



# MATERIAL SAFETY DATA SHEET

Revision date: 22-Dec-2009

Version: 4.0

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

Pfizer Animal Health  
Pfizer Inc  
235 East 42nd Street  
New York, NY 10017  
Poison Control Center Phone: 1-866-531-8896  
Technical Services Phone: 1-800-366-5288  
Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300  
Contact E-Mail: pfizer-MSDS@pfizer.com

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

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

### Material Name: Selamectin topical solution- Single dose tubes

Trade Name:	REVOLUTION; STRONGHOLD
Synonyms:	Selamectin formulation
Chemical Family:	Mixture
Intended Use:	Veterinary product used as Antiparasitic (veterinary); endectocide
Restrictions on Use:	Not for human use

## 2. HAZARDS IDENTIFICATION

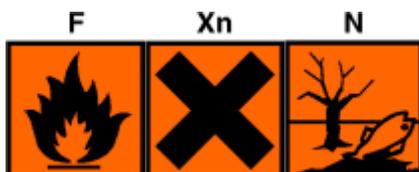
Appearance: Colorless to pale yellow solution  
Signal Word: WARNING

Statement of Hazard: Flammable liquid and vapor.  
Causes eye irritation.  
Suspected of damaging fertility or the unborn child.  
May cause drowsiness or dizziness.  
Very toxic to aquatic life.

Additional Hazard Information:  
Short Term: Not acutely toxic (based on components) .  
Long Term: Prolonged or repeated contact may cause defatting dermatitis (dryness and cracking of the skin). Repeat-dose studies in animals have shown a potential to cause adverse effects on : liver, reproductive system, and the developing fetus.

EU Indication of danger: Flammable  
Irritant  
Toxic to Reproduction: Category 3  
Dangerous for the Environment

EU Hazard Symbols:



EU Risk Phrases:

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### 2. HAZARDS IDENTIFICATION

R11 - Highly flammable.  
R36 - Irritating to eyes.  
R50 - Very toxic to aquatic organisms.  
R62 - Possible risk of impaired fertility.  
R63 - Possible risk of harm to the unborn child.  
R67 - Vapors may cause drowsiness and dizziness.  
Hazardous Substance. Dangerous Goods.

Australian Hazard Classification  
(NOHSC):

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

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Selamectin	165108-07-6	Not listed	N;R50 Repr. Cat.3;R62-63	7.4 - 14.2
Dipropylene glycol methyl ether	34590-94-8	252-104-2	Not Listed	*
Butylated hydroxytoluene	128-37-0	204-881-4	Not Listed	*
Isopropyl alcohol	67-63-0	200-661-7	F;R11 R67 Xi;R36	72.5 - 85.6

**Additional Information:** \* Proprietary  
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.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Carbon dioxide, dry chemical, or foam

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

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**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Flammable liquid. Vapors will form flammable or explosive mixtures with air at room temperature.

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

**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:** Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**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.

#### Selamectin

Pfizer OEL TWA-8 Hr: 200µg/m<sup>3</sup>

#### Dipropylene glycol methyl ether

ACGIH Threshold Limit Value (TWA) 100 ppm TWA

ACGIH Threshold Limit Value (STEL) 150 ppm STEL

ACGIH - Skin Absorption Designation Listed

Australia TWA 308 mg/m<sup>3</sup>

50 ppm

Austria OEL - MAKs Listed

Belgium OEL - TWA Listed

Bulgaria OEL - TWA Listed

Cyprus OEL - TWA Listed

Czech Republic OEL - TWA Listed

Denmark OEL - TWA Listed

Estonia OEL - TWA Listed

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany - TRGS 900 - TWAs	310 mg/m <sup>3</sup> 50 ppm
Germany (DFG) - MAK	310 mg/m <sup>3</sup> MAK 50 ppm MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Italy OEL - TWA	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Luxembourg OEL - TWA	Listed
Malta OEL - TWA	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	100 ppm 600 mg/m <sup>3</sup>
OSHA - Final PELs - Skin Notations:	Listed
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed
<b>Butylated hydroxytoluene</b>	
ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Denmark OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	20 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Portugal OEL - TWA	Listed
Slovenia OEL - TWA	Listed
<b>Isopropyl alcohol</b>	
ACGIH Threshold Limit Value (TWA)	200 ppm TWA
ACGIH Threshold Limit Value (STEL)	400 ppm STEL
Australia STEL	1230 mg/m <sup>3</sup> 500 ppm
Australia TWA	400 ppm 983 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
Germany - TRGS 900 - TWAs	200 ppm 500 mg/m <sup>3</sup>
Germany (DFG) - MAK	200 ppm MAK 500 mg/m <sup>3</sup> MAK
Germany - Biological Exposure Limit:	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Japan - OELs - Ceilings	400 ppm 980 mg/m <sup>3</sup>
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	400 ppm 980 mg/m <sup>3</sup>
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Romania - Biological Exposure Limit:	Listed
Slovak Republic - Biological Exposure Limit:	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

<b>Analytical Method:</b>	Analytical method available for selamectin. Contact Pfizer Inc for further information.
<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Solution	<b>Color:</b>	Yellow to colorless
<b>Odor:</b>	Characteristic alcohol odor	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture		
<b>Solubility:</b>	Miscible: Water		
<b>Boiling Point (°C):</b>	84		
<b>Relative Density:</b>	0.815 - 0.847		

Flash Point (Liquid) (°C): 19

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Polymerization: Will not occur

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

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

##### Isopropyl alcohol

Rat Oral LD50 > 2000 mg/kg  
Mouse Oral LD50 3600 mg/kg  
Rat Inhalation LC50-8h 16,000 ppm  
Rabbit Dermal LD50 12800 mg/kg  
Rat Inhalation LC50 30 mg/L

##### Dipropylene glycol methyl ether

Dog Oral LD50 7500 mg/kg  
Rat Oral LD 50 5400 µL/kg  
Rabbit Dermal LD 50 10 mL/kg

##### Butylated hydroxytoluene

Rat Oral LD50 1700 mg/kg  
Mouse Oral LD50 650 mg/kg  
Rat Oral LD50 890 mg/kg  
Mouse Intraperitoneal LD 50 138 mg/kg

##### Selamectin

Rat Oral LD50 > 1600 mg/kg  
Mouse Oral LD50 > 1600 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

##### Isopropyl alcohol

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

##### Dipropylene glycol methyl ether

Skin Irritation Rabbit Mild  
Eye Irritation Rabbit Mild

##### Butylated hydroxytoluene

Eye Irritation Rabbit Moderate

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### 11. TOXICOLOGICAL INFORMATION

Skin Irritation Rabbit Moderate

#### Selamectin

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Minimal  
Skin Sensitization - GPMT Guinea Pig Negative

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

##### Isopropyl alcohol

20 Week(s) Rat Inhalation 4000 ppm NOAEL Liver, Central nervous system  
104 Week(s) Rat Inhalation 5000 ppm Kidney

##### Butylated hydroxytoluene

4 Week(s) Rat Oral 5185 mg/kg LOAEL Liver  
4 Day(s) Mouse Oral 2000 mg/kg LOAEL Liver Kidney Ureter Bladder

#### Selamectin

3 Month(s) Rat Oral 5 mg/kg/day NOAEL Liver  
3 Month(s) Dog Oral 40 mg/kg/day NOAEL None identified

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

##### Isopropyl alcohol

Prenatal & Postnatal Development Rat Inhalation 7,000 ppm LOAEL Maternal toxicity, Fetotoxicity, Embryotoxicity  
2 Generation Reproductive Toxicity Rat Oral 1000 mg/kg/day LOAEL Maternal Toxicity, Fetal mortality  
Prenatal & Postnatal Development Rat Oral 1200 mg/kg/day NOAEL No effects at maximum dose

##### Butylated hydroxytoluene

Embryo / Fetal Development Rat Oral 6 g/kg LOEL Teratogenic

#### Selamectin

Reproductive & Fertility Rat 10 mg/kg/day NOAEL Fetotoxicity  
Prenatal & Postnatal Development Rat 10 mg/kg/day NOAEL Developmental toxicity  
Prenatal & Postnatal Development Rat Oral 40 mg/kg/day NOAEL Maternal Toxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Isopropyl alcohol

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Mammalian Cell Mutagenicity HGPRT Chinese Hamster Ovary (CHO) cells Negative  
*In Vitro* Sister Chromatid Exchange Negative

#### Selamectin

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vitro* Cytogenetics Human Lymphocytes Negative  
*In Vivo* Micronucleus Mouse Negative  
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells HGPRT Negative

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

#### Isopropyl alcohol

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### 11. TOXICOLOGICAL INFORMATION

IARC: Group 3

Butylated hydroxytoluene

IARC: Group 3

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** This mixture contains material that is toxic to aquatic life. Bioaccumulation and/or long term effects are not expected. Releases to the environment should be avoided.

**Bioaccumulation and Toxicity:** High acute toxicity to aquatic organisms is expected. See aquatic toxicity data, below.

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Selamectin

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 26 ng/L

*Mysidopsis bahia* (Mysid Shrimp) LC50 96 Hours 28 ng/L

*Cyprinodon variegatus* (Sheepshead Minnow) LC50 48 Hours > 500 ug/L

*Selenastrum capricornutum* (Green Alga) OECD EC50 72 Hours >763 ug/L

*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 266 ug/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

### 13. DISPOSAL CONSIDERATIONS

#### **Disposal Procedures:**

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.

### 14. TRANSPORT INFORMATION

This material is regulated for transportation as a hazardous material/dangerous good.

**Proper shipping name:** Marine pollutant when shipped in bulk quantities or by water . Manufactured **before** January 1, 2010: UN 1993, Flammable liquid, n.o.s. (Isopropanol), 3, II  
Manufactured **after** January 1, 2010: UN 1219, Isopropanol solution, 3, II, Marine Pollutant (Selamectin)

**Flash Point (°C):** 19

For small quantities packed in combination packaging [limited to inner packaging < 1.0L (0.3 gal) and outer packaging < 30 kg (66 lb.) gross weight], the following will apply:

#### **IATA / ICAO**

**IATA Proper shipping name:** Consumer Commodity

**IATA Limits:** [Inner packaging <= 500 mL (17 Fl. Oz); Outer packaging <= 30 kg (66 lb) gross weight.]

**IATA UN / ID No:** ID 8000

**IATA Hazard Class:** 9

#### **IMDG**

**IMDG Proper shipping name:** Isopropanol Solution Ltd Qty, Marine pollutant (Selamectin)

**IMDG UN / ID No:** UN 1219

**IMDG Hazard Class:** 3

**Flash Point (°C):** 19

**IMDG Packing Group:** II

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### 14. TRANSPORT INFORMATION

#### ADR/RID

ADR/RID Proper shipping name: Isopropanol Solution  
ADR UN/ID: UN 1219  
ADR / RID Hazard Class: 3  
ADR / RID Packing Group: II  
ADR/RID Note: ADR Limited Quantity is <= 3.0 liters per inner packaging.

#### DOT

DOT Proper shipping name: Consumer Commodity  
DOT Hazard Class: ORM-D

### 15. REGULATORY INFORMATION

EU Symbol: F ; Xn ; N  
EU Indication of danger: Flammable  
Irritant  
Toxic to Reproduction: Category 3  
Dangerous for the Environment

#### EU Risk Phrases:

R11 - Highly flammable.  
R36 - Irritating to eyes.  
R50 - Very toxic to aquatic organisms.  
R62 - Possible risk of impaired fertility.  
R63 - Possible risk of harm to the unborn child.  
R67 - Vapors may cause drowsiness and dizziness.

#### EU Safety Phrases:

S16 - Keep away from sources of ignition - No smoking.  
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
S36/37 - Wear suitable protective clothing and gloves.  
S53 - Avoid exposure - obtain special instructions before use.  
S57 - Use appropriate containment to avoid environmental contamination.

#### OSHA Label:

WARNING  
Flammable liquid and vapor.  
Causes eye irritation.  
Suspected of damaging fertility or the unborn child.  
May cause drowsiness or dizziness.  
Very toxic to aquatic life.

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

Class B, Division 2  
Class D, Division 2, Subdivision A  
Class D, Division 2, Subdivision B

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## 15. REGULATORY INFORMATION



### Dipropylene glycol methyl ether

#### CERCLA/SARA 313 Emission reporting

1.0% de minimis concentration applies to R-(OCH<sub>2</sub>CH<sub>2</sub>)<sub>n</sub>-OR', where n = 1, 2, or 3, R=alkyl C7 or less, or R = phenyl or alkyl substituted phenyl, R' = H or alkyl C7 or less, or OR' consisting of carboxylic acid ester, sulfate, phosphate, nitrate, or sulfonate

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

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

252-104-2

### Butylated hydroxytoluene

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

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

204-881-4

### Isopropyl alcohol

#### CERCLA/SARA 313 Emission reporting

1.0% de minimis concentration only if manufactured by the strong acid process, no supplier notification

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

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

200-661-7

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R11 - Highly flammable.

R36 - Irritating to eyes.

R50 - Very toxic to aquatic organisms.

R62 - Possible risk of impaired fertility.

R63 - Possible risk of harm to the unborn child.

R67 - Vapors may cause drowsiness and dizziness.

#### Data Sources:

Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

#### Reasons for Revision:

Updated Section 15 - Regulatory Information.

#### Prepared by:

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet