms	CAS number	%
Aluminum hydroxide gel		21645-51-2	1-3
Formaldehyde		50-00-0	0.1-1
Clostridium chauvoei		NOT ASSIGNED	*
Clostridium novyi		NOT ASSIGNED	*
Clostridium perfringens type C		NOT ASSIGNED	*
Clostridium perfringens type D		NOT ASSIGNED	*
Clostridium septicum		NOT ASSIGNED	*
Clostridium sordellii		NOT ASSIGNED	*
Haemophilus somnus		NOT ASSIGNED	*

#### **Composition comments**

\* Non-hazardous Ingredients

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

### 4. First-aid measures

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

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

Skin contact Remove contaminated clothing. In the case of skin contact, immediately wash the skin with plenty

of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention. In case of eczema or

other skin disorders: Seek medical attention and take along these instructions.

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if Eye contact

present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Difficulty in breathing. Skin irritation. May cause redness and pain. May cause an allergic

Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or

is having convulsions.

skin reaction. Dermatitis. Rash.

Most important

symptoms/effects, acute and

delayed

Ingestion

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

**General information** For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical

advice/attention. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse.

# 5. Fire-fighting measures

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Material name: Ultrabac 7 / Somubac 351 Version #: 01 Issue date: 06-16-2017 SDS US 2/9 Unsuitable extinguishing

media

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from

the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

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

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

No unusual fire or explosion hazards noted. General fire hazards

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Ventilate the contaminated area. Avoid inhalation of vapors or mists. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Ensure adequate ventilation. Avoid release to the environment.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Clean contaminated surface thoroughly.

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

Never return spills to original containers for re-use. Put material in suitable, covered, labeled containers. For waste disposal, see section 13 of the SDS.

**Environmental precautions** 

Avoid discharge into drains, water courses or onto the ground.

# 7. Handling and storage

Precautions for safe handling

Do not handle until all safety precautions have been read and understood. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities Store locked up. Store in original tightly closed container. Keep away from heat, sparks and open flame. Store in a well-ventilated place. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

\/ - I...

### 8. Exposure controls/personal protection

### Occupational exposure limits

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

# US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Туре	Value	
STEL	2 ppm	
TWA	0.75 ppm	
0)		
Туре	Value	Form
TWA	5 mg/m3	Respirable fraction.
	15 mg/m3	Total dust.
	50 mppcf	Total dust.
	15 mppcf	Respirable fraction.
Туре	Value	Form
TWA	1 mg/m3	Respirable fraction.
	STEL TWA  O) Type TWA  Type	TWA 0.75 ppm  Type Value  TWA 5 mg/m3  15 mg/m3  50 mppcf  15 mppcf  Type Value

Material name: Ultrabac 7 / Somubac

SDS US

3/9

**US. ACGIH Threshold Limit Values Form** Components Value Type Formaldehyde (CAS Ceiling 0.3 ppm 50-00-0) **US. NIOSH: Pocket Guide to Chemical Hazards** Components **Type** Value Formaldehyde (CAS Ceiling 0.1 ppm 50-00-0)

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

Control banding approach Not available.

Appropriate engineering

controls

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

0.016 ppm

General ventilation normally adequate.

**TWA** 

Individual protection measures, such as personal protective equipment

**Eye/face protection** Wear safety glasses or goggles if eye contact is possible.

Skin protection

**Hand protection** Wear appropriate chemical resistant gloves.

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

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

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

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

below the OEL.

Thermal hazards Not applicable.

General hygiene considerations

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

### 9. Physical and chemical properties

Appearance Liquid solution

Physical stateLiquid.FormLiquid.

ColorNot available.OdorNot available.Odor thresholdNot available.

**pH** 6 - 8

Melting point/freezing point Not available.

Initial boiling point and boiling

> 212 °F (> 100 °C)

range

Flash point Non-flammable
Evaporation rate Not available.
Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

(%)

Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Ippor pressure Not available.

Vapor pressureNot available.Vapor densityNot available.

Material name: Ultrabac 7 / Somubac

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.
(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

Specific gravity 0.8 - 1.2

# 10. Stability and reactivity

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

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Heat, flames and sparks. Sunlight. Protect from freezing.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

No hazardous decomposition products are known.

### 11. Toxicological information

### Information on likely routes of exposure

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

may be harmful.

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

Formaldehyde Species: Rabbit

Severity: Moderate to Severe

**Eye contact** Causes serious eye irritation.

Formaldehyde Species: Rabbit

Severity: Severe

**Ingestion** Health injuries are not known or expected under normal use.

Symptoms related to the physical, chemical and toxicological characteristics

Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Difficulty in breathing. Skin irritation. May cause redness and pain. May cause an allergic

skin reaction. Dermatitis. Rash.

### Information on toxicological effects

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

Product Species Test Results

Ultrabac 7 / Somubac

Acute Dermal

ATE > 10000 mg/kg

Inhalation

ATE 48 mg/l/4h

Oral

ATE 10000 mg/kg

Material name: Ultrabac 7 / Somubac 351 Version #: 01 Issue date: 06-16-2017 Components **Species Test Results** 

Aluminum hydroxide gel (CAS 21645-51-2)

**Acute** 

Other

LD50 Rat 150 mg/kg

Formaldehyde (CAS 50-00-0)

**Acute** 

**Dermal** 

LD50 Rabbit 270 mg/kg

Inhalation

LC50 Mouse 0.414 mg/L, 4 hours Rat

0.48 mg/L, 4 hours

Oral

LD50 Rat 100 mg/kg

**Chronic** Inhalation

LOAEL Mouse 15 ppm, 2 years Tumors

> Rat 15 ppm, 90 days Respiratory system

> > 6 ppm, 2 years Tumors

Skin corrosion/irritation Serious eye damage/eye

irritation

Causes skin irritation.

Causes serious eye irritation.

**Eve Contact** 

Formaldehyde Species: Rabbit

Severity: Severe

Respiratory or skin sensitization

**ACGIH** sensitization

FORMALDEHYDE (CAS 50-00-0) Dermal sensitization

Respiratory sensitization

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

Skin sensitization May cause an allergic skin reaction.

Skin sensitization

Formaldehyde Species: Guinea Pig

Severity: Positive

Germ cell mutagenicity Suspected of causing genetic defects.

Mutagenicity

Formaldehyde In Vitro Bacterial Mutagenicity (Ames)

> Result: Positive Species: Bacteria

In Vitro Chromosome Aberration

Result: Positive Species: Rodent

In Vitro Sister Chromatid Exchange

Result: Positive Species: Rodent

In Vivo Chromosome Aberration

Result: Positive Species: Not specified

Carcinogenicity May cause cancer.

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0) 1 Carcinogenic to humans. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Formaldehyde (CAS 50-00-0)

US. National Toxicology Program (NTP) Report on Carcinogens

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

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

**Developmental effects** 

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

Maternal toxicity Species: Mouse Organ: Oral

40 ppm Embryo / Fetal Development, Not Teratogenic

Maternal Toxicity Species: Rat Organ: Inhalation

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

Not classified.

repeated exposure

**Further information** 

**Aspiration hazard** Not an aspiration hazard.

> In the event of accidental injection, an allergic reaction may occur. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of

microorganisms.

### 12. Ecological information

**Ecotoxicity** 

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

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

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available for this product.

Mobility in soil

No data available.

Other adverse effects

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

### 13. Disposal considerations

Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. **Disposal instructions** 

Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container

in accordance with local/regional/national/international regulations.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

None known.

Waste from residues / unused

products

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

Disposal instructions).

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

emptied.

Material name: Ultrabac 7 / Somubac

SDS US

### 14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

**IMDG** 

Not regulated as dangerous goods.

Transport in bulk according to

Not established.

Annex II of MARPOL 73/78 and

the IBC Code

# 15. Regulatory information

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

Standard, 29 CFR 1910.1200.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Formaldehyde (CAS 50-00-0) Listed.

SARA 304 Emergency release notification

Formaldehyde (CAS 50-00-0) 100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Formaldehyde (CAS 50-00-0) Cancer

Skin sensitization Respiratory sensitization

Eye irritation Skin irritation

respiratory tract irritation

Acute toxicity Flammability

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

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

SARA 302 Extremely hazardous substance

**Chemical name CAS** number Reportable **Threshold Threshold** Threshold planning quantity, quantity planning quantity planning quantity, (pounds) (pounds) lower value upper value (pounds) (pounds)

Formaldehyde 50-00-0 100 500

SARA 311/312 Hazardous No

chemical

SARA 313 (TRI reporting)

Chemical nameCAS number% by wt.Formaldehyde50-00-00.1-1

Other federal regulations

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

Formaldehyde (CAS 50-00-0)

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

Formaldehyde (CAS 50-00-0)

Safe Drinking Water Act Not regulated.

(SDWA)

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

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

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

Material name: Ultrabac 7 / Somubac 351 Version #: 01 Issue date: 06-16-2017

SDS US

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

Formaldehyde (CAS 50-00-0)

#### International Inventories

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

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

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

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

**Issue date** 06-16-2017

Version # 01

List of abbreviations ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).

Disclaimer Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while

it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently

available.

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

Material name: Ultrabac 7 / Somubac