



MATERIAL SAFETY DATA SHEET

Revision date: 04-Dec-2006

Version: 1.5

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

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

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

Hazardous

| Ingredient | CAS Number | EU EINECS List | % |
|--------------------------|------------|----------------|------------|
| Quil-A saponin | 66594-14-7 | Not listed | * |
| Gentamicin | 1403-66-3 | 215-765-8 | ## |
| 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 | % |
|--------------------|--------------|----------------|------|
| Bovine coronavirus | NOT ASSIGNED | Not listed | * |
| Bovine rotavirus | NOT ASSIGNED | Not listed | * |
| Escherichia coli | NOT ASSIGNED | Not listed | * |
| Water, purified | 7732-18-5 | 231-791-2 | >90% |

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:

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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.

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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 | = 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 ³ STEL |
| Australia TWA | = 1 ppm TWA |
| | = 1.2 mg/m ³ TWA |

Merthiolate (as mercury)

| | |
|-------------------------------------|--|
| OSHA - Final PELs - TWAs: | = 0.01 mg/m ³ TWA |
| ACGIH Threshold Limit Value (TWA) | = 0.01 mg/m ³ TWA |
| ACGIH Threshold Limit Value (STEL) | = 0.03 mg/m ³ STEL |
| ACGIH - Skin Absorption Designation | Skin - potential significant contribution to overall exposure by the cutaneous route |
| Australia STEL | = 0.03 mg/m ³ STEL |
| Australia TWA | = 0.01 mg/m ³ 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 | Color: | No data available. |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |

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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

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Gentamicin

Eye Irritation Rabbit Non-irritating

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

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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

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Quil-A saponin

Australia (AICS): Present

Gentamicin

California Proposition 65
Australia (AICS): Aminoglycosides- developmental
Standard for the Uniform Scheduling
for Drugs and Poisons: Present
EU EINECS List Schedule 4
215-765-8

Formaldehyde

CERCLA/SARA 313 Emission reporting = 0.1 % de minimis concentration
CERCLA/SARA Hazardous Substances = 100 lb final RQ
and their Reportable Quantities: = 45.4 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous = 500 lb TPQ
TPQs
CERCLA/SARA - Section 302 Extremely Hazardous = 100 lb EPCRA RQ
Substances EPCRA RQs
California Proposition 65 carcinogen, initial date 1/1/88 (gas)
OSHA - Specifically Regulated Chemicals = 0.5 ppm Action Level
= 0.75 ppm TWA
= 2 ppm STEL Irritant and potential cancer hazard - see 29 CFR
1910.1048
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling Schedule 2
for Drugs and Poisons: Schedule 6
EU EINECS List 200-001-8

Merthiolate (as mercury)

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

Water, purified

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

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End of Safety Data Sheet