

SAFETY DATA SHEET



Revision date: 06-Jan-2014

Version: 2.0

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

Product Identifier

Material Name: Doxycycline Gel

Trade Name: Doxirobe (TM)
Chemical Family: Mixture

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

Intended Use: Veterinary product used as antibiotic agent

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 Control 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: Gel in a disposable syringe

Classification of the Substance or Mixture

GHS - Classification

Skin Corrosion/Irritation: Category 2
Serious Eye Damage/Eye Irritation: Category 2A
Reproductive Toxicity: Category 1A
Specific target organ systemic toxicity (single exposure): Category 3
Flammable liquids- Category 4

EU Classification:

EU Indication of danger: Toxic
Irritant

EU Symbol: T Xi

EU Risk Phrases:

R36/37/38 - Irritating to eyes, respiratory system and skin.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Label Elements

Signal Word: Danger

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2. HAZARDS IDENTIFICATION

Hazard Statements:

H315 - Causes skin irritation
H319 - Causes serious eye irritation
H360 - May damage fertility or the unborn child
H335 - May cause respiratory irritation
H227 - Combustible liquid

Precautionary Statements:

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P264 - Wash hands thoroughly after handling
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P271 - Use only outdoors or in a well-ventilated area
P370 + P378 - In case of fire: Use appropriate media for extinction
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P362 - Take off contaminated clothing and wash before reuse
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTRE/doctor/physician if you feel unwell
P233 - Keep container tightly closed
P403 - Store in a well-ventilated place
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Short Term:

Known Clinical Effects:

May be harmful if swallowed. May cause allergic reactions in susceptible individuals. May cause permanent discoloration of teeth if used during tooth development. May cause effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea. Photosensitivity has been reported in some individuals taking tetracyclines.

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

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
N-METHYL-2-PYRROLIDONE	872-50-4	212-828-1	Xi; R36/37/38 Repr.Cat.2; R61	STOT SE 3 (H335) Repr. 1B (H360) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	50-60
Doxycycline hyclate	24390-14-5	Not Listed	Repr.Cat 1;R61	Repr. 1A (H360)	8.5

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Poly(lactic acid-glycolic acid)	34346-01-5	Not Listed	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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 clothing and wash affected skin with soap and water. If irritation occurs or persists, get 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: Carbon dioxide, carbon monoxide, and oxides of nitrogen

Fire / Explosion Hazards: Combustible liquid.

Advice for Fire-Fighters

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Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Ensure adequate ventilation.

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: Remove all sources of ignition. Contain the source of spill if it is safe to do so. Collect spill with absorbent material. 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

Keep away from heat, sparks, flame and all other sources of ignition. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Prevent environmental releases. Use appropriate personal protective equipment.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging. Keep out of reach of children.

Incompatible Materials: Incompatible with strong acids and oxidising agents.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

N-METHYL-2-PYRROLIDONE

ACGIH - Biological Exposure Limit:	100 mg/L
Australia STEL	75 ppm
Australia TWA	309 mg/m ³
Austria OEL - MAKs	25 ppm
Bulgaria OEL - TWA	103 mg/m ³
Cyprus OEL - TWA	10 ppm
Czech Republic OEL - TWA	40 mg/m ³
Denmark OEL - TWA	40 mg/m ³
Estonia OEL - TWA	5 ppm
Finland OEL - TWA	20 mg/m ³
	10 ppm
	40 mg/m ³
	10 ppm
	40 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

France OEL - TWA	40 mg/m ³ 10 ppm
Germany - TRGS 900 - TWAs	20 ppm 82 mg/m ³
Germany (DFG) - MAK	20 ppm 82 mg/m ³
Germany - Biological Exposure Limit:	150 mg/L
Greece OEL - TWA	10 ppm 40 mg/m ³
Hungary OEL - TWA	40 mg/m ³
Ireland OEL - TWAs	25 ppm 101 mg/m ³
Latvia OEL - TWA	10 ppm 40 mg/m ³
Lithuania OEL - TWA	10 ppm 40 mg/m ³
Luxembourg OEL - TWA	40 mg/m ³ 10 ppm
Malta OEL - TWA	40 mg/m ³ 10 ppm
Netherlands OEL - TWA	40 mg/m ³
Poland OEL - TWA	40 mg/m ³
Romania OEL - TWA	10 ppm 40 mg/m ³
Slovenia OEL - TWA	19 ppm 80 mg/m ³
Spain OEL - TWA	10 ppm 40 mg/m ³
Sweden OEL - TWAs	50 ppm 200 mg/m ³
Switzerland OEL - TWAs	20 ppm 80 mg/m ³

Doxycycline hyclate
Zoetis OEL TWA 8-hr

25µg/m³

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.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Rubber gloves

Eyes:

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin:

Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection:

Not required for the normal use of this product. 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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Gel	Color:	Clear
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
No data available			
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		
Flammability:			
Autoignition Temperature (Solid) (°C):		245	
Flammability (Solids):		No data available	
Flash Point (Liquid) (°C):		91	Closed cup
Upper Explosive Limits (Liquid) (% by Vol.):		9.5	
Lower Explosive Limits (Liquid) (% by Vol.):		13	

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:	Keep away from heat, spark, flames and all other sources of ignition.
Incompatible Materials:	Incompatible with strong acids and oxidising agents.
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information included in this section describes the potential hazards of the individual ingredients.

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

N-METHYL-2-PYRROLIDONE

Rat	Oral	LD 50	3914 mg/kg
Mouse	Oral	LD 50	7725mg/kg
Rabbit	Dermal	LD 50	8000mg/kg

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11. TOXICOLOGICAL INFORMATION

Doxycycline hyclate

Mouse Oral LD50 1900 mg/kg (hydrochloride)
Rat Oral LD50 > 2000mg/kg (hydrochloride)
Rat Intravenous LD50 228mg/kg (hydrochloride)
Rat (weanling) Intraperitoneal LD50 262mg/kg (hydrochloride)

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

N-METHYL-2-PYRROLIDONE

Eye Irritation Rabbit Moderate

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

N-METHYL-2-PYRROLIDONE

28 Day(s) Rat Oral 6,000 ppm NOEL None identified
28 Day(s) Mouse Oral 2,500 ppm NOEL Kidney

Doxycycline hyclate

30 Day(s) Rat Oral 500 mg/kg NOEL None identified
18 Month(s) Rat Oral 50 mg/kg/day NOEL Thyroid, Bone
1 Year(s) Dog Oral < 10 mg/kg/day NOEL Liver

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

N-METHYL-2-PYRROLIDONE

Reproductive & Fertility Rat Dermal 237 mg/kg/day NOEL Maternal toxicity, Fetotoxicity
Embryo / Fetal Development Rat Inhalation 0.36 mg/L NOEL Maternal Toxicity, Not Teratogenic
Embryo / Fetal Development Rat Dermal 237 mg/kg NOEL Maternal Toxicity, Fetotoxicity, Not Teratogenic

Doxycycline hyclate

Reproductive & Fertility-Females Rat Oral 250 mg/kg/day NOEL No effects at maximum dose
Embryo / Fetal Development Monkey Oral 50 mg/kg/day NOEL No effects at maximum dose

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

N-METHYL-2-PYRROLIDONE

Bacterial Mutagenicity (Ames) *Salmonella* Negative

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

N-METHYL-2-PYRROLIDONE

2 Year(s) Rat Inhalation 0.4 mg/L NOEL Not carcinogenic

Carcinogen Status:

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

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12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:	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.
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14. TRANSPORT INFORMATION

This material is only regulated for transportation as a hazardous material/dangerous good when shipped in bulk packages ($\geq 450\text{L}/119$ gal. per package)

DOT	
DOT UN / ID No:	NA1993
DOT Proper shipping name:	Combustible Liquid, n.o.s. (n-Methylpyrrolidone) (Note: Combustible liquids in non-bulk packaging are not subject to the Dangerous Goods/Hazardous Material regulations)
DOT Packing Group:	III

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications

WHMIS hazard class:

Class B, Division 3
Class D, Division 2, Subdivision A
Class D, Division 2, Subdivision B

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15. REGULATORY INFORMATION



Poly(lactic acid-glycolic acid)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

N-METHYL-2-PYRROLIDONE

CERCLA/SARA 313 Emission reporting	1.0 %
California Proposition 65	developmental toxicity initial date 6/15/01
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
REACH - Toxic to Reproduction Category 2:	Schedule 6
EU EINECS/ELINCS List	Present
	212-828-1

Doxycycline hyclate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity initial date 10/1/91 internal use
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

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

H335 - May cause respiratory irritation
H360 - May damage fertility or the unborn child
H315 - Causes skin irritation
H319 - Causes serious eye irritation

R61 - May cause harm to the unborn child.
R36/37/38 - Irritating to eyes, respiratory system and skin.

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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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Zoetis 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 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