



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	Dectomax® (doramectin) pour-on solution
Chemical family	Avermectin macrocyclic lactone
Therapeutic use	Antiparasitic (veterinary); endectocide
Description	Clear, colorless solution or clear, blue solution

SECTION 2 - COMPOSITION

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Doramectin*	117704-25-3	<1.0%
Isopropyl alcohol*	67-63-0	79.1%
Cetearyl octanoate*	Not assigned	Trade secret
FD & C Blue No. 1	3844-45-9	Trade secret
Water for injection	7732-18-5	Trade secret
Triethanolamine*	102-71-6	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
Eye effects	May cause irritation based on components.
Skin effects	Not a skin irritant (based on components). Prolonged or repeated contact may cause defatting and drying of the skin. May be absorbed through the skin and cause systemic effects. See 'Other potential health effects', below.
Inhalation effects	An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8). See 'Other potential health effects', below.
Ingestion effects	May be harmful if swallowed (based on animal data).

SECTION 3 - HAZARDS IDENTIFICATION ... continued

Other potential health effects Signs and symptoms of isopropanol overexposure may include headache, dizziness, drowsiness, and loss of consciousness.

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. Get medical attention.

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

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.

Fire fighting instructions Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance. Dike and collect water used to fight fire.

Extinguishing media Carbon dioxide, dry chemical, or foam

Flash point 14.4°C (58°F)

Hazardous combustion products Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General Review Sections 3, 8 and 12 before proceeding with clean up.

Small spill Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly. Prevent discharge to drains.

SECTION 6 - ACCIDENTAL RELEASE MEASURES ... continued

Large spill Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material. Transfer all waste to a labeled 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 only in a well-ventilated area. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist.

Storage conditions Store out of direct sunlight in a cool, well ventilated dry area. Protect from light. Keep container tightly closed when not in use.

Temperature range for storage <30°C (<86°F)

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Doramectin	Pfizer	TWA-8 Hr	0.2 mg/m ³
Isopropyl alcohol	ACGIH	TWA-8 Hr	200 ppm
	ACGIH	STEL	400 ppm
	OSHA	TWA-8 Hr	400 ppm

Measurement method Doramectin: CAM-JWT-93-08 (contact Pfizer for additional details)

Ventilation Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk.

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

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ... continued

Color	Colorless or Blue
Clarity	Clear
Odor	Characteristic
Molecular weight	Mixture
Molecular formula	Mixture
pH	No data available
Boiling point	183 °F
Melting point	Not applicable (N/A)
Density	No data available
Vapor pressure	No data available
Water solubility	Doramectin is insoluble (25 ppb @ 25°C).
Solvent solubility	Doramectin is freely soluble in methylene chloride or methanol and soluble in isopropanol.
Specific gravity	0.796 - 0.799 at 25°C

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Stable
Conditions to avoid	Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity).
Incompatibilities	Strong oxidizers
Hazardous decomposition products	No data available
Hazardous polymerization	Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Toxicology summary	The information included in this section describes the potential hazards of the individual ingredients.
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SECTION 11 - TOXICOLOGY INFORMATION ... continued

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Result</u>
Doramectin	LD ₅₀	Oral	Rat (M)	1000-2000 mg/kg
	LD ₅₀	Oral	Rat (F)	500-1000 mg/kg
	LD ₅₀	Oral	Rat(M)	50-100 mg/kg
	LD ₅₀	Oral	Rat (F)	100-200 mg/kg
	Irritation	Ocular	Rabbit	Negative
	Irritation	Dermal	Rabbit	Negative
Isopropyl alcohol	LD ₅₀	Oral	Rat	>2000 mg/kg
	LC50-8h	Inhalation	Rat	16,000 ppm
	LD ₅₀	Dermal	Rabbit	13400 mg/kg
	Irritation	Ocular	Rabbit	Severe
	Irritation	Dermal	Rabbit	Mild

Eye See Acute toxicity table.

Skin See Acute toxicity table.

Inhalation See Acute toxicity table. The human NOEL for isopropanol is 200 ppm/8hr.

Ingestion See Acute toxicity table. When administered to rats in an aqueous suspension, the LD₅₀ ranges were 500-1000 mg/kg for females and 1000-2000 mg/kg for males. When administered in sesame oil the acute toxicity was greater, with LD₅₀ ranges of 50-100 mg/kg for female rats and 100-200 mg/kg for male rats.

Mutagenicity No evidence of mutagenicity was observed for doramectin when tested in vitro and in vivo in the following assays: the Ames test, the mouse lymphoma assay, and the unscheduled DNA synthesis (UDS) assay.

Sensitization There have been rare reports of severe cases of allergic contact dermatitis associated with isopropanol exposure.

Subchronic effects Doramectin was tested in both rats and dogs. In a 3-month rat study, the only treatment related effect noted was an increase in liver weight. A 3-month study in dogs produced only dose-dependent mydriasis.

Rats fed 0.5 to 10 percent isopropanol in drinking water for 27 weeks showed decreased body weight with no microscopic changes in any major organs.

Daily ingestion of up to 6.4 mg/kg of isopropanol produced no adverse effects in humans.

**Chronic effects/
carcinogenicity** The carcinogenic potential of a structurally related avermectin, abamectin, has been investigated in rodents. No evidence of carcinogenicity was seen in these studies.

Isopropanol was tested for carcinogenicity in mice and rats by inhalation. No increase in tumors was seen in mice. A slight increase in interstitial

SECTION 11 - TOXICOLOGY INFORMATION ... continued

Chronic effects/ carcinogenicity ... continued	cell adenomas of the testis was seen in male rats. An increased incidence of cancer of the paranasal sinuses and laryngeal cancer was observed in workers at factories where isopropanol was manufactured by the strong acid process. An investigation into the cancer risk associated with isopropanol occupational exposures did not reveal a significant increase in risk.
Carcinogen status	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
Reproductive effects	In a study with doramectin, decreased body weight gain was seen in F1 females during lactation. Isopropanol adversely affected mating in rats at doses of 1000 mg/kg/day.
Teratogenicity	Embryomortality was seen in mice but not in rats treated with doramectin. Delayed pubic bone ossification was seen in rabbits. Additional fetal anomalies seen in rabbits at higher doses were thought to be due to maternal toxicity. Isopropanol does not cause developmental or teratogenic effects at high doses.
At increased risk from exposure	Doramectin has been shown in rats to be excreted in milk and, as a result, to cause toxicity in young pups; nursing mothers should exercise caution regarding exposure.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview	In the environment, the active ingredient in this formulation is expected to bind tightly to soil or sediment and and not readily desorb. It is unlikely to reach groundwater and is also biodegradable by soil microflora. Harmful effects to aquatic organisms could occur.
Bioaccumulation and toxicity:	See aquatic toxicity data, below.

Aquatic toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Result</u>
Doramectin	EC50/48h	Daphnia magna	0.1 ppb
	LC50/96h	Bluegill Sunfish	11 ppb
	LC50/96h	Rainbow Trout	5.1 ppb
	MIC/24-48h	Aspergillus niger	600 mg/l
	MIC/24-48h	Clostridium perfringens	40 mg/l
	MIC/14days	Green Algae	<1 mg/l
	MIC/24-72h	Nostoc	60 mg/l

SECTION 13 - DISPOSAL INFORMATION

Disposal procedure 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)

Identification number UN 1993

Hazard class 3 (Flammable liquid)

Packing group II

Note: For small quantities, limited to inner packaging less than or equal to 1.0L (0.3 gal) and outer packaging less than or equal to 30 kg (66 lb.) gross weight, the following apply. *Note: If your commodity meets the definition of a limited quantity and is packaged for retail sale, it may also be considered a **Consumer Commodity** and excepted from additional requirements as applicable.*

U.S. DOT proper shipping name Consumer Commodity

U.S. DOT Identification number Not applicable

U.S. DOT hazard class ORM-D

U.S. DOT packing group Not applicable

IATA proper shipping name Consumer Commodity

IATA identification number ID 8000

IATA hazard class Not applicable

IATA packing group Not applicable

Miscellaneous Mark with **ORM-D Air**

IMDG proper shipping name Flammable liquid, n.o.s. (contains isopropanol)

IMDG Identification No. UN 1993

IMDG hazard class 3

IMDG packing group II

SECTION 15 - REGULATORY INFORMATION

EU Classification Flammable; Irritant

EU Labelling F; Xi

EU Label Pictogram(s)



Risk phrases R11 - Highly flammable.
R36 - Irritating to eyes.
R67 - Vapors may cause drowsiness and dizziness

Safety phrases S7 - Keep container tightly closed.
S16 - Keep away from sources of ignition - No smoking.
S24/25 - Avoid contact with eyes and skin.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Canadian WHMIS Class D, Division 2, Subdivision B
Class B, Division 2 (flammable liquid)

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.**