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

Material Name: Bovine Rota-Coronavirus, Killed Virus-Escherichia Coli Bacterin
Trade Name: ScourGuard 3®(K)
Chemical Family: Mixture
Intended Use: Veterinary Vaccine

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quil-A saponin</td>
<td>66594-14-7</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>215-765-8</td>
<td>##</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>200-001-8</td>
<td>0.1 - 1.0%</td>
</tr>
<tr>
<td>Merthiolate (as mercury)</td>
<td>54-64-8</td>
<td>200-210-4</td>
<td>##</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bovine coronavirus</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Bovine rotavirus</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>&gt;90%</td>
</tr>
</tbody>
</table>

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

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, skin and respiratory tract 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. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

EU Indication of danger: Irritant

EU Hazard Symbols: 

EU Risk Phrases: R43 - May cause sensitization by skin contact.

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

### 4. FIRST AID MEASURES

**Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash skin with soap and water. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** As for primary cause of fire.

**Hazardous Combustion Products:** Not known

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

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

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment.

Storage Conditions: Store under refrigeration in closed container.

Storage Temperature: 2-7°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Formaldehyde

OSHA - Final PELS - TWAs: 0.75 ppm TWA
OSHA - Specifically Regulated Chemicals

ACGIH Ceiling Threshold Limit: 0.3 ppm Ceiling
ACGIH - Sensitizer Designation Sensitizer
Australia STEL 2 ppm STEL
Australia TWA 1 ppm TWA

Australia STEL 2.5 mg/m³ STEL
Australia TWA 1.2 mg/m³ TWA

Merthiolate (as mercury)

OSHA - Final PELS - TWAs: 0.01 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) 0.01 mg/m³ TWA
ACGIH Threshold Limit Value (STEL) 0.03 mg/m³ STEL
ACGIH - Skin Absorption Designation Skin - potential significant contribution to overall exposure by the cutaneous route
Australia STEL 0.03 mg/m³ STEL
Australia TWA 0.01 mg/m³ 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:

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Safety glasses or goggles
Skin: Wear protective clothing when working with large quantities. Wash hands and arms thoroughly after handling this material.
Respiratory protection: In the event of a spill where the applicable Occupational Exposure Limit (OEL) may be exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Liquid solution in multiple-dose vials
Molecular Formula: Mixture
Color: No data available.
Molecular Weight: Mixture
Material Name: Bovine Rota-Coronavirus, Killed Virus-Escherichia Coli Bacterin
Revision date: 04-Dec-2006

Solubility: Soluble: Water (based on components)

pH: 7.0 +/- 1.5

Boiling Point (°C): >100

Vapor Pressure (kPa): Expected to be negligible

Specific Gravity: 1.0 +/-0.2

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

10. STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.

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

Hazardous Decomposition Products: None expected under normal conditions.

Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The primary hazards are due to the formaldehyde content. The information included in this section describes the potential hazards of the individual ingredients.

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

Formaldehyde
- Rat Oral LD50 800 mg/kg

Quil-A saponin
- Rat IV LD50 670 ug/kg

Merthiolate (as mercury)
- Rat Oral LD50 75 mg/kg
- Rat Subcutaneous LD50 98 mg/kg

Gentamicin
- Rat Oral LD50 6600 mg/kg
- Rat Subcutaneous LD50 710 mg/kg
- Mouse IM LD50 167 mg/kg
- Rat IM LD50 463 mg/kg

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

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

Formaldehyde
- Eye Irritation Rabbit Severe
- Skin Irritation Rabbit Moderate Severe

Merthiolate (as mercury)
- Eye Irritation Rabbit Mild
Material Name: Bovine Rota-Coronavirus, Killed Virus-
Escherichia Coli Bacterin
Revision date: 04-Dec-2006

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.

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**

**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. See below

**Formaldehyde**
- **IARC:** Group 1
- **NTP:** Reasonably Anticipated To Be A Carcinogen
- **OSHA:** Present
12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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.

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
MATERIAL SAFETY DATA SHEET

Material Name: Bovine Rota-Coronavirus, Killed Virus-
Escherichia Coli Bacterin
Revision date: 04-Dec-2006

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
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End of Safety Data Sheet