

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078912851

**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).**

078912820



# MATERIAL SAFETY DATA SHEET

Revision date: 04-Dec-2006

Version: 1.6

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

Pfizer Animal Health  
Pfizer Inc  
235 East 42nd Street  
New York, NY 10017  
Poison Control Center Phone: 1-866-531-8896  
Technical Services Phone: 1-800-366-5288

Pfizer Ltd,  
Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

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

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

**Material Name: Haemophilus Somnus Bacterin**

Trade Name: Somubac (R)  
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
Merthiolate (as mercury)	54-64-8	200-210-4	##

Ingredient	CAS Number	EU EINECS List	%
EDTA solution	NOT ASSIGNED	Not listed	*
Aluminum hydroxide gel	21645-51-2	244-492-7	*
Water, purified	7732-18-5	231-791-2	>90
Haemophilus somnus	NOT ASSIGNED	Not listed	*

**Additional Information:** \* Proprietary  
## Trace  
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:**  
**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:** Irritant

**EU Hazard Symbols:**

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### 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

<b>Eye Contact:</b>	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
<b>Skin Contact:</b>	Wash skin with soap and water. If irritation occurs or persists, get medical attention.
<b>Ingestion:</b>	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Inhalation:</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

## 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	As for primary cause of fire.
<b>Hazardous Combustion Products:</b>	Not known
<b>Fire Fighting Procedures:</b>	Dike and collect water used to fight fire.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

## 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment.
<b>Storage Conditions:</b>	Store under refrigeration in closed container.

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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/m <sup>3</sup> STEL
Australia TWA	= 1 ppm TWA
	= 1.2 mg/m <sup>3</sup> TWA

### Merthiolate (as mercury)

OSHA - Final PELs - TWAs:	= 0.01 mg/m <sup>3</sup> TWA
ACGIH Threshold Limit Value (TWA)	= 0.01 mg/m <sup>3</sup> TWA
ACGIH Threshold Limit Value (STEL)	= 0.03 mg/m <sup>3</sup> STEL
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia STEL	= 0.03 mg/m <sup>3</sup> STEL
Australia TWA	= 0.01 mg/m <sup>3</sup> TWA

**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:

<b>Hands:</b>	Wear impervious gloves if skin contact is possible.
<b>Eyes:</b>	Safety glasses or goggles
<b>Skin:</b>	Wear protective clothing when working with large quantities. Wash hands and arms thoroughly after handling this material.
<b>Respiratory protection:</b>	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:

<b>Physical State:</b>	Liquid solution in multiple-dose vials	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solubility:</b>	Soluble: Water (based on components)		
<b>pH:</b>	7.0 +/- 1.5		
<b>Boiling Point (°C):</b>	>100		
<b>Vapor Pressure (kPa):</b>	Expected to be negligible		
<b>Specific Gravity:</b>	1.0 +/-0.2		
<b>Flash Point (Liquid) (°C):</b>	Non-flammable		

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### 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)

##### **Merthiolate (as mercury)**

Rat Oral LD50 75 mg/kg  
Rat Subcutaneous LD50 98 mg/kg

##### **Aluminum hydroxide gel**

Rat Intraperitoneal LD50 150 mg/kg

##### **Formaldehyde**

Rat Oral LD50 800 mg/kg

**Inhalation Acute Toxicity** Not determined for this mixture. However, irritation may occur based on effects of individual components.

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

##### **Merthiolate (as mercury)**

Eye Irritation Rabbit Mild

##### **Formaldehyde**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Moderate Severe

**Skin Irritation / Sensitization** This product contains formaldehyde and merthiolate which are considered to be skin sensitizers.

#### 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.

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### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Formaldehyde

Embryo / Fetal Development Mouse Oral 185 mg/kg/day Not teratogenic, Maternal toxicity  
Embryo / Fetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

#### Reproductive Effects

Not considered to be a reproductive hazard.

#### 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 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:

Observe all local and national regulations when disposing of this material. This product contains trace quantities of mercury and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP).

#### Formaldehyde

RCRA - U Series Wastes

waste number U122

## 14. TRANSPORT INFORMATION

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

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## 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)	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 and their Reportable Quantities:	= 100 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 45.4 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 500 lb TPQ
California Proposition 65	= 100 lb EPCRA RQ
OSHA - Specifically Regulated Chemicals	carcinogen, initial date 1/1/88 (gas)
	= 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

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

<b>Merthiolate (as mercury)</b>	
CERCLA/SARA 313 Emission reporting	= 1.0 % Supplier notification limit
California Proposition 65	Developmental
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-210-4

<b>Water, purified</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

## 16. OTHER INFORMATION

**Reasons for Revision:** 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 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**



# SAFETY DATA SHEET



Revision date: 22-Apr-2014

Version: 2.0

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## 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

**Trade Name:** Ultrabac 7 - Somubac  
**Chemical Family:** Mixture

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

**Intended Use:** Veterinary Vaccine

### Details of the Supplier of the Safety Data Sheet

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

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

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

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

## 2. HAZARDS IDENTIFICATION

**Appearance:** Liquid solution in multiple-dose vials

### Classification of the Substance or Mixture

#### GHS - Classification

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

#### EU Classification:

EU Indication of danger: Irritant  
Carcinogenic: Category 3

EU Symbol: Xi T  
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

## SAFETY DATA SHEET

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

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



**Other Hazards**  
**Short Term:**

May cause eye and skin irritation. May cause allergic skin reaction . In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.  
 Hazardous Substance. Non-Dangerous Goods.

**Australian Hazard Classification (NOHSC):**

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 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%

## SAFETY DATA SHEET

Material Name: Clostridium Chauvoei-Septicum-Novyi-Sordelli-Perfringens Types C&D Haemophilus Somnus Bacterin-Toxoid  
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Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
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 Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** 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 CO<sub>2</sub>, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

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

#### Advice for Fire-Fighters

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

## SAFETY DATA SHEET

Material Name: Clostridium Chauvoei-Septicum-Novyi-Sordelli-Perfringens Types C&D Haemophilus Somnus Bacterin-Toxoid  
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### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

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

#### Environmental Precautions

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

#### Methods and Material for Containment and Cleaning Up

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

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

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

#### Conditions for Safe Storage, Including any Incompatibilities

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

**Storage Temperature:** 2-7°C

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Aluminum hydroxide gel

ACGIH Threshold Limit Value (TWA)	1 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup>
	1.5 mg/m <sup>3</sup>
Latvia OEL - TWA	6 mg/m <sup>3</sup>
Lithuania OEL - TWA	6 mg/m <sup>3</sup>
Poland OEL - TWA	2.5 mg/m <sup>3</sup>
	1.2 mg/m <sup>3</sup>
Slovakia OEL - TWA	1.5 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>

#### Formaldehyde

ACGIH Ceiling Threshold Limit:	0.3 ppm
ACGIH - Sensitizer Designation	Sensitizer
Australia STEL	2 ppm
	2.5 mg/m <sup>3</sup>
Australia TWA	1 ppm
	1.2 mg/m <sup>3</sup>

## SAFETY DATA SHEET

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	0.5 ppm
	0.6 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1.0 mg/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>
Japan - OELs - Ceilings	0.2 ppm
	0.24 mg/m <sup>3</sup>
Latvia OEL - TWA	0.5 mg/m <sup>3</sup>
Lithuania OEL - TWA	0.5 ppm
	0.6 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.15 mg/m <sup>3</sup>
Vietnam OEL - TWAs	0.5 mg/m <sup>3</sup>
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 <sup>3</sup>
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>
Slovenia OEL - TWA	0.5 ppm
	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. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

##### Hands:

Wear impervious gloves if skin contact is possible.

##### Eyes:

Safety glasses or goggles

##### Skin:

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

##### Respiratory protection:

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

## SAFETY DATA SHEET

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid Solution in multiple-dose vials	<b>Color:</b>	No data available.
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>Solubility:</b>	Soluble: Water (based on components)		
<b>pH:</b>	7.0 +/- 1.5		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	>100		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	Expected to be negligible		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Specific Gravity:</b>	1.0 +/-0.2		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>		No data available	
<b>Flammability (Solids):</b>		No data available	
<b>Flash Point (Liquid) (°C):</b>		Non-flammable	
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Polymerization:</b>		Will not occur	

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	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.

## SAFETY DATA SHEET

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

IARC: Group 1 (Carcinogenic to Humans)

## SAFETY DATA SHEET

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



**SAFETY DATA SHEET**

**Material Name: Clostridium Chauvoei-Septicum-Novyi-Sordelli-Perfringens Types C&D Haemophilus Somnus Bacterin-Toxoid**  
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**15. REGULATORY INFORMATION**

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B



**Haemophilus somnus**

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

**Aluminum hydroxide gel**

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

**Formaldehyde**

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

**Clostridium sordellii**

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

**Clostridium novyi**

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

## SAFETY DATA SHEET

Material Name: Clostridium Chauvoei-Septicum-Novyi-Sordelli-Perfringens Types C&D Haemophilus Somnus Bacterin-Toxoid  
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### 15. REGULATORY INFORMATION

#### Clostridium chauvoei

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

#### Clostridium perfringens type D

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

#### Clostridium septicum

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

#### Clostridium perfringens type C

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

### 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.

## SAFETY DATA SHEET

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

# SAFETY DATA SHEET



## 1. Identification

**Product identifier** Somubac®  
**Other means of identification**  
**Synonyms** Somubac \* SOMBUBAC \* Haemophilus Somnus Bacterin  
**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** Not classified.  
**Environmental hazards** Not classified.  
**OSHA defined hazards** Not classified.

### Label elements

**Hazard symbol** None.  
**Signal word** None.  
**Hazard statement** The mixture does not meet the criteria for classification.  
**Precautionary statement**  
**Prevention** Observe good industrial hygiene practices.  
**Response** Wash hands after handling.  
**Storage** Store away from incompatible materials.  
**Disposal** Dispose of waste and residues in accordance with local authority requirements.

**Hazard(s) not otherwise classified (HNOC)** None known.

**Supplemental information** Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an allergic reaction may occur.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Water, purified		7732-18-5	>90
Aluminum hydroxide gel		21645-51-2	<10

Material name: Somubac®

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Chemical name	Common name and synonyms	CAS number	%
Formaldehyde		50-00-0	<0.1
Haemophilus somnus		NOT ASSIGNED	*
Merthiolate (as mercury)		54-64-8	##

#### Composition comments

## Trace

\* Non-hazardous Ingredients

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

## 4. First-aid measures

#### Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

#### Skin contact

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.

#### Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.

#### Ingestion

Rinse mouth. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

#### Most important symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.

#### Indication of immediate medical attention and special treatment needed

Treat symptomatically.

#### General information

For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

#### Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

#### 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.

#### General fire hazards

No unusual fire or explosion hazards noted.

## 6. Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

#### Methods and materials for containment and cleaning up

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

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

#### Environmental precautions

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

## 7. Handling and storage

### Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapor. Avoid accidental injection. Wash thoroughly after handling. When using, do not eat, drink or smoke. Wear personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

### Conditions for safe storage, including any incompatibilities

Store out of direct sunlight in dark, dry conditions. @ 2 - 7°C (36 - 45°F). Do not freeze. Store in original tightly closed container. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

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

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

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	2 ppm
	TWA	0.75 ppm

#### US. OSHA Table Z-2 (29 CFR 1910.1000)

Components	Type	Value
Merthiolate (as mercury) (CAS 54-64-8)	Ceiling	0.04 mg/m <sup>3</sup>
	TWA	0.01 mg/m <sup>3</sup>

#### US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Aluminum hydroxide gel (CAS 21645-51-2)	TWA	5 mg/m <sup>3</sup>	Respirable fraction.
		15 mg/m <sup>3</sup>	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

#### US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Aluminum hydroxide gel (CAS 21645-51-2)	TWA	1 mg/m <sup>3</sup>	Respirable fraction.
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m <sup>3</sup>	
	TWA	0.01 mg/m <sup>3</sup>	

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm
	TWA	0.016 ppm
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m <sup>3</sup>
	TWA	0.01 mg/m <sup>3</sup>

### Biological limit values

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

### Exposure guidelines

#### US - California OELs: Skin designation

Merthiolate (as mercury) (CAS 54-64-8) Can be absorbed through the skin.

#### US - Tennessee OELs: Skin designation

Merthiolate (as mercury) (CAS 54-64-8) Can be absorbed through the skin.

#### US ACGIH Threshold Limit Values: Skin designation

Merthiolate (as mercury) (CAS 54-64-8) Can be absorbed through the skin.

#### US NIOSH Pocket Guide to Chemical Hazards: Skin designation

Merthiolate (as mercury) (CAS 54-64-8) Can be absorbed through the skin.

### Control banding approach

Not available.

<b>Appropriate engineering controls</b>	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear protective gloves. Wear impervious gloves if skin contact is possible.
<b>Other</b>	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.
<b>Thermal hazards</b>	Not applicable.
<b>General hygiene considerations</b>	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.

## 9. Physical and chemical properties

<b>Appearance</b>	Liquid Solution in multiple-dose vials
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	6 - 8
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	> 212 °F (> 100 °C)
<b>Flash point</b>	Non-flammable
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	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. Sunlight. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.  
**Incompatible materials** Strong oxidizing agents. This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.  
**Hazardous decomposition products** No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

**Inhalation** No adverse effects due to inhalation are expected.  
**Skin contact** Prolonged skin contact may cause temporary irritation.  
 Formaldehyde Species: Rabbit  
 Severity: Moderate to Severe

**Eye contact** Direct contact with eyes may cause temporary irritation.  
 Merthiolate (as mercury) Species: Rabbit  
 Severity: Mild

Formaldehyde Species: Rabbit  
 Severity: Severe

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

**Symptoms related to the physical, chemical and toxicological characteristics** Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.

### Information on toxicological effects

#### Acute toxicity

Components	Species	Test Results
Aluminum hydroxide gel (CAS 21645-51-2)		
<b>Acute</b>		
<b>Other</b>		
LD50	Rat	150 mg/kg
Formaldehyde (CAS 50-00-0)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rabbit	270 mg/kg
<b>Inhalation</b>		
LC50	Mouse	0.414 mg/L, 4 hours
	Rat	0.48 mg/L, 4 hours
<b>Oral</b>		
LD50	Rat	100 mg/kg
<b>Chronic</b>		
<b>Inhalation</b>		
LOAEL	Mouse	15 ppm, 2 years Tumors
	Rat	15 ppm, 90 days Respiratory system



Components	Species	Test Results
Merthiolate (as mercury) (CAS 54-64-8)		6 ppm, 2 years Tumors
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	75 mg/kg
<b>Subcutaneous</b>		
LD50	Rat	98 mg/kg
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation.	
<b>Eye Contact</b>		
Merthiolate (as mercury)	Species: Rabbit	Severity: Mild
Formaldehyde	Species: Rabbit	Severity: Severe
<b>Respiratory or skin sensitization</b>		
<b>ACGIH sensitization</b>		
FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization	Respiratory sensitization
<b>Respiratory sensitization</b>	Not a respiratory sensitizer.	
<b>Skin sensitization</b>	This product contains formaldehyde and merthiolate which are considered to be skin sensitizers. This product is not expected to cause skin sensitization.	
<b>Skin sensitization</b>		
Formaldehyde	Species: Guinea Pig	Severity: Positive
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Mutagenicity</b>		
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
<b>Carcinogenicity</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. No known carcinogens are present at greater than 0.1%.	
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Formaldehyde (CAS 50-00-0)	1 Carcinogenic to humans.	
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>		
Formaldehyde (CAS 50-00-0)	Cancer	
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>		
Formaldehyde (CAS 50-00-0)	Known To Be Human Carcinogen.	
<b>Reproductive toxicity</b>	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

<b>Specific target organ toxicity - single exposure</b>	Not classified.
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.
<b>Aspiration hazard</b>	Not an aspiration hazard.
<b>Chronic effects</b>	Prolonged inhalation may be harmful.
<b>Further information</b>	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
<b>Aquatic</b>			
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

<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	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

<b>Disposal instructions</b>	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. 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. This product contains trace quantities of mercury and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP). Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company. This product contains trace quantities of mercury, releases to the environment should be avoided.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

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

## 15. Regulatory information

**US federal regulations** This product is not known to be 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 - No  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

### SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
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Formaldehyde	50-00-0	100	500		
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**SARA 311/312 Hazardous chemical** No

### SARA 313 (TRI reporting)

Not regulated.

### Other federal regulations

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

Formaldehyde (CAS 50-00-0)  
Merthiolate (as mercury) (CAS 54-64-8)

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

Formaldehyde (CAS 50-00-0)

**Safe Drinking Water Act (SDWA)** Not regulated.

### US state regulations

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

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

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

**US - California Proposition 65 - CRT: Listed date/Developmental toxin**

Merthiolate (as mercury) (CAS 54-64-8)

Listed: July 1, 1990

**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

\*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** 05-05-2017**Version #** 01

**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.