SAFETY DATA SHEET

1. Identification

Product identifier	**DiroCHEK®**
Other means of identification	
Synonyms	DiroCHEK® Canine heartworm antigen test kit
Recommended use	Veterinary product used as diagnostic aid
Recommended restrictions	Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison & Drug Safety	1-866-531-8896
Product Support/Technical Services	1-888-963-8471
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium
Telephone	+32 10 808080
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A
	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
	Reproductive toxicity (the unborn child)	Category 1B
	Specific target organ toxicity, single exposure	Category 3 respiratory tract irritation
	Specific target organ toxicity, repeated exposure	Category 2 (kidney, liver)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements

Signal word	Danger
Hazard statement	Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation. May damage the unborn child. May cause damage to organs (kidney, liver) through prolonged or repeated exposure.

Precautionary statement

Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist/vapors. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. In case of inadequate ventilation wear respiratory protection.
Response	If on skin: Wash with plenty of water. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If exposed or concerned: Get medical advice/attention. If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. If experiencing respiratory symptoms: Call a poison center/doctor. Take off contaminated clothing and wash it before reuse.
Storage	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)	This mixture does not contain substances assessed to be vPvB / PBT according to Regulation (EC) No 1907/2006, Annex XIII.
Supplemental information	Handle as potentially infectious. With sample collection:

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
1,2-propylene Carbonate		108-32-7	5-10
N-METHYL-2-PYRROLIDONE		872-50-4	5-10
2,2-oxybisethanol diethylene glycol		111-46-6	1-5
Amphotericin B		1397-89-3	≤2
Gentamicin sulfate		1405-41-0	≥0.1 - <1.0

Other components below reportable levels.

Composition comments	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

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
Skin contact	Wash off with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Eye contact	Remove contact lenses, if present and easy to do. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	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. Skin irritation. May cause redness and pain. Edema. Jaundice. Prolonged exposure may cause chronic effects. Rash. Difficulty in breathing. May cause an allergic skin reaction.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Symptoms may be delayed.
General information	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. For personal protection, see section 8 of the SDS.

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. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. Handle as potentially infectious. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	The standard biosafety practices for handling infectious materials should be followed. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Ensure adequate ventilation. Prevent product from entering drains. 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. Handle as potentially infectious. 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	Obtain special instructions before use. 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. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Do not use in areas without adequate ventilation. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Do not empty into drains. Wash contaminated clothing before reuse. Observe good industrial hygiene practices. With sample collection: Handle as potentially infectious.
Conditions for safe storage, including any incompatibilities	Store locked up. Keep away from heat and sources of ignition. Keep tightly closed in a dry, cool and well-ventilated place. Store away from direct sunlight. Store at 2 - 7˚C (36 - 45˚F). Do not freeze. Store away from incompatible materials (see Section 10 of the SDS).

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.

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value
2,2-oxybisethanol diethylene glycol (CAS 111-46-6)	TWA	10 mg/m3
N-METHYL-2-PYRROLIDONE (CAS 872-50-4)	STEL	120 mg/m3
		30 ppm
	TWA	60 mg/m3
		15 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 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. Ensure adequate ventilation, especially in confined areas. Provide eyewash station and safety shower.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear appropriate chemical resistant gloves. Impervious gloves.

Other Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection No personal respiratory protective equipment normally required. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

Thermal hazards Not applicable.

General hygiene considerations Observe any medical surveillance requirements. 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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Liquid.

Color Not available.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point >199.4 °F (>93.0 °C) estimated

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

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 Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties Not explosive.

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 No dangerous reaction known under conditions of normal use.

Conditions to avoid Keep away from heat, spark, open flames and other sources of ignition. Sunlight. Contact with incompatible materials. Do not allow material to freeze.

Incompatible materials Strong oxidizing agents. Halogens. Nitrates. Peroxides. Phenols.

Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Amines. Nitrogen compounds. Carbon oxides.

11. Toxicological information

Information on likely routes of exposure

Inhalation May cause irritation to the respiratory system. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Prolonged inhalation may be harmful.

Skin contact Causes skin irritation. May cause an allergic skin reaction. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.

Eye contact Causes serious eye irritation.

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

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 Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause respiratory irritation. Difficulty in breathing. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash. Edema. Jaundice.

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
2,2-oxybisethanol diethylene glycol (CAS 111-46-6)		
Acute		
Dermal		
LD50	Rabbit	11890 mg/kg
Oral		
LD50	Rat	12570 mg/kg
Amphotericin B (CAS 1397-89-3)		
Acute		
Intraperitoneal		
LD50	Mouse	27.7 mg/kg
	Rat	> 5000 mg/kg
Intravenous		
LD50	Mouse	1.2 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
Subacute		
Intravenous		
LOAEL	Dog	37 mg/kg/day, 30 days (Kidney)
		16.5 mg/kg/day, 2 months (Kidney)

Components	Species	Test Results
Subchronic		
Oral		
NOAEL	Dog	1.6 mg/kg/day, 13 weeks (Male reproductive system, Female reproductive system)
	Rat	2 mg/kg/day, 13 weeks (Male reproductive system, Female reproductive system)
Gentamicin sulfate (CAS 1405-41-0)		
Acute		
Intramuscular		
LD50	Rat	384 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
N-METHYL-2-PYRROLIDONE (CAS 872-50-4)		
Acute		
Dermal		
LD50	Rabbit	8000 mg/kg
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 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization May cause an allergic skin reaction.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Mutagenicity

Amphotericin B	Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella , E. coli
N-METHYL-2-PYRROLIDONE	Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella
Gentamicin sulfate	DNA Binding Assay Result: Negative Species: E. coli
Amphotericin B	In Vitro Chromosome Aberration Result: Negative Species: Chinese Hamster Ovary (CHO) cells

Mutagenicity

Amphotericin B	In Vivo Micronucleus Result: Negative Species: Mouse

Carcinogenicity 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 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity May damage the unborn child.

Developmental effects

N-METHYL-2-PYRROLIDONE	0.36 mg/L Embryo / Fetal Development, Maternal Toxicity Not Teratogenic Result: NOEL Species: Rat Organ: Inhalation
Amphotericin B	10 mg/kg/day Embryo / Fetal Development, Not Teratogenic Fetotoxicity Result: NOAEL Species: Rabbit Organ: Oral
N-METHYL-2-PYRROLIDONE	237 mg/kg Embryo / Fetal Development, Maternal Toxicity Fetotoxicity Not Teratogenic Result: NOAEL Species: Rat Organ: Dermal
Gentamicin sulfate	375 mg/kg/day Embryo / Fetal Development, Developmental toxicity Result: LOAEL Species: Rat Organ: Intraperitoneal 660 mg/kg/day Prenatal & Postnatal Development, Developmental toxicity Result: LOAEL Species: Rat Organ: Subcutaneous 660 mg/kg/day Prenatal & Postnatal Development, Neonatal toxicity Result: LOAEL Species: Rat Organ: Subcutaneous
Amphotericin B	7.5 mg/kg/day Embryo / Fetal Development, Not teratogenic Fetotoxicity Result: NOAEL Species: Rat Organ: Oral

Reproductivity

N-METHYL-2-PYRROLIDONE	237 mg/kg/day Reproductive & Fertility, Maternal toxicity Fetotoxicity Result: NOEL Species: Rat Organ: Dermal

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

Specific target organ toxicity - repeated exposure	May cause damage to organs (kidney, liver) through prolonged or repeated exposure.
Aspiration hazard	Not an aspiration hazard.
Chronic effects	Prolonged inhalation may be harmful. May cause damage to organs through prolonged or repeated exposure.
Further information	May cause allergic respiratory and skin reactions. With sample collection: Handle as potentially infectious.

12. Ecological information

Ecotoxicity Avoid release to the environment. Based on available data, the classification criteria are not met for hazardous to the aquatic environment. 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.

Components	Species	Test Results
2,2-oxybisethanol diethylene glycol (CAS 111-46-6)		
Aquatic		
Acute		
Fish	LC50	Western mosquitofish (Gambusia affinis) > 32000 mg/l, 96 hours

Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available for this product.
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. Handle as potentially infectious. Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. 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.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Do not re-use empty containers.

14. Transport information

DOT

Not regulated as dangerous goods.

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.

15. Regulatory information

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

Toxic Substances Control Act (TSCA) One or more components of the mixture are not on the TSCA 8(b) inventory or are designated “inactive”.

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

N-METHYL-2-PYRROLIDONE (CAS 872-50-4) 1.0 % Annual Export Notification required.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories
Skin corrosion or irritation
Serious eye damage or eye irritation
Respiratory or skin sensitization
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	5-10

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) Contains component(s) regulated under the Safe Drinking Water Act.

US state regulations

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)

California Proposition 65

WARNING: This product can expose you to 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

N-METHYL-2-PYRROLIDONE (CAS 872-50-4) Listed: June 15, 2001

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	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	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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, including date of preparation or last revision

Issue date	11-21-2016
Revision date	06-16-2023
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.