SAFETY DATA SHEET

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

Product Identifier

Material Name: Doramectin Injectable Solution 10 mg/ml

Trade Name: DECTOMAX®
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as Antiparasitic (veterinary); endectocide
Restrictions on Use: Not for human use

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 and Drug 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

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

Contact E-Mail: VMIPSrecords@zoetis.com

2. HAZARDS IDENTIFICATION

Appearance: Colorless to pale yellow solution

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2
Reproductive Toxicity: Effects on or via lactation
Acute aquatic toxicity: Category 1
Chronic aquatic toxicity: Category 1

EU Classification:

EU Indication of danger: N - Dangerous for the environment

EU Symbol: N
EU Risk Phrases:

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Label Elements

Signal Word: Warning
Hazard Statements: H361 - Suspected of damaging fertility or the unborn child
H362 - May cause harm to breast-fed children
H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P263 - Avoid contact during pregnancy/while nursing
P270 - Do not eat, drink or smoke when using this product
P264 - Wash hands thoroughly after handling
P273 - Avoid release to the environment
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P391 - Collect spillage
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

Short Term: May be harmful if swallowed. May cause nervous system effects . May cause eye and skin irritation .

Long Term: May cause effects on nervous system

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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	%
Doramectin	117704-25-3	Not Listed	Xn;R22 N;R50/53 Repr.Cat.3;R63 R64	Acute Tox. 4 (H302) Repr. 2 (H361) Lact (H362) Aq. Acute 1 (H400) Aq. Chronic 1 (H410)	1

3. COMPOSITION/INFORMATION ON INGREDIENTS

PHENOL	108-95-2	203-632-7	T; R23/24/25 C; R34 Xn; R48/20/21/22 Muta. Cat. 3; R68	Acute Tox. Cat 3 (H301) Acute Tox. Cat. 3 (H311) Acute Tox. Cat 3 (H331) Skin Corr. Cat. 1B (H314) Mut. Cat. 2 (341) STOT RE Cat. 2 (H373) Aquatic Tox. Cat. 2 (H401)	<0.5

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sesame oil	8008-74-0	232-370-6	Not Listed	Not Listed	*
Ethyl oleate	111-62-6	203-889-5	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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: 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.

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.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Ensure adequate ventilation. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Avoid contact with skin, eyes and clothing .

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 the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. 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

Use only in a well-ventilated area. Minimize generating airborne mists and vapors. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid accidental injection. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Storage Temperature: < 30 °C
Specific end use(s): Antiparasitic (veterinary); endectocide

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Doramectin

Zoetis OEL TWA 8-hr 200µg/m^3

PHENOL

ACGIH Threshold Limit Value (TWA) = 5 ppm TWA
ACGIH - Biological Exposure Limit: 250 mg/g creatinine

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia TWA	= 1 ppm TWA = 4 mg/m^3 TWA
Austria OEL - MAKs	2 ppm 8 mg/m^3
Belgium OEL - TWA	2 ppm 8 mg/m^3
Bulgaria OEL - TWA	8 mg/m^3 2 ppm
Bulgaria - Biological Exposure Limit:	200 mg/L
Cyprus OEL - TWA	8 mg/m^3 2 ppm
Czech Republic OEL - TWA	7.5 mg/m^3
Denmark OEL - TWA	1 ppm 4 mg/m^3
OSHA - Final PELS - TWAs:	= 19 mg/m^3 TWA = 5 ppm TWA
OSHA - Final PELs - Skin Notations:	prevent or reduce skin absorption

Exposure Controls

Engineering Controls:	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.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	**Color:**	Colorless to pale-yellow
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	Highly soluble: Polar organic solvents
Water Solubility:	No data available
Solubility:	Insoluble: Water
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)
Doramectin
Measured Log P 4.4

Decomposition Temperature (°C):	No data available.
Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available

Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
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 under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
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
Hazardous Decomposition Products: Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: skin contact , eye contact

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

Doramectin
Rat (M) Oral LD50 1000-2000 mg/kg
Rat (F) Oral LD50 500-1000mg/kg

PHENOL
Rat Oral LD50 317 mg/kg
Rat Dermal LD50 535mg/kg
Rabbit Dermal LD50 630mg/kg
Mouse Oral LD50 270mg/kg

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

Doramectin
Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Non-irritating

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

Doramectin
3 Month(s) Rat Oral 2 mg/kg/day NOEL Liver
3 Month(s) Dog Oral 0.1 mg/kg/day NOEL Central Nervous System,

11. TOXICOLOGICAL INFORMATION

Chronic Effects/Carcinogenicity No carcinogenic data available. However, the carcinogenic potential of a structurally related avermectin, abamectin, has been investigated in rodents. No evidence of carcinogenicity was seen in these studies.

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

Doramectin

Embryo / Fetal Development	Rat	Oral	>6 mg/kg/day	NOEL	Not teratogenic
Embryo / Fetal Development	Mouse	Oral	3 mg/kg/day	NOEL	Fetotoxicity, Not Teratogenic
Embryo / Fetal Development	Rabbit	Oral	0.75 mg/kg/day	NOEL	Maternal Toxicity, Teratogenic

PHENOL

2 Generation Reproductive Toxicity	Rat	Oral	1000 ppm	NOAEL	No effects at maximum dose
Embryo / Fetal Development	Rat	Oral	120 mg/kg	LOAEL	Fetotoxicity, Not Teratogenic
Fertility and Embryonic Development	Rat	Oral	53 mg/kg	LOAEL	Maternal Toxicity, Fetotoxicity, Not Teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	200 mg/kg	NOAEL	No effects at maximum dose

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

Doramectin

Bacterial Mutagenicity (Ames)	*Salmonella*	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
Unscheduled DNA Synthesis	Rat Hepatocyte	Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

PHENOL

103 Week(s)	Rat	Oral	5,000 ppm	NOAEL	Not carcinogenic
103 Week(s)	Mouse	Oral	5,000 ppm	NOAEL	Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

PHENOL
IARC: Group 3

Product Level Toxicity Data
Acute Toxicity Estimate (ATE), Oral >5000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. 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.

Toxicity:

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

Doramectin
Daphnia magna (Water Flea) TAD EC50 48 Hours 0.00010 mg/L
Lepomis macrochirus (Bluegill Sunfish) TAD LC50 96 Hours 0.011 mg/L
Oncorhynchus mykiss (Rainbow Trout) TAD LC50 96 Hours 0.0051 mg/L

PHENOL
Selenastrum capricornutum (Green Alga) EC50 96 Hours 150 mg/L
Pimephales promelas (Fathead Minnow) LC50 96 Hours 24 mg/L
Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 8.9 mg/L
Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 23.88 mg/L
Daphnia magna (Water Flea) LC50 48 Hours 13 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Doramectin
Aspergillus niger (Fungus) TAD MIC 600 mg/L
Clostridium perfingens (Bacterium) TAD MIC 40 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential:

Doramectin
Measured Log P 4.4

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Should not be released into the environment. 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.

PHENOL
RCRA - U Series Wastes Waste Number U188

14. TRANSPORT INFORMATION

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.

UN number:	UN 3082
UN proper shipping name:	Environmentally hazardous substances, liquid, n.o.s. (Doramectin)
Transport hazard class(es):	9
Packing group:	III
Environmental Hazard(s):	Marine Pollutant

Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

DOT / ANTT: Not regulated for transportation

U.S. DOT Reportable Quantity (RQ), 49 CFR 172.101 Appendix A:

PHENOL

CERCLA/SARA Hazardous Substances	= 1000 lb final RQ
and their Reportable Quantities:	= 454 kg final RQ

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Doramectin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling	Schedule 5
for Drugs and Poisons:	Schedule 6
	Schedule 7

15. REGULATORY INFORMATION

EU EINECS/ELINCS List	Not Listed

Sesame oil

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-370-6

Ethyl oleate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-889-5

PHENOL

CERCLA/SARA 313 Emission reporting	= 1.0% de minimis concentration
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 10000 lb upper threshold TPQ = 500 lb lower threshold TPQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 1000 lb EPCRA RQ
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4 Schedule 5 Schedule 6
EU EINECS/ELINCS List	203-632-7

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects
Acute toxicity, dermal-Cat.3; H311 - Toxic in contact with skin
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

T - Toxic
C - Corrosive
Xn - Harmful
Toxic to Reproduction: Category 3
Mutagenic: Category 3
N - Dangerous for the environment

R22 - Harmful if swallowed.
R68 - Possible risks of irreversible effects.
R63 - Possible risk of harm to the unborn child.
R64 - May cause harm to breastfed babies.
R34 - Causes burns.
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.
R48/20/21/22 - Harmful: danger of serious damage to health by prolonged exposure through 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 2 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 11 - Toxicology Information. Updated Section 14 - Transport Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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.

End of Safety Data Sheet