SAFETY DATA SHEET

1. Identification

Product identifier **Doramectin Injectable Solution 10 mg/ml**

Other means of identification

Synonyms DECTOMAX® * Dectomax injectable solution (with phenol preservative)

Recommended use Veterinary antiparasitic (endectocide)

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (USA) Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)

Rocky Mountain Poison and Drug Center 1-866-531-8896

Product Support/Technical Services 1-800-366-5288

Emergency telephone numbers CHEMTREC (24 hours): 1-800-424-9300

International CHEMTREC (24 hours): +1-703-527-3887

Company Name (CA) Zoetis Canada Inc.
16740 Trans-Canada Highway
Kirkland, Quebec, H9H 4M7

Emergency telephone number International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail productsupport@zoetis.com

Product Support 1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at https://www.zoetis.ca/sds/sds.aspx

Supplier Not available.

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards	Reproductive toxicity	Category 2
	Reproductive toxicity	Effects on or via lactation
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 1
	Hazardous to the aquatic environment, long-term hazard	Category 1

Label elements

Signal word Warning

Hazard statement Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children. Very toxic to aquatic life with long lasting effects.

Precautionary statement

Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapour. Avoid contact during pregnancy and while nursing. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.
Response	IF exposed or concerned: Get medical advice/attention. Collect spillage.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Doramectin		117704-25-3	1
Phenol		108-95-2	0.25

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
Skin contact	Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
Ingestion	Rinse mouth. Call a physician or poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Mild skin irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause an allergic skin reaction. Dermatitis. Rash. May cause central nervous system effects. May cause reproductive effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Symptoms may be delayed.
General information	For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Remove sources of ignition. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Clean contaminated surface thoroughly.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Wear appropriate personal protective equipment. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in a well-ventilated place. Store below 30°C. Do not allow material to freeze. Store in a tightly closed container. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits

Zoetis

Components	Type	Value
Doramectin (CAS 117704-25-3)	TWA	200 µg/m³

US. ACGIH Threshold Limit Values

Components	Type	Value
Phenol (CAS 108-95-2)	TWA	5 ppm

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value
Phenol (CAS 108-95-2)	TWA	19 mg/m3 5 ppm

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value
Phenol (CAS 108-95-2)	TWA	5 ppm

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value
Phenol (CAS 108-95-2)	TWA	5 ppm

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Phenol (CAS 108-95-2)	TWA	5 ppm

Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Phenol (CAS 108-95-2)	TWA	19 mg/m3 5 ppm

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling time
Phenol (CAS 108-95-2)	250 mg/g	Phenol with hydrolysis	Creatinine in urine	*

* - For sampling details, please see the source document.

Exposure guidelines

Canada - Alberta OELs: Skin designation

Phenol (CAS 108-95-2)	Can be absorbed through the skin.

Canada - British Columbia OELs: Skin designation

Phenol (CAS 108-95-2)	Can be absorbed through the skin.

Canada - Manitoba OELs: Skin designation

Phenol (CAS 108-95-2)	Can be absorbed through the skin.

Canada - Ontario OELs: Skin designation

Phenol (CAS 108-95-2)	Can be absorbed through the skin.

Canada - Quebec OELs: Skin designation

Phenol (CAS 108-95-2)	Can be absorbed through the skin.

Canada - Saskatchewan OELs: Skin designation

Phenol (CAS 108-95-2)	Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Phenol (CAS 108-95-2)	Can be absorbed through the skin.

Control banding approach Not available.

Appropriate engineering controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses or goggles if eye contact is possible.

Skin protection

Hand protection Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Other Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. 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.

Thermal hazards Not applicable.

General hygiene considerations Observe any medical surveillance requirements. When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Liquid.

Colour Colorless to pale-yellow.

Odour Not available.

Odour threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Keep away from heat, sparks and open flame. Avoid release to the environment.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Prolonged skin contact may cause temporary irritation. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.
Doramectin	Species: Rabbit Severity: Non-irritating
Eye contact	Direct contact with eyes may cause temporary irritation.
Doramectin	Species: Rabbit Severity: Non-irritating
Ingestion	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Mild skin irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause an allergic skin reaction. Dermatitis. Rash. May cause reproductive effects. Prolonged exposure may cause chronic effects. May cause central nervous system effects.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Product	Species	Test results
Doramectin Injectable Solution 10 mg/ml		
Acute		
Dermal		
ATE		> 5000 mg/kg

Product	Species	Test results
Inhalation		
ATE		> 10 mg/l
Oral		
ATE		> 5000 mg/kg

Components	Species	Test results
Doramectin (CAS 117704-25-3)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg
Inhalation		
LC50	Rat	0.54 mg/l, 4 hours
Oral		
LD50	Rat (F)	500 - 1000 mg/kg
	Rat (M)	1000 - 2000 mg/kg
Subchronic		
Oral		
NOEL	Dog	0.1 mg/kg/day, 3 months (Central Nervous System)
	Rat	2 mg/kg/day, 3 months (Liver)
Phenol (CAS 108-95-2)		
Acute		
Dermal		
LD50	Rabbit	630 mg/kg
	Rat	535 mg/kg
Oral		
LD50	Mouse	270 mg/kg
	Rat	317 mg/kg
Chronic		
Oral		
NOAEL	Mouse	5000 ppm, 103 weeks (Not carcinogenic)
	Rat	5000 ppm, 103 weeks (Not carcinogenic)

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Doramectin	Species: Rabbit Severity: Non-irritating

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye contact

Doramectin	Species: Rabbit Severity: Non-irritating

Respiratory or skin sensitisation

Respiratory sensitisation Not a respiratory sensitizer.

Skin sensitisation This product is not expected to cause skin sensitisation.

Skin sensitisation

Doramectin	LLNA Result: negative Species: Mouse

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Doramectin	Bacterial Mutagenicity (Ames) Result: negative Species: Salmonella In vivo Micronucleus Result: negative Species: Mouse Mammalian Cell Mutagenicity Result: negative Species: Mouse Lymphoma Unscheduled DNA Synthesis Result: negative Species: Rat Hepatocyte

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

ACGIH Carcinogens

Phenol (CAS 108-95-2)	A4 Not classifiable as a human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Phenol (CAS 108-95-2)	Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Phenol (CAS 108-95-2)	3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity May cause harm to breastfed babies. Suspected of damaging fertility or the unborn child.

Developmental effects

Doramectin	> 6 mg/kg/day Embryo / Fetal Development, Not teratogenic Result: NOEL Species: Rat Organ: Oral 0.75 mg/kg/day Embryo / Fetal Development, Maternal Toxicity, Teratogenic Result: NOEL Species: Rabbit Organ: Oral
Phenol	120 mg/kg Embryo / Fetal Development, Fetotoxicity Not Teratogenic Result: LOAEL Species: Rat Organ: Oral 200 mg/kg Embryo / Fetal Development, No effects at maximum dose Result: NOAEL Species: Rat Organ: Intraperitoneal
Doramectin	3 mg/kg/day Embryo / Fetal Development, Fetotoxicity, Not Teratogenic Result: NOEL Species: Mouse Organ: Oral
Phenol	53 mg/kg Fertility and Embryonic Development, Maternal Toxicity Fetotoxicity Not Teratogenic Result: LOAEL Species: Rat Organ: Oral

Reproductivity

Doramectin	0.3 mg/kg/day 2-generation, No effects except lower pup weight during lactation Result: NOEL Species: Rat Organ: Oral
Phenol	1000 ppm 2 Generation Reproductive Toxicity, No effects at maximum dose Result: NOAEL Species: Rat Organ: Oral

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met. This product may affect Nervous system. through prolonged or repeated exposure.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged exposure may cause chronic effects.

Further information CAUTION! Occupational exposure to the substance or mixture may cause adverse effects. May cause central nervous system disorder (e.g., narcosis involving a loss of coordination, weakness, fatigue, mental confusion and blurred vision) and/or damage.

12. Ecological information

Ecotoxicity Very toxic to aquatic life with long lasting effects. Avoid release to the environment.

Components		Species	Test results
Doramectin (CAS 117704-25-3)			
	EC50	Activated sludge	> 1000 mg/l, 3 hours
	MIC	Aspergillus niger (Fungus)	600 mg/l
		Clostridium perfingens (Bacterium)	40 mg/l
Acute			
	EC50	Daphnia magna (Water Flea)	0.0001 mg/l, 48 Hours
	LC50	Eisenia foetida (Earthworm)	> 1000 mg/kg, 14 days
			> 1000 mg/kg, 7 days
		Lepomis macrochirus (Bluegill Sunfish)	0.011 mg/l, 96 Hours
		Oncorhynchus mykiss (Rainbow Trout)	0.0051 mg/l, 96 Hours
Aquatic			
Chronic			
Algae	MIC	Green algae (Selenastrum capricornutum)	> 0.026 mg/l, 14 days
Phenol (CAS 108-95-2)			
	EC50	Selenastrum capricornutum (Green Alga)	150 mg/l, 96 Hours
	LC50	Daphnia magna (Water Flea)	13 mg/l, Hours
		Lepomis macrochirus (Bluegill Sunfish)	23.88 mg/l, 96 Hours
		Oncorhynchus mykiss (Rainbow Trout)	8.9 mg/l, Hours
		Pimephales promelas (Fathead Minnow)	24 mg/l, 96 Hours
Aquatic			
Crustacea	EC50	Water flea (Daphnia obtusa)	4.7 - 6.4 mg/l, 48 hours
Fish	LC50	Asiatic knifefish (Notopterus notopterus)	8 - 8.25 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product. As with other members of the avermectin family, doramectin is highly toxic to fish and certain aquatic organisms. However, once in contact with soil, it is tightly bound and does not readily desorb. It is unlikely to reach groundwater and is also biodegradable by soil microflora.

Biodegradability

Percent degradation (Aerobic biodegradation)

Doramectin	25.5 % OECD 301D Test Duration: 28 days

Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol / water (log Kow)

Doramectin	4.4

Mobility in soil No data available. The active ingredient in this formulation is expected to bind to soil or sediment.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

TDG

Not regulated as dangerous goods.

IATA

UN number UN3082

UN proper shipping name Environmentally hazardous substances, liquid, n.o.s. (Doramectin, Phenol)

Transport hazard class(es)

Class 9

Subsidiary risk -

Packing group III

Environmental hazards Yes

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IMDG

UN number UN3082

UN proper shipping name Environmentally hazardous substances, liquid, n.o.s. (Doramectin, Phenol), MARINE POLLUTANT (Doramectin, Phenol)

Transport hazard class(es)

Class 9

Subsidiary risk -

Packing group III

Environmental hazards

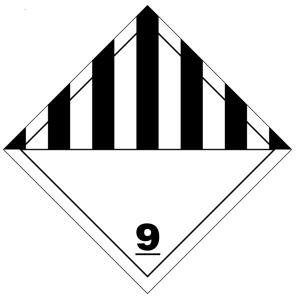
Marine pollutant Yes

EmS F-A, S-F

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

IATA; IMDG



Marine pollutant

General information

IMDG Regulated Marine Pollutant. As of January 1, 2015, materials offered for transport that are classified for transportation only as Marine Pollutants and which are packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 Liters or less for liquids or having a net mass per single or inner packaging of 5 kilograms or less for solids are NOT subject to ICAO/IATA, IMDG, or ADR transport regulations provided the general packaging requirements of those regulations are met. Refer to ICAO/IATA A197, IMDG 2.10.2.7, ADR SP 375. Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

15. Regulatory information

Canadian regulations

This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Ontario. Toxic Substances. Toxic Reduction Act, 2009. Regulation 455/09 (July 1, 2011)

Phenol (CAS 108-95-2)

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date 07-June-2017

Version No. 01

List of abbreviations ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).

Disclaimer Zoetis Inc. believes that the information contained in this 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. The information in the sheet was written based on the best knowledge and experience currently available.

Revision information Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Toxicological Information: Toxicological Data
Transport Information: Material Transportation Information
GHS: Classification