

SAFETY DATA SHEETS

This SDS packet was issued with item:

078695533

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078913133 078934740

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078912898 078912918 078913132

SAFETY DATA SHEET



Revision date: 24-Feb-2015

Version: 5.5

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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
Contact E-Mail: VMIPSrecords@zoetis.com

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

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

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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 |

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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

None known

Aggravated by Exposure:

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.

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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/m³

PHENOL

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

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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 | | |

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

Flammability:

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,

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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) | <i>Salmonella</i> | 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), >5000 mg/kg
Oral

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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

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

PHENOL

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

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

Doramectin

| | | | |
|--|-----|-----|----------|
| <i>Aspergillus niger</i> (Fungus) | TAD | MIC | 600 mg/L |
| <i>Clostridium perfringens</i> (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

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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
and their Reportable Quantities:**

| |
|--------------------|
| = 1000 lb final RQ |
| = 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 for Drugs and Poisons: | Schedule 5 |
| | Schedule 6 |
| | Schedule 7 |

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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

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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