1. IDENTIFICATION

Product identifier

Product code: DE121

Product Name: DEXAMETHASONE, MICRONIZED, USP

Other means of identification

Synonyms: 1-Dehydro-16-alpha-methyl-9-alpha-fluorohydrocortisone
16-alpha-Methyl-9-alpha-fluoro-1,4-pregnadiene-11-beta,17-alpha,21-triol-3,20-dione
16-alpha-Methyl-9-alpha-fluoro-1-dehydrocortisol
16-alpha-Methyl-9-alpha-fluoro-11-beta,17-alpha,21-trihydroxyprogna-1,4-diene-3,20-dione
16-alpha-Methyl-9-alpha-fluoro-delta(sup 1)-hydrocortisone
16-alpha-Methyl-9-alpha-fluoroprednisolone
4-alpha-Fluoro-16-alpha-methyl-11-beta,17,21-trihydroxyprogna-1,4-diene-3,20-dione
9-Fluoro-11-beta,17,21-trihydroxy-16-alpha-methylpregna-1,4-diene-3,20-dione
9-alpha-Fluoro-11-beta,17-alpha,21-trihydroxy-16-alpha-methylpregna-1,4-diene-3,20-dione
9-alpha-Fluoro-16-alpha-methyl-1,4-pregnadiene-11-beta,17-alpha,21-triol-3,20-dione
9-alpha-Fluoro-16-alpha-methylprednisolone

CAS #: 50-02-2
RTECS #: TU3980000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication.
Uses advised against: No information available

Supplier: Spectrum Chemical Mfg. Corp
14422 South San Pedro St.
Gardena, CA  90248
(310) 516-8000.

Order Online At: https://www.spectrumchemical.com
Emergency telephone number: Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

| Serious eye damage/eye irritation | Category 2A |

Product code: DE121  Product name: DEXAMETHASONE, MICRONIZED, USP
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>100</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention.
Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Immediate medical attention is required.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms: Causes serious eye irritation. May cause skin irritation. May cause irritation of respiratory tract. Central nervous system effects. May affect the cardiovascular system. May cause hyperglycemia. It may affect the kidneys. Muscle weakness. Causes digestive (gastrointestinal) tract irritation. Ingestion may cause vomiting and nausea. It may cause abdominal (stomach) distention. Hiccups. Headache. Glucocorticoids (Corticosteroids) may cause osteoporosis and bone fractures, back pain, joint pain/stiffness, numbness, weakness, infection, delayed wound healing, thinning skin, bruising, acne, menstrual irregularities, headache, sweating, eye pain, vision changes, mental and behavior changes, fever, muscle pain, immune system depression, purple lines on skin, tremors, Cushing's syndrome, electrolyte imbalance (sodium and fluid retention, potassium loss (hypokalemia)).

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders
First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media
Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO2). Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, and possibly, but unlikely, hydrogen fluoride gas

Hazardous Combustion Products: No information available.

Specific hazards: May be combustible at high temperatures

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions:
Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Remove all sources of ignition.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment
Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up
Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:
Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice
Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:
Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:
Oxidizing agents
Acids

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WHEEL</th>
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Canada

<table>
<thead>
<tr>
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<th>CAS-No.</th>
<th>Canada - Alberta</th>
<th>Canada - British Columbia</th>
<th>Canada - Ontario</th>
<th>Canada - Quebec</th>
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<td>None</td>
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<td>None</td>
</tr>
</tbody>
</table>

Product code: DE121
Product name: DEXAMETHASONE, MICRONIZED, USP
Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Goggles or Safety glasses with side-shields
Skin and body protection: Long sleeved clothing. Chemical resistant apron. Gloves.
Respiratory protection: Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds), inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical state:</th>
<th>Appearance:</th>
<th>Color:</th>
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<tbody>
<tr>
<td>Solid</td>
<td>Crystalline powder.</td>
<td>White. Practically white.</td>
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<table>
<thead>
<tr>
<th>Odor:</th>
<th>Taste</th>
<th>Formula:</th>
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<tbody>
<tr>
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<table>
<thead>
<tr>
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<th>Flashpoint (°C/°F):</th>
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<table>
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<th>Lower Explosion Limit (%):</th>
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<th>Decomposition temperature(°C/°F):</th>
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<th>pH:</th>
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<tr>
<th>Evaporation rate:</th>
<th>Vapor density:</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Odor threshold (ppm):</th>
<th>Partition coefficient</th>
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<tr>
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</table>

<table>
<thead>
<tr>
<th>Product code:</th>
<th>Product name:</th>
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</thead>
<tbody>
<tr>
<td>DE121</td>
<td>DEXAMETHASONE, MICRONIZED, USP</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity
Reactive with oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Incompatible materials.

Incompatible Materials: Oxidizing agents, Acids

Hazardous decomposition products: Carbon oxides.

Other Information
Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion, Inhalation.

Acute Toxicity

Component Information

Dexamethasone

CAS-No. 50-02-2

LD50/oral/rat = > 3 g/kg Oral LD50 Rat
LD50/oral/mouse = No information available
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

Product code: DE121
Product name: DEXAMETHASONE, MICRONIZED, USP
LD50/oral/rat =
VALUE- Acute Tox Oral = > 3000 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = No information available

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms
Skin Contact: May cause skin irritation.
Eye Contact: Causes serious eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion May cause hyperglycemia. May cause gastrointestinal tract irritation. May cause upset stomach. May cause constipation. May cause abdominal distension. May cause headache, nausea, vomiting. May cause central nervous system effects (affect behavior).

Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity Prolonged or repeated ingestion: May cause gastrointestinal tract irritation with nausea, constipation, malaise, abdominal distension, peritonitis, hiccups. May cause ulcerative esophagitis, peptic ulcer with possible subsequent perforation and hemorrhage. May affect behavior/central nervous system (convulsions, vertigo, dizziness, headache, psychic disturbances, anxiety, nervousness, irritability, insomnia), cardiovascular system, brain, endocrine system (menstrual irregularities, suppression of growth in children, Cushing’s syndrome, adrenocortical and pituitary unresponsiveness, decreased carbohydrate tolerance, hyperglycemia, manifestations of latent diabetes mellitus, increased requirements for insulin or oral hypoglycemic agents in diabetics), eyes (posterior subcapsular cataracts, increased intraocular pressure, glaucoma), metabolism (weight gain, increased appetite, electrolyte imbalance, water retention), musculoskeletal system (muscle weakness, loss of muscle mass, steroid myopathy, Osteoporosis, vertebral compression fractures, pathologic fractures of long bones, tendon rupture), skin (impaired wound healing, thin fragile skin or skin atrophy, easy bruising, petechiae and ecchymoses, erythema, burning or itching, urticaria, acneform eruptions, hypopigmentation), blood (thromboembolism), kidneys. It may also cause increased hair growth. May cause anaphylactoid or hypersensitivity reactions.
Prolonged or repeated administration onto the skin may cause skin irritation with redness, burning itching, dryness, folliculitis, increased hair growth, acneform eruptions, hypopigmentation, hives, petechiae and ecchymosis, skin atrophy and allergic contact dermatitis.

**Sensitization:**

No information available.

**Mutagenic Effects:**

No information available

**Carcinogenic effects:**

Dexamethasone is a glucocorticoid. Glucocorticoid therapy has been linked to an increased risk of development of Kaposi's sarcoma.

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>IARC</th>
<th>ACGIH - Carcinogens</th>
<th>NTP</th>
<th>OSHA HCS - Carcinogens</th>
<th>Australia - Notifiable Carcinogenic Substances</th>
<th>Australia - Prohibited Carcinogenic Substances</th>
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<tbody>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
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<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
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</tr>
</tbody>
</table>

**ACGIH (American Conference of Governmental Industrial Hygienists)**

**IARC (International Agency for Research on Cancer)**

**NTP (National Toxicology Program)**

**OSHA (Occupational Safety and Health Administration of the US Department of Labor)**

**Reproductive toxicity**

Suspected of damaging fertility or the unborn child

**Reproductive Effects:**

May cause adverse reproductive effects based on animal data

**Developmental Effects:**

May cause adverse developmental effects based on animal data

**Teratogenic Effects:**

May cause birth defects (teratogenic effects) based on animal test data

**Specific Target Organ Toxicity**

STOT - single exposure: No information available.

STOT - repeated exposure: No information available.

Target Organs: No information available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

Ecotoxicity effects: No data available.

**Persistence and degradability:**

No information available

**Bioaccumulative potential:**

No information available.

**Mobility:**

No information available.

**13. DISPOSAL CONSIDERATIONS**

**Disposal Methods**

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.
Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

<table>
<thead>
<tr>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

14. TRANSPORT INFORMATION

DOT
- **UN-No.:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Class:** No information available
- **Packing group:** No information available
- **Emergency Response Guide Number:** No information available
- **Marine Pollutant:** No data available
- **DOT RQ (lbs):** No information available
- **Special Provisions:** No Information available
- **Symbol(s):** No information available
- **Description:** No information available

TDG (Canada)
- **UN-No.:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Risk:** No information available
- **Packing Group:** No information available
- **Marine Pollutant:** No Information available
- **Description:** No information available

ADR
- **UN-No.:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Packing Group:** No information available
- **Subsidiary Risk:** No information available

IMO / IMDG
- **UN-No.:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Packing Group:** No information available
- **Subsidiary Risk:** No information available

RID
- **UN-No.:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Risk:** No information available
- **Packing Group:** No information available

ICAO
- **UN-No.:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available

**Product code:** DE121 **Product name:** DEXAMETHASONE, MICRONIZED, USP
Subsidiary Risk: No information available
Packing Group: No information available

IATA
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
ERG Code: No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

<table>
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<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>U.S. TSCA</th>
<th>KOREA KECL</th>
<th>Philippines (PICCS)</th>
<th>Japan ENCS</th>
<th>CHINA</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
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<tbody>
<tr>
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<td>Present KE-17063</td>
<td>Present</td>
<td>Not present</td>
<td>Present</td>
<td>Present</td>
<td>Present 200-003-9</td>
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</table>

U.S. Regulations


Chemicals Known to the State of California to Cause Cancer:
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity:</th>
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CERCLA/SARA

<table>
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<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>CERCLA - Hazardous Substances and their Reportable Quantities</th>
<th>Section 302 Extremely Hazardous Substances and TPQs</th>
<th>Section 302 Extremely Hazardous Substances and RQs</th>
<th>Section 313 - Chemical Category</th>
<th>Section 313 - Reporting de minimis</th>
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<tbody>
<tr>
<td>Dexamethasone</td>
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<td>None</td>
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U.S. TSCA

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)</th>
<th>TSCA 8(d) - Health and Safety Reporting</th>
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</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
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</table>

Canada

WHMIS hazard class:
D2A Very toxic materials
D2B Toxic materials

Canada Controlled Products Regulation:
This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS
contains all of the information required by the CPR.

**Inventory**

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<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
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<th>Canada (NDSL)</th>
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<th>Components</th>
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<th>Components</th>
<th>CAS-No.</th>
<th>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
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<tbody>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
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</table>

**EU Classification**

**R-phrase(s)**
R36 - Irritating to eyes.
R63 - Possible risk of harm to the unborn child.

**S -phrase(s)**
S37 - Wear suitable gloves.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration Limits:</th>
<th>Safety Phrases</th>
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The product is classified in accordance with Annex VI to Directive 67/548/EEC

**Indication of danger:**
Xn - Harmful.

**16. OTHER INFORMATION**

<table>
<thead>
<tr>
<th>Preparation Date:</th>
<th>8/23/2016</th>
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<tbody>
<tr>
<td>Revision Date:</td>
<td>8/23/2016</td>
</tr>
<tr>
<td>Prepared by:</td>
<td>Sonia Owen</td>
</tr>
</tbody>
</table>

**Disclaimer:**
All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the...
completeness or accuracy of the information contained herein.

End of Safety Data Sheet