# SAFETY DATA SHEET

## 1. Identification

| | |
|---|---|
| **Product identifier** | **Doxycycline Gel** |
| **Other means of identification** | |
| **Synonyms** | Doxirobe® Gel * Doxirobe |
| **Recommended use** | Veterinary product used as antibiotic agent |
| **Recommended restrictions** | Not for human use |

**Manufacturer/Importer/Supplier/Distributor information**

| | |
|---|---|
| **Company Name (US)** | Zoetis Inc.<br>10 Sylvan Way<br>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<br>International CHEMTREC (24 hours): +1-703-527-3887 |
| **Company Name (EU)** | Zoetis Belgium S.A.<br>Mercuriusstraat 20<br>1930 Zaventem<br>Belgium |
| **Emergency telephone number** | International CHEMTREC (24 hours): +1-703-527-3887 |
| **Contact E-Mail** | VMIPSrecords@zoetis.com |

## 2. Hazard(s) identification

| | | |
|---|---|---|
| **Physical hazards** | Flammable liquids | Category 4 |
| **Health hazards** | Skin corrosion/irritation | Category 2 |
| | Serious eye damage/eye irritation | Category 2A |
| | Reproductive toxicity (the unborn child) | Category 1A |
| | Specific target organ toxicity, single exposure | Category 3 respiratory tract irritation |
| **Environmental hazards** | Not classified. | |
| **OSHA defined hazards** | Not classified. | |

**Label elements**

| | |
|---|---|
| **Signal word** | Danger |
| **Hazard statement** | Combustible liquid. Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. May damage the unborn child. |
| **Precautionary statement** | |
| **Prevention** | Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Keep away from flames and hot surfaces-No smoking. Avoid breathing mist/vapor. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection. |

| | |
|---|---|
| **Response** | If exposed or concerned: Get medical advice/attention. If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash before reuse. In case of fire: Use appropriate media to extinguish. |
| **Storage** | Keep cool. Store in a well-ventilated place. Keep container tightly closed. Store locked up. |
| **Disposal** | Dispose of contents/container in accordance with local/regional/national/international regulations. |
| **Hazard(s) not otherwise classified (HNOC)** | None known. |
| **Supplemental information** | None. |

## 3. Composition/information on ingredients

**Mixtures**

| Chemical name | Common name and synonyms | CAS number | % |
|---|---|---|---|
| N-METHYL-2-PYRROLIDONE | | 872-50-4 | 50-60 |
| Doxycycline hyclate | | 24390-14-5 | 8.5 |
| Poly(lactic acid-glycolic acid) | | 34346-01-5 | * |

**Composition comments** *Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

## 4. First-aid measures

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|---|---|
| **Inhalation** | Move to fresh air. Call a poison center or doctor/physician if you feel unwell. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary. |
| **Skin contact** | Wash off with soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. |
| **Eye contact** | Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. |
| **Ingestion** | Rinse mouth. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person. |
| **Most important symptoms/effects, acute and delayed** | Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause respiratory irritation. Coughing. Skin irritation. May cause redness and pain. May cause effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea. |
| **Indication of immediate medical attention and special treatment needed** | Provide general supportive measures and treat symptomatically. Symptoms may be delayed. In case of shortness of breath, give oxygen. |
| **General information** | IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. 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. |

## 5. Fire-fighting measures

| | |
|---|---|
| **Suitable extinguishing media** | Water fog. Alcohol resistant 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. Combustible. |
| **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** | In case of fire and/or explosion do not breathe fumes. 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** | Combustible liquid. |

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**

Keep unnecessary personnel away. Ensure adequate ventilation. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist/vapor. 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. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Keep combustibles (wood, paper, oil, etc.) away from spilled material. Avoid release to the environment.

Large Spills: Stop the flow of material, if this is without risk. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Clean surface thoroughly to remove residual contamination.

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 discharge into drains, water courses or onto the ground.

## 7. Handling and storage

**Precautions for safe handling**

Do not handle until all safety precautions have been read and understood. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Use with adequate ventilation. Wear appropriate personal protective equipment. Avoid contact with eyes, skin, and clothing. 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 in a well-ventilated place. @ 15-30°C (59-86°F). Do not handle or store near an open flame, heat or other sources of ignition. Store away from direct sunlight. 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**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

**Zoetis**

| Components | Type | Value |
|---|---|---|
| Doxycycline hyclate (CAS 24390-14-5) | TWA | 250 µg/m³ |

**US. Workplace Environmental Exposure Level (WEEL) Guides**

| Components | Type | Value |
|---|---|---|
| N-METHYL-2-PYRROLIDONE (CAS 872-50-4) | TWA | 40 mg/m3 |
| | | 10 ppm |

**Biological limit values**

**ACGIH Biological Exposure Indices**

| Components | Value | Determinant | Specimen | Sampling Time |
|---|---|---|---|---|
| N-METHYL-2-PYRROLIDONE (CAS 872-50-4) | 100 mg/l | 5-Hydroxy-N-methyl-2-pyrrolidone | Urine | * |

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

**Exposure guidelines**

**US - California OELs: Skin designation**

N-METHYL-2-PYRROLIDONE (CAS 872-50-4) Can be absorbed through the skin.

**US WEEL Guides: Skin designation**

N-METHYL-2-PYRROLIDONE (CAS 872-50-4) 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** | If contact is likely, safety glasses with side shields are recommended. |
| **Skin protection** | |
| **Hand protection** | Wear appropriate chemical resistant gloves. Rubber gloves. |
| **Other** | Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. |
| **Respiratory protection** | No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. 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** | Wear appropriate thermal protective clothing, when necessary. |
| **General hygiene considerations** | Observe any medical surveillance requirements. When using do not 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** | Gel. |
| **Physical state** | Liquid. |
| **Form** | Liquid. |
| **Color** | Clear. |
| **Odor** | Not available. |
| **Odor threshold** | Not available. |
| **pH** | Not available. |
| **Melting point/freezing point** | 393.8 °F (201 °C) estimated |
| **Initial boiling point and boiling range** | Not available. |
| **Flash point** | 195.8 °F (91.0 °C) Closed Cup |
| **Evaporation rate** | Not available. |
| **Flammability (solid, gas)** | Not applicable. |

**Upper/lower flammability or explosive limits**

| | |
|---|---|
| **Explosive limit - lower (%)** | 9.5 % v/v |
| **Explosive limit - upper (%)** | 13 % v/v |
| **Vapor pressure** | Not available. |
| **Vapor density** | Not available. |
| **Relative density** | Not available. |
| **Solubility(ies)** | |
| **Solubility (water)** | Not available. |
| **Partition coefficient (n-octanol/water)** | Not available. |
| **Auto-ignition temperature** | 473 °F (245 °C) |
| **Decomposition temperature** | Not available. |
| **Viscosity** | Not available. |
| **Other information** | |
| **Explosive properties** | Not explosive. |
| **Flammability class** | Combustible IIIA estimated |
| **Oxidizing properties** | Not oxidizing. |

## 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** | Hazardous polymerization does not occur. |
| **Conditions to avoid** | Contact with incompatible materials. Sunlight. Excessive heat. Avoid temperatures exceeding the flash point. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. |
| **Incompatible materials** | Strong oxidizing agents. Strong acids. Peroxides. Phenols. |
| **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** | May cause irritation to the respiratory system. |
| **Skin contact** | Causes skin irritation. |
| **Eye contact** | Causes serious eye irritation. |
| N-METHYL-2-PYRROLIDONE | Species: Rabbit<br>Severity: Moderate |
| **Ingestion** | Health injuries are not known or expected under normal use. |
| **Symptoms related to the physical, chemical and toxicological characteristics** | Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause respiratory irritation. Coughing. Skin irritation. May cause redness and pain. May cause effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea. Symptoms of chronic exposure to tetracyclines include redness and swelling of the skin, rash, chills, tooth discoloration, yellowing of the skin and eyes, nausea, vomiting, diarrhea, stomach pain, and chest pain. |

**Information on toxicological effects**

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

| Components | Species | Test Results |
|---|---|---|
| Doxycycline hyclate (CAS 24390-14-5) | | |
| **Acute** | | |
| **Intraperitoneal** | | |
| LD50 | Rat | 262 mg/kg (hydrochloride) |
| **Intravenous** | | |
| LD50 | Rat | 228 mg/kg (hydrochloride) |
| **Oral** | | |
| LD50 | Mouse | 1900 mg/kg (hydrochloride) |
| | Rat | > 2000 mg/kg (hydrochloride) |
| **Chronic** | | |
| **Oral** | | |
| NOEL | Dog | < 10 mg/kg/day, 1 years (Target organs: Liver) |
| | Rat | 50 mg/kg/day, 18 months (Target organs: Thyroid, Bone) |
| **Subacute** | | |
| **Oral** | | |
| NOEL | Rat | 500 mg/kg/day, 30 days (Target organs: None identified) |
| N-METHYL-2-PYRROLIDONE (CAS 872-50-4) | | |
| **Acute** | | |
| **Dermal** | | |
| LD50 | Rabbit | 8000 mg/kg |

| Components | Species | Test Results |
|---|---|---|
| **Oral** | | |
| LD50 | Mouse | 7725 mg/kg |
| | Rat | 3914 mg/kg |
| **Chronic** | | |
| **Inhalation** | | |
| NOEL | Rat | 0.4 mg/L, 2 years Not carcinogenic |
| **Subacute** | | |
| **Oral** | | |
| NOAEL | Mouse | 2500 ppm, 28 days Kidney |
| | Rat | 6000 ppm, 28 days None identified |

**Skin corrosion/irritation** Causes skin irritation.

**Serious eye damage/eye irritation** Causes serious eye irritation.

**Eye Contact**

N-METHYL-2-PYRROLIDONE — Species: Rabbit; Severity: Moderate

**Respiratory or skin sensitization**

**Respiratory sensitization** Based on available data, the classification criteria are not met.

**Skin sensitization** Based on available data, the classification criteria are not met. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Photosensitivity has been reported in some individuals taking tetracyclines.

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

**Mutagenicity**

N-METHYL-2-PYRROLIDONE — Bacterial Mutagenicity (Ames); Result: Negative; Species: Salmonella

**Carcinogenicity** Due to partial or complete lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity** May damage the unborn child. May cause permanent discoloration of teeth if used during tooth development.

**Developmental effects**

| | |
|---|---|
| N-METHYL-2-PYRROLIDONE | 0.36 mg/L Embryo / Fetal Development, Maternal Toxicity Not Teratogenic<br>Result: NOEL<br>Species: Rat<br>Organ: Inhalation |
| | 237 mg/kg Embryo / Fetal Development, Maternal Toxicity Fetotoxicity Not Teratogenic<br>Result: NOAEL<br>Species: Rat<br>Organ: Dermal |
| Doxycycline hyclate | 50 mg/kg/day Embryo / Fetal Development, No effects at maximum dose<br>Result: NOEL<br>Species: Monkey<br>Organ: Oral |

**Reproductivity**

| | |
|---|---|
| N-METHYL-2-PYRROLIDONE | 237 mg/kg/day Reproductive & Fertility, Maternal toxicity Fetotoxicity<br>Result: NOEL<br>Species: Rat<br>Organ: Dermal |
| Doxycycline hyclate | 250 mg/kg/day Reproductive & Fertility-Females, No effects at maximum dose<br>Result: NOEL<br>Species: Rat<br>Organ: Oral |

**Specific target organ toxicity - single exposure** May cause respiratory irritation.

**Specific target organ toxicity - repeated exposure** Not classified.

**Aspiration hazard** Not an aspiration hazard.

**Further information** High doses of tetracyclines can cause a liver condition known as fatty liver. Individuals who suffer from high cholesterol, high triglycerides, or have alcoholic liver disease may be more susceptible. May produce kidney toxicity if kidney damage already exists (based on animal data).

## 12. Ecological information

**Ecotoxicity** Due to partial or complete lack of data the classification for hazardous to the aquatic environment, is not possible. The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available for this product. Not expected to bioaccumulate.

**Mobility in soil** No data available for this product.

**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. 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

**DOT**

**UN number** NA1993

**UN proper shipping name** Combustible Liquid, n.o.s. (N-METHYL-2-PYRROLIDONE)

**Transport hazard class(es)**

**Class** Combustible Liquid

**Subsidiary risk** -

**Packing group** III

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

**IATA**

Not regulated as dangerous goods.

**IMDG**

Not regulated as dangerous goods.

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

**General information** U.S. DOT: This material is only regulated for transportation as a hazardous material/dangerous good when shipped in bulk packaging (capacity >450L/119 gal.).

## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**Classified hazard categories**
Flammable (gases, aerosols, liquids, or solids)
Skin corrosion or irritation
Serious eye damage or eye irritation
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

**SARA 313 (TRI reporting)**

| Chemical name | CAS number | % by wt. |
|---|---|---|
| N-METHYL-2-PYRROLIDONE | 872-50-4 | 50-60 |

**Other federal regulations**

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations**

**California Proposition 65**

**WARNING:** This product can expose you to chemicals including N-METHYL-2-PYRROLIDONE, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

**California Proposition 65 - CRT: Listed date/Developmental toxin**

Doxycycline hyclate (CAS 24390-14-5) Listed: October 1, 1991
N-METHYL-2-PYRROLIDONE (CAS 872-50-4) Listed: June 15, 2001

**US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))**

N-METHYL-2-PYRROLIDONE (CAS 872-50-4)

**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 |
| Canada | Non-Domestic Substances List (NDSL) | No |

| Country(s) or region | Inventory name | On inventory (yes/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 |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | Yes |
| 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, including date of preparation or last revision

**Issue date** 01-06-2014

**Revision date** 01-24-2019

**Version #** 03

**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** This document has undergone significant changes and should be reviewed in its entirety.