# SAFETY DATA SHEET

## 1. Identification

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|---|---|
| **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 (USA)** | Zoetis Inc.<br>10 Sylvan Way<br>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<br>International CHEMTREC (24 hours): +1-703-527-3887 |
| **Company Name (CA)** | Zoetis Canada Inc.<br>16740 Trans-Canada Highway<br>Kirkland, Quebec, H9H 4M7 |
| **Emergency telephone number** | International CHEMTREC (24 hours): +1-703-527-3887 |
| **Contact E-Mail** | productsupport@zoetis.com |
| **Product Support** | 1-800-461-0917<br><br>All Safety Data Sheets are available via our Zoetis Canada website at https://www.zoetis.ca/sds/sds.aspx |
| **Supplier** | Not available. |

## 2. Hazard identification

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

**Label elements**

**Signal word** Danger

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|---|---|
| **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/vapours. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. 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 CENTRE/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. |
| **Supplemental information** | Handle as potentially infectious. With sample collection: |
| **Other hazards** | This mixture does not contain substances assessed to be vPvB / PBT according to Regulation (EC) No 1907/2006, Annex XIII. |

## 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.
All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

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|---|---|
| **Composition comments** | 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 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 centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious 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. Oedema. 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

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| **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. |

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| **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

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| **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 vapour. 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.<br><br>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.<br><br>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.<br><br>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

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|---|---|
| **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**

**Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)**

| Components | Type | Value |
|---|---|---|
| N-methyl-2-pyrrolidone (CAS 872-50-4) | TWA | 400 mg/m3 |

**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.

| | |
|---|---|
| **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**

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|---|---|
| **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. |
| **Colour** | Not available. |
| **Odour** | Not available. |
| **Odour threshold** | Not available. |
| **pH** | Not available. |
| **Melting point/freezing point** | Not available. |
| **Initial boiling point and boiling range** | Not available. |
| **Flash point** | >93.0 °C (>199.4 °F) 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. |
| **Vapour pressure** | Not available. |
| **Vapour 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. |
| **Oxidising properties** | Not oxidising. |

## 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 oxidising 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<br>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. Oedema. 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 |
| 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) |
| **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 |

| Components | Species | Test Results |
|---|---|---|
| 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<br>Severity: Moderate |

**Respiratory or skin sensitisation**

**Respiratory sensitisation** May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Skin sensitisation** 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)<br>Result: Negative<br>Species: Salmonella , E. coli |
| N-methyl-2-pyrrolidone | Bacterial Mutagenicity (Ames)<br>Result: Negative<br>Species: Salmonella |
| Gentamicin sulfate | DNA Binding Assay<br>Result: Negative<br>Species: E. coli |
| Amphotericin B | In Vitro Chromosome Aberration<br>Result: Negative<br>Species: Chinese Hamster Ovary (CHO) cells |
| | In Vivo Micronucleus<br>Result: Negative<br>Species: Mouse |

**Carcinogenicity** Due to partial or complete lack of data the classification is not possible.

**Reproductive toxicity** May damage the unborn child.

**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 |

**Developmental effects**

| | |
|---|---|
| Amphotericin B | 10 mg/kg/day Embryo / Fetal Development, Not Teratogenic Fetotoxicity<br>Result: NOAEL<br>Species: Rabbit<br>Organ: Oral |
| N-methyl-2-pyrrolidone | 237 mg/kg Embryo / Fetal Development, Maternal Toxicity Fetotoxicity Not Teratogenic<br>Result: NOAEL<br>Species: Rat<br>Organ: Dermal |
| Gentamicin sulfate | 375 mg/kg/day Embryo / Fetal Development, Developmental toxicity<br>Result: LOAEL<br>Species: Rat<br>Organ: Intraperitoneal<br><br>660 mg/kg/day Prenatal & Postnatal Development, Developmental toxicity<br>Result: LOAEL<br>Species: Rat<br>Organ: Subcutaneous<br><br>660 mg/kg/day Prenatal & Postnatal Development, Neonatal toxicity<br>Result: LOAEL<br>Species: Rat<br>Organ: Subcutaneous |
| Amphotericin B | 7.5 mg/kg/day Embryo / Fetal Development, Not teratogenic Fetotoxicity<br>Result: NOAEL<br>Species: Rat<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 |

**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

**TDG**

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

**Canadian regulations** This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

**Controlled Drugs and Substances Act**

Not regulated.

**Export Control List (CEPA 1999, Schedule 3)**

Not listed.

**Greenhouse Gases**

Not listed.

**Precursor Control Regulations**

Not regulated.

**International regulations**

**Stockholm Convention**

Not applicable.

**Rotterdam Convention**

Not applicable.

**Kyoto Protocol**

Not applicable.

**Montreal Protocol**

Not applicable.

**Basel Convention**

Not applicable.

**International Inventories**

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|---|---|---|
| Australia | Australian Inventory of Industrial Chemicals (AICIS) | No |

| Country(s) or region | Inventory name | On inventory (yes/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

**Issue date** 21-November-2016

**Revision date** 16-June-2023

**Version No.** 04

**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.