

SAFETY DATA SHEET



Revision date: 14-Jan-2014

Version: 2.0

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

Product Identifier

Material Name: Bovine Rota-Coronavirus, Killed Virus, Escherichia Coli Bacterin

Trade Name: ScourGuard 4(K)
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. May cause allergic skin reaction. Acute toxicity following ingestion is not expected. 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.

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|--------------------------|------------|-----------------------------|--|---|------|
| Quil-A saponin | 66594-14-7 | Not Listed | Not Listed | Not Listed | <1.0 |
| 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 EINECS/ELINCS List | EU Classification | GHS Classification | % |
|--------------------|--------------|-----------------------------|-------------------|-----------------------|---|
| Bovine coronavirus | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | * |
| Bovine rotavirus | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | * |
| Escherichia coli | 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: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

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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.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus. 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 / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

7. HANDLING AND STORAGE

Precautions for Safe Handling

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

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Storage Conditions: Store under refrigeration in closed container.
Storage Temperature: 2-7°C
Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Formaldehyde

| | |
|---|---|
| ACGIH Ceiling Threshold Limit: | 0.3 ppm |
| ACGIH - Sensitizer Designation | Sensitizer |
| Australia STEL | 2 ppm |
| | 2.5 mg/m ³ |
| Australia TWA | 1 ppm |
| | 1.2 mg/m ³ |
| Austria OEL - MAKs | 0.5 ppm |
| | 0.6 mg/m ³ |
| Bulgaria OEL - TWA | 1.0 mg/m ³ |
| Czech Republic OEL - TWA | 0.5 mg/m ³ |
| Estonia OEL - TWA | 0.5 ppm |
| | 0.6 mg/m ³ |
| Finland OEL - TWA | 0.3 ppm |
| | 0.37 mg/m ³ |
| France OEL - TWA | 0.5 ppm |
| Germany (DFG) - MAK | 0.3 ppm |
| | 0.37 mg/m ³ no irritation should occur during mixed exposure |
| Greece OEL - TWA | 2 ppm |
| | 2.5 mg/m ³ |
| Hungary OEL - TWA | 0.6 mg/m ³ |
| Ireland OEL - TWAs | 2 ppm |
| | 2.5 mg/m ³ |
| Japan - OELs - Ceilings | 0.2 ppm |
| | 0.24 mg/m ³ |
| Latvia OEL - TWA | 0.5 mg/m ³ |
| Lithuania OEL - TWA | 0.5 ppm |
| | 0.6 mg/m ³ |
| Netherlands OEL - TWA | 0.15 mg/m ³ |
| Vietnam OEL - TWAs | 0.5 mg/m ³ |
| OSHA - Final PELs - TWAs: | 0.75 ppm |
| OSHA - Specifically Regulated Chemicals | 2 ppm |
| | 0.5 ppm |
| | 0.75 ppm |
| Poland OEL - TWA | 0.5 mg/m ³ |
| Romania OEL - TWA | 1 ppm |
| | 1.20 mg/m ³ |
| Slovakia OEL - TWA | 0.3 ppm |
| | 0.37 mg/m ³ |
| Slovenia OEL - TWA | 0.5 ppm |
| | 0.62 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|-----------------------|-----------------------------------|
| Sweden OEL - TWAs | 0.3 ppm 0.37 mg/m ³ |
| Switzerland OEL -TWAs | 0.3 ppm 0.37 mg/m ³ |

Gentamicin

| | |
|--------------------|-----------------------|
| Bulgaria OEL - TWA | 0.1 mg/m ³ |
|--------------------|-----------------------|

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/m ³ to < 1000ug/m ³) |
|------------|---|

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

Hands: Wear impervious gloves if skin contact is possible.

Eyes: Safety glasses or goggles

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

Respiratory protection: 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: | in multiple-dose vials Liquid solution | Color: | 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 available |
| Relative Density: | No data available |
| Specific Gravity: | 1.0 +/-0.2 |
| Viscosity: | No data available |

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Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

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

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization:

Will not occur

10. STABILITY AND REACTIVITY

Reactivity:

No data available

Chemical Stability:

Stable

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: None expected under normal conditions.

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)

Merthiolate (as mercury)

Rat Oral LD50 75 mg/kg

Rat Subcutaneous LD50 98mg/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

Formaldehyde

Rat Oral LD50 800 mg/kg

Quil-A saponin

Rat IV LD50 670 ug/kg

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11. TOXICOLOGICAL INFORMATION

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

Merthiolate (as mercury)

Eye Irritation Rabbit Mild

Gentamicin

Eye Irritation Rabbit Non-irritating

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 Tumors

2 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

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11. TOXICOLOGICAL INFORMATION

12. ECOLOGICAL INFORMATION

| | |
|---------------------------------------|--|
| Environmental Overview: | The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided. |
| Toxicity: | No data available |
| Persistence and Degradability: | No data available |
| Bio-accumulative Potential: | No data available |
| Mobility in Soil: | No data available |

13. DISPOSAL CONSIDERATIONS

| | |
|---------------------------------|--|
| Waste Treatment Methods: | Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental 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). |
|---------------------------------|--|

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

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15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

Bovine coronavirus

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

Bovine rotavirus

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

Escherichia coli

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| 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 and their Reportable Quantities: | 100 lb |
| CERCLA/SARA - Section 302 Extremely Hazardous TPQs | 45.4 kg |
| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | 500 lb |
| California Proposition 65 | 100 lb |
| OSHA - Specifically Regulated Chemicals | carcinogen initial date 1/1/88 gas |
| | 2 ppm |
| | 0.5 ppm |
| | 0.75 ppm |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 2 |
| | 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 |

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15. REGULATORY INFORMATION

| | |
|-----------------------|-----------|
| EU EINECS/ELINCS List | 200-210-4 |
|-----------------------|-----------|

Gentamicin

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | 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.
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 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. 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.

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