



MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF PRODUCT AND COMPANY

Pfizer Inc	Emergency telephone	1-866-531-8896
Pfizer Animal Health	Hours of operation	24 Hours
235 East 42nd Street	Telephone	1-800-366-5288
New York, NY 10017		

Product name	REVOLUTION® - Single dose tubes
Synonyms	Selamectin formulation
Chemical family	Avermectin/milbemycin derivative
Therapeutic use	Antiparasitic (veterinary); endectocide
Description	Clear, yellow to colorless liquid, with a slight adherent texture; characteristic alcohol odor packaged in 2 mL or less single dose tubes

SECTION 2 - COMPOSITION

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Selamectin*	165108-07-6	7.4 - 14.2%
Isopropyl alcohol*	67-63-0	72.5 - 85.6%
Dipropylene glycol methyl ether*	34590-94-8	Trade secret
Butylated hydroxytoluene*	128-37-0	Trade secret

*Hazardous

Note: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

SECTION 3 - HAZARDS IDENTIFICATION

Signal word	WARNING!
Statements of hazard	FLAMMABLE LIQUID AND VAPOR
	MAY CAUSE EYE IRRITATION
	MAY CAUSE LIVER AND REPRODUCTIVE SYSTEM EFFECTS
	POSSIBLE RISK OF HARM TO THE UNBORN CHILD
	DANGEROUS FOR THE ENVIRONMENT
Eye effects	May cause eye irritation (based on animal data).
Skin effects	Prolonged or repeated contact may cause defatting dermatitis (dryness and cracking of the skin).

SECTION 3 - HAZARDS IDENTIFICATION ... continued

Inhalation effects	An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8). See 'Statements of hazard' and/or 'Other potential health effects' in this section.
Ingestion effects	Not acutely toxic (based on animal data). See 'Statements of hazard' and 'Other potential health effects' in this section.
Other potential health effects	Signs and symptoms of isopropanol overexposure may include headache, dizziness, drowsiness, and loss of consciousness. Repeat-dose studies in animals have shown a potential to cause adverse effects on the liver and reproductive system and harm to the developing fetus.
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.

SECTION 4 - FIRST AID MEASURES

Skin	Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.
Eyes	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. 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.

SECTION 5 - FIRE FIGHTING MEASURES

General hazard	Flammable liquid Vapors may form explosive mixture with air. Toxic gases may be emitted in fires of this material.
Fire fighting instructions	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. All reasonable attempts should be made to prevent firewaters from entering surface waters.
Extinguishing media	Carbon dioxide, dry chemical, or foam
Flash point	66 °F

SECTION 5 - FIRE FIGHTING MEASURES ... continued

Autoignition	No data available
Minimum explosive concentration for dust/vapor	Not known
Flammability limits	No data available
Hazardous combustion products	Not known

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General	Review Sections 3, 8 and 12 before proceeding with clean up.
Small spill	Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly. Prevent discharge to drains.
Large spill	Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Close container and move it to a secure holding area. Prevent discharge to drains.

SECTION 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. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist.
Storage conditions	Store in a cool, dry place away from direct sunlight. Store above freezing point (19 °F).
Temperature range for storage	< 30 °C

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits			
<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Selamectin	Pfizer	TWA-8 Hr	0.2 mg/m ³
Isopropyl alcohol	OSHA	TWA-8 Hr	400 ppm
	ACGIH	TWA-8 Hr	200 ppm
	ACGIH	STEL (15 min)	400 ppm
Dipropylene glycol methyl ether	OSHA	TWA-8 Hr	100 ppm (skin)
	ACGIH	TWA-8 Hr	150 ppm

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ... continued

Exposure limits ...
continued

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
	OSHA	STEL	100 ppm (skin)
	OSHA	TWA-8 Hr	150 ppm
Butylated hydroxytoluene	ACGIH	TWA-8 Hr	10 mg/m ³

Measurement method Selamectin: CAM-KAS-99-006 (Contact Pfizer for further details).

Ventilation Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system. For laboratory use, handle in a lab fume hood.

Respiratory protection 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.

Eye protection Safety glasses or goggles

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

Hand protection Rubber gloves

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form	Liquid
Color	Yellow to colorless
Clarity	Clear
Odor	Characteristic alcohol odor
Molecular weight	Mixture
Molecular formula	Mixture
pH	No data available
Boiling point	183 °F
Melting point	Not applicable
Density	0.815 - 0.847 g/mL at 25 °C
Vapor pressure	No data available
Water solubility	Miscible
Solvent solubility	Not applicable

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Stable under normal conditions of use.
Conditions to avoid	Avoid direct sunlight, conditions that might generate heat, and sources of ignition.
Incompatibilities	None known
Hazardous decomposition products	None known
Hazardous polymerization	Will not occur
Oxidizing properties	No data available

SECTION 11 - TOXICOLOGY INFORMATION

Toxicology summary The information included in this section describes the potential hazards of the individual ingredients, except where noted.

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Result</u>
Selamectin	LD ₅₀	Oral	Rat	>1600 mg/kg
	Irritation	Dermal	Rabbit	Very slight
	Irritation	Ocular	Rabbit	Slight
Isopropyl alcohol	LD ₅₀	Oral	Rat	>2000 mg/kg
	LC50-8h	Inhalation	Rat	16,000 ppm
	LD ₅₀	Dermal	Rabbit	13400 mg/kg
	LC50	Inhalation	Rat	30 mg/l
	Irritation	Ocular	Rabbit	Severe
	Irritation	Dermal	Rabbit	Mild
Dipropylene glycol methyl ether	LD ₅₀	Oral	Dog	7500 mg/kg
Butylated hydroxytoluene	LD ₅₀	Oral	Rat	890 mg/kg

Eye See Acute toxicity table.

Skin Transfer of selamectin across human skin has been evaluated in *in vitro* models. These studies show that a very small amount of selamectin is transferred across human skin. Further analysis to predict user safety was conducted assuming a worst case scenario. Results of this analysis suggests that, if the entire 2 ml dose was spilled onto the skin and was not washed off, the amount absorbed would be 279 times less than the dose which showed no effect in rat toxicity studies.

REVOLUTION® was not irritating in animal studies.

Inhalation See Acute toxicity table

Ingestion See Acute toxicity table.

SECTION 11 - TOXICOLOGY INFORMATION ... continued

Mutagenicity	Selamectin and isopropanol have been tested extensively and are not mutagenic.
Sensitization	Selamectin was negative in the guinea pig maximization test.
Subchronic effects	Selamectin was administered to male and female rats for 3 months. Effects seen included increased liver enzymes and hematological changes along with decreased cholesterol, triglyceride, and glucose levels. Histological changes, including changes to the liver (mild to moderate fatty changes), lymphatics (lymphatic dilatation of the GI tract) and adrenals (hypertrophy) were also observed. The NOAEL for females was 5 mg/kg/day. There was no NOAEL in males. Dogs treated for 3 months exhibited emesis, salivation, and loose stools with no other signs of toxicity. The emesis was not dose related and the loose stools could have been due to the vehicle. The NOAEL in this study was 40 mg/kg/day.
Chronic effects/ carcinogenicity	No data available
Carcinogen status	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
Reproductive effects	Treatment with selamectin resulted in reduced fertility (females only), and litter size, with a corresponding decrease in pup survival, in rats receiving the 60 mg/kg/day dose. An increase in the length of gestation was seen in animals receiving 25 and 60 mg/kg/day. Maternal toxicity was evident at 60 mg/kg/day.
Teratogenicity	The offspring of rats treated with 40 and 60 mg/kg/day of selamectin showed an increased incidence of enlarged right atria, along with an increase in fibrin material in the thoracic cavity. Maternal toxicity was evident at 60 mg/kg/day but not at 40 mg/kg/day.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview	In the environment, the active ingredient in this formulation is expected to bind tightly to soil and sediment, and persist. Harm to aquatic organisms is expected.
Mobility, persistence, and degradability:	The active ingredient in this formulation is poorly water soluble and binds tightly to soil. It is expected to partition to soil, sediment, and to solids in a wastewater treatment facility and persist.
Bioaccumulation and toxicity:	High acute toxicity to aquatic organisms is expected. The active ingredient in this formulation has the potential to bioconcentrate and long term effects are possible. No toxicity to wastewater treatment microorganisms is expected.

SECTION 12 - ECOLOGICAL INFORMATION ... continued

Aquatic toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Result</u>
Selamectin	LC50/48h	Daphnia magna	26 ng/l
	LC50/96h	Mysid Shrimp	28 ng/l
	LC50/48h	Sheepshead Minnow	>500 mcg/l
	NOEC	Selenastrum capricornutum	>763 mcg/l
	LC50/96h	Rainbow Trout	266 mcg/l
	EC50	Red Algae	28 mcg/l

Note: A greater than (>) symbol indicates that toxic effects were not observed at the maximum solubility.

SECTION 13 - DISPOSAL INFORMATION

Disposal procedure Do not dispose of even small amounts in the sanitary sewer, stormwater sewer, lakes, streams, or ponds. Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

SECTION 14 - TRANSPORTATION INFORMATION

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

Proper shipping name Flammable liquid, n.o.s. (contains isopropanol)
Marine pollutant when shipped in bulk quantities or by water

Identification number UN 1993

Hazard class 3 (Flammable liquid)

Packing group II

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

U.S. DOT proper shipping name Consumer Commodity

U.S. DOT hazard class ORM-D

IATA proper shipping name Consumer Commodity

IATA identification number ID 8000

IATA hazard class Miscellaneous (mark *ORM-D Air*)

SECTION 14 - TRANSPORTATION INFORMATION ... continued

IMDG proper shipping name Flammable liquid, n.o.s. (contains isopropanol), Ltd. Qty, Marine Pollutant

IMDG Identification No. UN 1993

IMDG hazard class 3

IMDG packing group II
Flashpoint = 66°F

SECTION 15 - REGULATORY INFORMATION

EU Classification Flammable; Irritant; Toxic to Reproduction; Category 3; Dangerous for the Environment

EU Labelling F; Xn; N

EU Label Pictogram(s)



Risk phrases

R11 - Highly flammable.
R36 - Irritating to eyes.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R67 - Vapors may cause drowsiness and dizziness

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.

Canadian WHMIS

Class B, Division 2 (flammable liquid)
Class D, Division 2, Subdivision A
Class D, Division 2, Subdivision B

SECTION 16 - OTHER

Disclaimer **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 a warranty of any kind, expressed or implied.**