This SDS packet was issued with item:

078912879

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

078403627 078404098 078695517

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).

078912835



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IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health Pfizer Inc 235 East 42nd Street New York, NY 10017

Poison Control Center Phone: 1-866-531-8896 Technical Services Phone: 1-800-366-5288

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300 Contact E-Mail: pfizer-MSDS@pfizer.com Pfizer Ltd Ramsgate Road Sandwich, Kent CT13 9NJ United Kingdom +00 44 (0)1304 616161

Emergency telephone number:

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

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Virus, Clostridium Perfringens Type C-Escherichia Coli Bacterin-Toxoid

Trade Name: ScourGuard 4KC
Chemical Family: Mixture

Intended Use: Veterinary Vaccine

2. HAZARDS IDENTIFICATION

Appearance: Liquid solution in multiple-dose vials

Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Contains formaldehyde: potential cancer hazard

Additional Hazard Information:

Short Term: May cause eye, skin and respiratory tract irritation In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the

nearest emergency room and the appropriate therapy instituted. Saponins have little toxicity

for humans when ingested but have hemolytic effects when injected intravenously.

EU Classification

EU Indication of danger: Irritant

EU Hazard Symbols:



EU Risk Phrases:

Australian Hazard Classification (NOHSC):

R43 - May cause sensitization by skin contact. 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.

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Material Name: Bovine Rota-Coronavirus Vaccine, Killed

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 28-Oct-2011 Version: 2.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Quil-A saponin	66594-14-7	Not Listed	Not Listed	*
Formaldehyde	50-00-0	200-001-8	C;R34 Carc. Cat.3;R40 R43 T;R23/24/25	0.1 - 1.0%
Gentamicin	1403-66-3	215-765-8	Not Listed	##
Merthiolate (as mercury)	54-64-8	200-210-4	N; R50/53 R33 T+; R26/27/28	##

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Bovine coronavirus	NOT ASSIGNED	Not Listed	Not Listed	*
Bovine rotavirus	NOT ASSIGNED	Not Listed	Not Listed	*
Escherichia coli	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium perfringens type C	NOT ASSIGNED	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	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 mentioned in this Section, see Section 16

4. 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.

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

Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

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

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Page 3 of 9

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 28-Oct-2011 Version: 2.0

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-

contained breathing apparatus.

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

6. ACCIDENTAL RELEASE MEASURES

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

Section 8). Minimize exposure.

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

area thoroughly.

Measures for Environmental

Protections:

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

avoid environmental release.

Additional Consideration for Large

Spills:

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

situations immediately. Clean up operations should only be undertaken by trained personnel.

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 as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Formaldehyde

ACGIH Ceiling Threshold Limit: ACGIH - Sensitizer Designation Australia STEL	0.3 Sensitizer 2 2.5
Australia TWA	1 1.2
Austria OEL - MAKs	0.5 0.6
Bulgaria OEL - TWA Czech Republic OEL - TWA Estonia OEL - TWA	1.0 0.5 0.5 0.6
Finland OEL - TWA	0.3 0.37
France OEL - TWA Germany (DFG) - MAK	0.5 0.3 0.37
Greece OEL - TWA	2 2.5
Hungary OEL - TWA Ireland OEL - TWAs	0.6 2 2.5

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Page 4 of 9

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 28-Oct-2011 Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Japan - OELs - Ceilings

0.2

0.24

Latvia OEL - TWA

0.5

Lithuania OEL - TWA

0.5

0.6

0.15

OSHA - Final PELS - TWAs: 0.75
OSHA - Specifically Regulated Chemicals 2
0.5

0.5 0.75 Poland OEL - TWA 0.5 Romania OEL - TWA 1

1.20
Slovakia OEL - TWA
0.3
0.37
Slovenia OEL - TWA
0.5
0.62
Sweden OEL - TWAs
0.5

0.6

Gentamicin

Bulgaria OEL - TWA 0.1

Merthiolate (as mercury)

Netherlands OEL - TWA

Bulgaria - Biological Exposure Limit:ListedGermany - Biological Exposure Limit:ListedRomania - Biological Exposure Limit:ListedSlovak Republic - Biological Exposure Limit:Listed

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

monitoring may be necessary to determine requirements.

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

legislation.

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

protective equipment (PPE).

Hands: Wear impervious gloves if skin contact is possible.

Eves: Safety glasses or goggles

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

after handling this material.

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

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

below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

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

Molecular Formula: Mixture Molecular Weight: Mixture

Solubility: Soluble: Water (based on components)

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

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Page 5 of 9

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 28-Oct-2011 Version: 2.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Vapor Pressure (kPa): Expected to be negligible

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

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

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

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

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

metals.

11. TOXICOLOGICAL INFORMATION

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

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

content. The information included in this section describes the potential hazards of the

individual ingredients.

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

Formaldehyde

Rat Oral LD50 800 mg/kg

Quil-A saponin

IV Rat LD50 670 ug/kg

Gentamicin

Rat Oral LD50 6600 mg/kg

Subcutaneous LD50 710 mg/kg Rat

Mouse IM LD50 167 mg/kg

Rat IM LD50 463 mg/kg

Merthiolate (as mercury)

LD50 75 mg/kg Rat Oral

Rat Subcutaneous LD50 98 mg/kg

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

Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

Gentamicin

Eve Irritation Rabbit Non-irritating

Merthiolate (as mercury)

Eye Irritation Rabbit Mild

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Page 6 of 9

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 28-Oct-2011 Version: 2.0

11. TOXICOLOGICAL INFORMATION

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

Formaldehyde

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

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

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

Formaldehyde

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

Gentamicin

Embryo / Fetal Development Rat Intramuscular 75 mg/kg/day LOAEL Developmental 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

<u>Carcinogen Status:</u> Contains formaldehyde: potential cancer hazard. See below

Formaldehyde

IARC: Group 1 (Carcinogenic to Humans)

NTP: Reasonably Anticipated To Be A Human 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.

Material Name: Bovine Rota-Coronavirus Vaccine, Killed
Page 7 of 9

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 28-Oct-2011 Version: 2.0

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. This product contains trace quantities of m-cresol 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 U122

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

EU Symbol: Xi EU Indication of danger: Irritant

EU Risk Phrases:

R43 - May cause sensitization by skin contact.

EU Safety Phrases:

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

OSHA Label:

WARNING

May cause allergic skin reaction.

Contains formaldehyde: potential cancer hazard

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Material Name: Bovine Rota-Coronavirus Vaccine, Killed Page 8 of 9

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 28-Oct-2011 Version: 2.0

100

15. REGULATORY INFORMATION

Quil-A saponin

Australia (AICS): Present

Formaldehyde

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

TPQs

CERCLA/SARA - Section 302 Extremely Hazardous

Substances EPCRA RQs

California Proposition 65 carcinogen

OSHA - Specifically Regulated Chemicals 2
0.5
0.75

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

Australia (AICS):

Standard for the Uniform Scheduling
for Drugs and Poisons:

EU EINECS/ELINCS List

Present
Schedule 2
Schedule 6
200-001-8

Gentamicin

California Proposition 65 Aminoglycosides- developmental

Australia (AICS):PresentStandard for the Uniform SchedulingSchedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List 215-765-8

Water, purified

PZ00379

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

Australia (AICS):

REACH - Annex IV - Exemptions from the

Present

Present

obligations of Register:

EU EINECS/ELINCS List 231-791-2

Merthiolate (as mercury)

California Proposition 65 Developmental

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

Australia (AICS):

EU EINECS/ELINCS List

Present
200-210-4

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Page 9 of 9

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 28-Oct-2011 Version: 2.0

R34 - Causes burns.

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

R33 - Danger of cumulative effects.

R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed. R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.

Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 13

- Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communications

Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet



Revision date: 14-Jan-2014 Version: 3.0 Page 1 of 10

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

Product Identifier

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Virus, Clostridium Perfringens Type C-

Escherichia Coli Bacterin-Toxoid

Trade Name: ScourGuard 4KC

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 Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Signal Word: Not Classified

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

Short Term: May cause eye, skin and respiratory tract irritation In the event of accidental injection, an

allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. Saponins have little toxicity

for humans when ingested but have hemolytic effects when injected intravenously.

Australian Hazard Classification

(NOHSC):

Non-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.

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Material Name: Bovine Rota-Coronavirus Vaccine, Killed Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 14-Jan-2014 Version: 3.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Quil-A saponin	66594-14-7	Not Listed	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. 2 (H351) Acute Tox. 3 (H331)	<0.1
Merthiolate (as mercury)	54-64-8	200-210-4	T+; R26/27/28 R33 N; R50/53	Acute Tox. 2 (H330) Acute Tox. 2 (H310) Acute Tox. 1 (H300) STOT RE 2 (H373) Aq. Acute 1 (H400) Aq. Chronic 1 (H410)	##
Gentamicin	1403-66-3	215-765-8	Not Listed	Not Listed	##

Ingredient	CAS Number	EU	EU Classification	GHS	%
		EINECS/ELINCS		Classification	
		List			
Bovine coronavirus	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Bovine rotavirus	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Clostridium perfringens type C	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*

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.

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Page 3 of 10

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 14-Jan-2014 Version: 3.0

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

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. Dike and collect water used to fight fire.

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

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

Keep away from heat, sparks, and flame. 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 as directed by product packaging.

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

metals.

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Page 4 of 10

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 14-Jan-2014 Version: 3.0

No data available Specific end use(s):

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Formaldehyde

ACGIH Ceiling Threshold Limit: 0.3 ppm **ACGIH - Sensitizer Designation** Sensitizer **Australia STEL** 2 ppm 2.5 mg/m³ **Australia TWA** 1 ppm 1.2 mg/m³ 0.5 ppm **Austria OEL - MAKs** 0.6 mg/m^{3} **Bulgaria OEL - TWA** 1.0 mg/m³ Czech Republic OEL - TWA 0.5 mg/m³ **Estonia OEL - TWA** 0.5 ppm 0.6 mg/m^{3} **Finland OEL - TWA** 0.3 ppm 0.37 mg/m³ France OEL - TWA 0.5 ppm Germany (DFG) - MAK 0.3 ppm 0.37 mg/m³ no irritation should occur during mixed exposure **Greece OEL - TWA** 2 ppm 2.5 mg/m³ **Hungary OEL - TWA** 0.6 mg/m^{3} **Ireland OEL - TWAs** 2 ppm 2.5 mg/m³ Japan - OELs - Ceilings 0.2 ppm

0.24 mg/m³ 0.5 mg/m^{3} Latvia OEL - TWA Lithuania OEL - TWA 0.5 ppm 0.6 mg/m^3 **Netherlands OEL - TWA** 0.15 mg/m³ **Vietnam OEL - TWAs** 0.5 mg/m³ **OSHA - Final PELS - TWAs:** 0.75 ppm

OSHA - Specifically Regulated Chemicals 2 ppm 0.5 ppm

> 0.75 ppm 0.5 mg/m³ 1 ppm

Poland OEL - TWA Romania OEL - TWA 1.20 mg/m³ Slovakia OEL - TWA 0.3 ppm

0.37 mg/m³ Slovenia OEL - TWA 0.5 ppm 0.62 mg/m³

Sweden OEL - TWAs 0.3 ppm 0.37 mg/m³

Switzerland OEL -TWAs 0.3 ppm 0.37 mg/m³

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Page 5 of 10

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 14-Jan-2014 Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Gentamicin

Bulgaria OEL - TWA 0.1 mg/m³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Gentamicin

Zoetis OEB OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Exposure Controls

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

monitoring may be necessary to determine requirements.

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

Equipment: protective equipment (PPE).

Hands: Wear impervious gloves if skin contact is possible.

Eyes: Safety glasses or goggles

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

laboratory areas.

Respiratory protection: 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 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):

No data available
Plammability (Solids):

No data available

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Page 6 of 10

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 14-Jan-2014 Version: 3.0

Flash Point (Liquid) (°C):

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

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

Polymerization:

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 primary hazards are due to the formaldehyde content. The information included in this section describes the potential hazards of the individual ingredients.

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

Quil-A saponin

Rat IV LD50 670 ug/kg

Gentamicin

Rat Oral LD50 6600 mg/kg

Rat Subcutaneous LD50 710mg/kg

Mouse IM LD50 167 mg/kg Rat IM LD50 463 mg/kg

Merthiolate (as mercury)

Rat Oral LD50 75 mg/kg

Rat Subcutaneous LD50 98mg/kg

Formaldehyde

Rat Oral LD50 800 mg/kg

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

Gentamicin

PZ00379

Eye Irritation Rabbit Non-irritating

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Material Name: Bovine Rota-Coronavirus Vaccine, Killed

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 14-Jan-2014 Version: 3.0

11. TOXICOLOGICAL INFORMATION

Merthiolate (as mercury)

Eye Irritation Rabbit Mild

Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

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

Formaldehyde

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

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

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

Gentamicin

Embryo / Fetal Development Rat Intramuscular 75 mg/kg/day LOAEL Developmental toxicity

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: No known carcinogens are present at greater than 0.1%

Formaldehyde

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

OSHA: Listed

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 14-Jan-2014 Version: 3.0

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. This product contains trace quantities of m-cresol and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP).

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Formaldehyde

RCRA - U Series Wastes Listed

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications
WHMIS hazard class:
None required

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Material Name: Bovine Rota-Coronavirus Vaccine, Killed

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 14-Jan-2014 Version: 3.0

15. REGULATORY INFORMATION

Bovine coronavirus

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

Bovine rotavirus

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

Clostridium perfringens type C

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

Quil-A saponin

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

Formaldehyde

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

CERCLA/SARA - Section 302 Extremely Hazardous 100 lb

Substances EPCRA RQs

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

OSHA - Specifically Regulated Chemicals 2 ppm

0.5 ppm 0.75 ppm

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

Merthiolate (as mercury)

CERCLA/SARA 313 Emission reporting Not Listed **California Proposition 65** Not Listed Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present **EU EINECS/ELINCS List** 200-210-4

Gentamicin

Not Listed **CERCLA/SARA 313 Emission reporting**

Material Name: Bovine Rota-Coronavirus Vaccine, Killed Page 10 of 10

Virus, Clostridium Perfringens Type C-Escherichia Coli

Bacterin-Toxoid

Revision date: 14-Jan-2014 Version: 3.0

15. REGULATORY INFORMATION

California Proposition 65

Australia (AICS):

Standard for the Uniform Scheduling
for Drugs and Poisons:

Not Listed
Present
Schedule 4

EU EINECS/ELINCS List 215-765-8

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

H351 - Suspected of causing cancer

H331 - Toxic if inhaled

H330 - Fatal if inhaled

H310 - Fatal in contact with skin

H300 - Fatal if swallowed

H373 - May cause damage to organs through prolonged or repeated exposure

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

R34 - Causes burns.

PZ00379

R40 - Limited evidence of a carcinogenic effect

R43 - May cause sensitization by skin contact.

R33 - Danger of cumulative effects.

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

R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources,

raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 -

Regulatory Information.

Prepared by: Toxicology and Hazard Communication

Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet



1. Identification

Product identifier ScourGuard® 4KC

Other means of identification

Synonyms ScourGuard 4KC * Bovine Rota-Coronavirus Vaccine, Killed Virus, Clostridium Perfringens Type

C-Escherichia Coli Bacterin-Toxoid

Veterinary vaccine Recommended use **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

Company Name (EU) Zoetis Belgium S.A.

> Mercuriusstraat 20 1930 Zaventem

Belgium

Emergency telephone

number

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

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

Contact E-Mail VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards Not classified. Not classified. **Health hazards** Not classified. **Environmental hazards OSHA** defined hazards Not classified.

Label elements

None. Hazard symbol Signal word None.

The mixture does not meet the criteria for classification. **Hazard statement**

Precautionary statement

Prevention Observe good industrial hygiene practices.

Wash hands after handling. Response

Store away from incompatible materials. Storage

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	%
Quil-A saponin		66594-14-7	<5

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Chemical name	Common name and synonyms	CAS number	%
Formaldehyde		50-00-0	<0.1
Bovine coronavirus		NOT ASSIGNED	*
Bovine rotavirus		NOT ASSIGNED	*
Clostridium perfringens type C		NOT ASSIGNED	*
Escherichia coli		NOT ASSIGNED	*
Gentamicin		1403-66-3	##
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. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

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 Unsuitable extinguishing media

General information

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). 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 General fire hazards Use standard firefighting procedures and consider the hazards of other involved materials.

No unusual fire or explosion hazards noted.

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.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

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

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7. Handling and storage

Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapor. Avoid accidental Precautions for safe handling

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

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

Components	Туре	Value	
Formaldehyde (CAS 50-00-0)	STEL	2 ppm	
,	TWA	0.75 ppm	
US. OSHA Table Z-2 (29 CFR 191	0.1000)		
Components	Туре	Value	
Merthiolate (as mercury) (CAS 54-64-8)	Ceiling	0.04 mg/m3	
,	TWA	0.01 mg/m3	
US. ACGIH Threshold Limit Value	es		
Components	Туре	Value	
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m3	
,	TWA	0.01 mg/m3	
US. NIOSH: Pocket Guide to Che	mical Hazards		
Components	Туре	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/m3	
	TWA	0.01 mg/m3	

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.

Gentamicin: Zoetis OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3) Control banding approach

this section. General ventilation normally adequate. controls

Individual protection measures, such as personal protective equipment If contact is likely, safety glasses with side shields are recommended.

Skin protection

Eye/face protection

Appropriate engineering

Hand protection Wear impervious gloves if skin contact is possible.

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

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

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Keep air contamination levels below the exposure limits or within the OEB range listed above in

wear suitable respiratory equipment. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. 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.

Thermal hazards Not applicable.

General hygiene considerations

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

Appearance Liquid Solution in multiple-dose vials

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.

Por pressure Not available.

Vapor pressureNot available.Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not 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. Sunlight. Store at 2-7°C. Prolonged exposure to higher

temperatures may adversely affect potency. Do not freeze.

Material name: ScourGuard® 4KC 479 Version #: 01 Issue date: 05-05-2017 SDS US

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

InhalationNo adverse effects due to inhalation are expected.Skin contactProlonged skin contact may cause temporary irritation.

Formaldehyde Species: Rabbit

Severity: Moderate Severe

Eye contact Direct contact with eyes may cause temporary irritation.

Merthiolate (as mercury) Species: Rabbit

Severity: Mild

Gentamicin Species: Rabbit

Severity: Non-irritating

Formaldehyde Species: Rabbit Severity: Severe

0010111,1001

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
Formaldehyde (CAS 50-00-0)		
<u>Acute</u>		
Inhalation		
LC50	Rat	0.48 mg/l, 4 Hours
Oral		
LD50	Rat	800 mg/kg
		100 mg/kg
Chronic		
Inhalation		
LOAEL	Mouse	15 ppm, 2 years Tumors
	Rat	15 ppm, 9 days Respiratory system
		6 ppm, 2 years Tumors
Gentamicin (CAS 1403-66-3)		
<u>Acute</u>		
Intramuscular		
LD50	Mouse	167 mg/kg
	Rat	463 mg/kg
Oral		
LD50	Rat	6600 mg/kg
Subcutaneous		
LD50	Rat	710 mg/kg

Material name: ScourGuard® 4KC

SDS US

Components Species Test Results

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

Acute Oral

LD50 Rat 75 mg/kg

Subcutaneous

LD50 Rat 98 mg/kg

Quil-A saponin (CAS 66594-14-7)

<u>Acute</u>

Intravenous

LD50 Rat 670 ug/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation. **Serious eye damage/eye** Direct contact with eyes may cause temporary irritation.

irritation

Eye Contact

Merthiolate (as mercury) Species: Rabbit

Severity: Mild

Gentamicin Species: Rabbit

Severity: Non-irritating

Formaldehyde Species: Rabbit

Severity: Severe

Respiratory or skin sensitization

ACGIH sensitization

FORMALDEHYDE (CAS 50-00-0)

Dermal sensitization

Respiratory sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product contains formaldehyde and merthiolate which are considered to be skin sensitizers.

This product is not expected to cause skin sensitization.

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

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 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%.

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)

Cancer

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

Gentamicin 75 mg/kg/day Embryo / Fetal Development, Developmental

> toxicity Result: LOAEL Species: Rat

Organ: Intramuscular

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

Not an aspiration hazard. **Aspiration hazard**

Prolonged inhalation may be harmful. **Chronic effects**

The antigens included in this product are non-infectious. All have been prepared from killed or **Further information**

inactivated preparations of microorganisms. Saponins have little toxicity for humans when

ingested but have hemolytic effects when injected intravenously.

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 5	50-00-0)		
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. No data available. Mobility in soil

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

Disposal instructions 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.

Local disposal regulations

Hazardous waste code

Dispose in accordance with all applicable regulations.

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.

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).

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

emptied.

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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 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 **Threshold Threshold** Threshold quantity planning 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)

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 N

479 Version #: 01 Issue date: 05-05-2017

Not regulated.

(SDWA)

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

Material name: ScourGuard® 4KC sps us

8/9

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.

SDS US 9 / 9



1. Identification

Product identifier ScourGuard® 4KC

Other means of identification

Synonyms ScourGuard 4KC * Bovine Rota-Coronavirus Vaccine, Killed Virus, Clostridium Perfringens Type

C-Escherichia Coli 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. Not classified. **Health hazards** Not classified. **Environmental hazards OSHA** defined hazards Not classified.

Label elements

None. Hazard symbol Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Wash hands after handling. Response

Store away from incompatible materials. Storage

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	%
Quil-A saponin		66594-14-7	<5

Material name: ScourGuard® 4KC 479 Version #: 01 Issue date: 05-05-2017

Chemical name	Common name and synonyms	CAS number	%
Formaldehyde		50-00-0	<0.1
Bovine coronavirus		NOT ASSIGNED	*
Bovine rotavirus		NOT ASSIGNED	*
Clostridium perfringens type C		NOT ASSIGNED	*
Escherichia coli		NOT ASSIGNED	*
Gentamicin		1403-66-3	##
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. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

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 Unsuitable extinguishing media

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

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

Specific methods General fire hazards

equipment/instructions

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

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.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

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

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

Components	Туре	Value	
Formaldehyde (CAS 50-00-0)	STEL	2 ppm	
,	TWA	0.75 ppm	
US. OSHA Table Z-2 (29 CFR 1916	0.1000)		
Components	Туре	Value	
Merthiolate (as mercury) (CAS 54-64-8)	Ceiling	0.04 mg/m3	
(TWA	0.01 mg/m3	
US. ACGIH Threshold Limit Value	es		
Components	Туре	Value	
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m3	
(TWA	0.01 mg/m3	
US. NIOSH: Pocket Guide to Che	mical Hazards		
Components	Туре	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/m3	
	TWA	0.01 mg/m3	

Biological limit valuesNo 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 Gentamicin: Zoetis OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3)

controls this section. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Appropriate engineering

Hand protection Wear impervious gloves if skin contact is possible.

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

Keep air contamination levels below the exposure limits or within the OEB range listed above in

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

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

wear suitable respiratory equipment. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. 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.

Thermal hazards Not applicable.

General hygiene considerations

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

Appearance Liquid Solution in multiple-dose vials

Liquid. Physical state **Form** Liquid.

Not available. Color Odor Not available. **Odor threshold** Not available.

6 - 8 pН

Not available. Melting point/freezing point > 212 °F (> 100 °C) Initial boiling point and boiling

range

Non-flammable Flash point Not available. **Evaporation rate** 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. Vapor pressure Not available. Not available. Vapor density Relative density Not available.

Solubility(ies)

Solubility (water) Not available. **Partition coefficient** Not available.

(n-octanol/water)

Auto-ignition temperature Not available. Not available. **Decomposition temperature** Viscosity Not available.

Other information

Explosive properties Not explosive. Oxidizing properties Not oxidizing. 0.8 - 1.2Specific gravity

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

InhalationNo adverse effects due to inhalation are expected.Skin contactProlonged skin contact may cause temporary irritation.

Formaldehyde Species: Rabbit

Severity: Moderate Severe

Eye contact Direct contact with eyes may cause temporary irritation.

Merthiolate (as mercury) Species: Rabbit

Severity: Mild

Gentamicin Species: Rabbit

Severity: Non-irritating

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
Formaldehyde (CAS 50-00-0)		
<u>Acute</u>		
Inhalation		
LC50	Rat	0.48 mg/l, 4 Hours
Oral		
LD50	Rat	800 mg/kg
		100 mg/kg
Chronic		
Inhalation		
LOAEL	Mouse	15 ppm, 2 years Tumors
	Rat	15 ppm, 9 days Respiratory system
		6 ppm, 2 years Tumors
Gentamicin (CAS 1403-66-3)		
<u>Acute</u>		
Intramuscular		
LD50	Mouse	167 mg/kg
	Rat	463 mg/kg
Oral		
LD50	Rat	6600 mg/kg
Subcutaneous		
LD50	Rat	710 mg/kg

Material name: ScourGuard® 4KC

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Components Species Test Results

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

Acute Oral

LD50 Rat 75 mg/kg

Subcutaneous

LD50 Rat 98 mg/kg

Quil-A saponin (CAS 66594-14-7)

<u>Acute</u>

Intravenous

LD50 Rat 670 ug/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation. **Serious eye damage/eye** Direct contact with eyes may cause temporary irritation.

irritation

Eye Contact

Merthiolate (as mercury)

Species: Rabbit

Severity: Mild

Gentamicin Species: Rabbit

Severity: Non-irritating

Formaldehyde Species: Rabbit

Severity: Severe

Respiratory or skin sensitization

ACGIH sensitization

FORMALDEHYDE (CAS 50-00-0)

Dermal sensitization
Respiratory sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product contains formaldehyde and merthiolate which are considered to be skin sensitizers.

This product is not expected to cause skin sensitization.

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

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 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%.

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)

Cancer

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

Gentamicin 75 mg/kg/day Embryo / Fetal Development, Developmental

toxicity Result: LOAEL Species: Rat Organ: Intramuscular

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

Further information The antigens included in this product are non-infectious. All have been prepared from killed or

inactivated preparations of microorganisms. Saponins have little toxicity for humans when

ingested but have hemolytic effects when injected intravenously.

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)

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.

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

Disposal instructionsAvoid 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.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

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.

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.

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 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)

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 **Threshold** Threshold **Threshold** quantity planning quantity planning quantity, planning quantity, (pounds) (pounds) lower value upper value (pounds) (pounds)

500 Formaldehyde 50-00-0 100 No

SARA 311/312 Hazardous

chemical

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

Not regulated.

(SDWA)

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

Material name: ScourGuard® 4KC 479 Version #: 01 Issue date: 05-05-2017

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

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