SAFETY DATA SHEET

Enrofloxacin (2.5%) Formulation

SECTION 1. IDENTIFICATION

Product name: Enrofloxacin (2.5%) Formulation
Other means of identification: No data available

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure: Category 1 (cartilage, Testis)

GHS label elements
Hazard pictograms: 

Signal Word: Danger

Hazard Statements: H361f Suspected of damaging fertility.
H372 Causes damage to organs (cartilage, Testis) through prolonged or repeated exposure.

Precautionary Statements: 
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Enrofloxacin</td>
</tr>
<tr>
<td></td>
<td>Benzyl alcohol</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air. Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Suspected of damaging fertility. Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.
### SAFETY DATA SHEET

**Enrofloxacin (2.5%) Formulation**

<table>
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<tr>
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<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<tbody>
<tr>
<td>5.3</td>
<td>10/10/2020</td>
<td>633909-00013</td>
<td>09/13/2019</td>
<td>04/27/2016</td>
</tr>
</tbody>
</table>

#### Specific hazards during fire fighting
- Exposure to combustion products may be a hazard to health.

#### Hazardous combustion products
- Carbon oxides

#### Specific extinguishing methods
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

#### Special protective equipment for fire-fighters
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### Environmental precautions
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g., by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

### Methods and materials for containment and cleaning up
- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## SECTION 7. HANDLING AND STORAGE

### Technical measures
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

### Local/Total ventilation
- Use only with adequate ventilation.

### Advice on safe handling
- Do not breathe mist or vapors.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure.
SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
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</thead>
<tbody>
<tr>
<td>Enrofloxacin</td>
<td>93106-60-6</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
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</tr>
</tbody>
</table>

Engineering measures

- Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection

- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Combined particulates and organic vapor type

Hand protection

Material: Chemical-resistant gloves

Eye protection

- Wear safety glasses with side shields or goggles.
  - If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
  - Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection

- Work uniform or laboratory coat.

Hygiene measures

- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the
**SAFETY DATA SHEET**

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</tr>
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</table>

use of administrative controls.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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<th>Value</th>
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<tr>
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<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>pH</td>
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</tr>
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<td>Initial boiling point and boiling range</td>
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<tr>
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<td>Decomposition temperature</td>
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<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Enrofloxacin (2.5%) Formulation

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Particle size: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:
Enrofloxacin:
Acute oral toxicity: LD50 (Rabbit): 500 - 800 mg/kg
LD50 (Rat): > 5,000 mg/kg
LD50 (Mouse): > 5,000 mg/kg

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Benzyl alcohol:
Acute oral toxicity: LD50 (Rat): 1,620 mg/kg
Acute inhalation toxicity:
LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Skin corrosion/irritation:
Not classified based on available information.

Components:
Enrofloxacin:
Result: No skin irritation

Benzyl alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Serious eye damage/eye irritation:
Not classified based on available information.

Components:
Enrofloxacin:
Result: Mild eye irritation

Benzyl alcohol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Respiratory or skin sensitization:

Skin sensitization:
Not classified based on available information.

Respiratory sensitization:
Not classified based on available information.

Components:
Enrofloxacin:
Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Benzyl alcohol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Germ cell mutagenicity
Not classified based on available information.

Components:

**Enrofloxacin:**
- Genotoxicity in vitro: Test Type: Chromosomal aberration
  - Result: positive
- Genotoxicity in vivo: Test Type: Micronucleus test
  - Species: Mouse
  - Result: negative
  - Test Type: Mammalian bone marrow sister chromatid exchange
  - Species: Hamster
  - Result: negative
  - Test Type: Chromosomal aberration
  - Species: Rat
  - Result: negative

**Benzyl alcohol:**
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Intraperitoneal injection
  - Result: negative

Carcinogenicity
Not classified based on available information.

Components:

**Enrofloxacin:**
- Species: Rat
- Application Route: Oral
- Exposure time: 2 Years
- Result: negative

**Benzyl alcohol:**
- Species: Mouse
- Application Route: Ingestion
Exposure time: 103 weeks
Method: OECD Test Guideline 451
Result: negative

Reproductive toxicity
Suspected of damaging fertility.

Components:

Enrofloxacin:
Effects on fertility: Test Type: Two-generation study
Species: Rat
Application Route: Oral
Fertility: LOAEL: 15 mg/kg body weight
Result: Effects on fertility, alteration in sperm morphology

Effects on fetal development: Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 210 mg/kg body weight
Result: Reduced fetal weight, No teratogenic effects.
Remarks: Maternal toxicity observed.

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 25 mg/kg body weight
Result: No fetotoxicity, No teratogenic effects.

Reproductive toxicity - Assessment: Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

Benzyl alcohol:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Embryo-fetal development
Species: Mouse
Application Route: Ingestion
Result: negative

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Causes damage to organs (cartilage, Testis) through prolonged or repeated exposure.

Components:

Enrofloxacin:
Target Organs: cartilage, Testis
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Enrofloxacin:
Species : Rat
NOAEL : 36 mg/kg
LOAEL : 150 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Testis

Species : Dog
NOAEL : 3 mg/kg
LOAEL : 9.6 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : cartilage

Species : Cat
NOAEL : 25 mg/kg
Application Route : Oral
Exposure time : 30 Days
Remarks : No significant adverse effects were reported

Benzyl alcohol:
Species : Rat
NOAEL : 1.072 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 28 Days
Method : OECD Test Guideline 412

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Enrofloxacin:
Ingestion : Symptoms: Gastrointestinal disturbance, central nervous system effects, Sensitivity to light

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Enrofloxacin:
Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 79.5 mg/l
### Exposure time: 96 h

- **LC50 (Oncorhynchus mykiss (rainbow trout))**: > 196 mg/l
- **LC50 (Oryzias latipes (Japanese medaka))**: > 100 mg/l

### Toxicity to daphnia and other aquatic invertebrates

- **EC50 (Hyalella azteca (Amphipod))**: > 206 mg/l
- **EC50 (Daphnia magna (Water flea))**: 79.9 mg/l

### Toxicity to algae/aquatic plants

- **EC50 (Pseudokirchneriella subcapitata (green algae))**: 3.1 mg/l
- **EC50 (Microcystis aeruginosa (blue-green algae))**: 0.049 mg/l

### Benzyl alcohol:

#### Toxicity to fish

- **LC50 (Pimephales promelas (fathead minnow))**: 460 mg/l

#### Toxicity to daphnia and other aquatic invertebrates

- **EC50 (Daphnia magna (Water flea))**: 230 mg/l

#### Toxicity to algae/aquatic plants

- **EC50 (Pseudokirchneriella subcapitata (green algae))**: 770 mg/l

#### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

- **NOEC (Daphnia magna (Water flea))**: 9.8 mg/l
- **NOEC (Daphnia magna (Water flea))**: 5 mg/l
- **LOEC (Daphnia magna (Water flea))**: 15 mg/l
Persistence and degradability

**Components:**

**Benzyl alcohol:**
Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Bioaccumulative potential

**Components:**

**Enrofloxacin:**
Partition coefficient: n-octanol/water : log Pow: 0.5

**Benzyl alcohol:**
Partition coefficient: n-octanol/water : log Pow: 1.05

Mobility in soil

**Components:**

**Enrofloxacin:**
Distribution among environmental compartments : Koc: 5.55

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

**UNRTDG**
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Enrofloxacin)

Class : 9
Packing group : III
Labels : 9

**IATA-DGR**
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
## Enrofloxacin (2.5%) Formulation

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<th>Class</th>
<th>Packing group</th>
<th>Labels</th>
<th>Packing instruction (cargo aircraft)</th>
<th>Packing instruction (passenger aircraft)</th>
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### IMDG-Code

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<tr>
<td>UN 3082</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1-Cyclopropyl-7-(1-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quino)</td>
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<tr>
<th>Class</th>
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<th>Labels</th>
<th>EmS Code</th>
<th>Marine pollutant</th>
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<td>9</td>
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</table>

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### TDG

<table>
<thead>
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</tbody>
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<tr>
<th>Class</th>
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<th>Labels</th>
<th>ERG Code</th>
<th>Marine pollutant</th>
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<tbody>
<tr>
<td>9</td>
<td>III</td>
<td>9</td>
<td>171</td>
<td>yes (1-Cyclopropyl-7-(1-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quino)</td>
</tr>
</tbody>
</table>

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>AICS</th>
<th>DSL</th>
<th>IECSC</th>
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</thead>
<tbody>
<tr>
<td>not determined</td>
<td>not determined</td>
<td>not determined</td>
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</tbody>
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Version 5.3  Revision Date: 10/10/2020  SDS Number: 633909-00013  Date of last issue: 09/13/2019
Date of first issue: 04/27/2016

SECTION 16. OTHER INFORMATION

Full text of other abbreviations:

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet:


Revision Date: 10/10/2020
Date format: mm/dd/yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guideline for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.
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CA / Z8