Amitriptyline Hydrochloride, USP

Section 1 Identification of the substance/mixture and of the company/undertaking

Product Identifier:
Identification on the label/ Tradename: Amitriptyline Hydrochloride, USP
Identification of the Product: CAS# 549-18-8
RTECS No.: HO9450000
Cl No.: Not Available

Synonyms:
Amitriptyline chloride; Damilen hydrochloride; Deprex; Laroxyl; Lentizol; Limbitrol DS; Miketorin; Proheptadien monohydrochloride; 1-Propanamine, 3-(10,11-dihydro-5H-dibenzo(a,d)cyclohepten-5 ylidene)-N,N-dimethyl-,hcl; Rantorin; Saroten; Triavil; 10,11-Dihydro-N,N-dimethyl-5H dibenzo[a,d]cycloheptene-delta(sup 5,gamma)-propylamine HCl; 5-(3-Dimethylamino propylidene)dibenz(o,a)(1,4)cycloheptadienecycloheptene hydrochloride; Domical; Elavil hydrochloride; Endep; Etrafon; Tryptizol

Relevant identified uses of the substance and uses advised against:
Identified Uses: Medication. Antidepressant.
Uses Advised Against: No information available

Name, address, and telephone number of the manufacturer:
Refer to Supplier

Name, address, and telephone number of the supplier:
Encore Scientific 801 W. New Orleans St., Broken Arrow, Ok 74011
Supplier's Telephone #
800-454-2304 Monday to Friday 8:00 am to 6:00 pm (Central time)
24 Hr. Emergency Tel #
INFOTRAC: (800) 535-5053 (Within Continental US and Canada); (352)323-3500 (International)

Section 2 Hazards Identification

Classification
This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Label Elements:
Warning!
Harmful if swallowed. May cause skin and eye irritation. May cause irritation of respiratory tract.
SAFETY DATA SHEET

Section 3 Composition/information on ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS No.</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitriptyline Hydrochloride</td>
<td>549-18-8</td>
<td>100</td>
</tr>
</tbody>
</table>

Section 4 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 clothes and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

**Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist call a physician.

**Inhalation:** Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. WARNING! It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.

**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Toxic if swallowed. Immediate medical attention is required. Call a physician or Poison Control Centre immediately.

**Notes to Physician:** Treat symptomatically

Section 5 Fire-Fighting measures

**Extinguishing Media**

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

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon monoxide; Carbon dioxide; Nitrogen oxides

**Specific hazards:** May be combustible at high temperatures. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard

**Special Protective Actions for Firefighters**

**Specific Methods:** Dike fire-control water for later disposal; do not scatter the material. For larger fires, use water spray or fog. Cool containers with flooding quantities of water until well after fire is out.

**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.
Amitriptyline Hydrochloride, USP

SAFETY DATA SHEET

Section 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

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

Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter 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. In case of large spill, dike if needed. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up: Sweep up and shovel into suitable containers for disposal. Use a suitable vacuum cleaner. Clean contaminated surface thoroughly.

Section 7 Handling and storage

Precautions for safe handling

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

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 vapors or 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.
SAFETY DATA SHEET

Section 8 Exposure Controls/Personal Protection

Control Parameters
National occupational exposure limits: Not determined

United States

<table>
<thead>
<tr>
<th>Components</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA Wheel</th>
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<tr>
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<td>None</td>
<td>None</td>
<td>None</td>
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<tr>
<td>549-18-8</td>
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</tbody>
</table>

Canada

Canada Occupational Exposure Limits: Not determined

<table>
<thead>
<tr>
<th>Components</th>
<th>Alberta</th>
<th>British Columbia</th>
<th>Ontario</th>
<th>Quebec</th>
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<tr>
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<td>None</td>
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<tr>
<td>549-18-8</td>
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<td></td>
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</table>

Australia and Mexico

Occupational Exposure Limits for Australia and Mexico: Not determined

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<thead>
<tr>
<th>Components</th>
<th>Australia</th>
<th>Mexico</th>
</tr>
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<td>None</td>
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<tr>
<td>549-18-8</td>
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</tbody>
</table>

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: Safety glasses. Safety glasses with side-shields.


Respiratory protection: Wear respirator with dust filter.

Hygiene measures: Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.
Amitriptyline Hydrochloride, USP

Section 9 Physical and chemical properties

Information on basic physical and chemical properties:

<table>
<thead>
<tr>
<th>Physical state:</th>
<th>Appearance:</th>
<th>Color:</th>
<th>Odor:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid.</td>
<td>Crystalline powder</td>
<td>White. Practically white</td>
<td>None.</td>
</tr>
<tr>
<td>Taste</td>
<td>Molecular/Formula weight:</td>
<td>Lower Explosion Limit (%):</td>
<td>Upper Explosion Limit (%):</td>
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<td>No information available</td>
<td>313.86</td>
<td>No information available</td>
<td>No information available</td>
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<tr>
<td>Flash point (°C):</td>
<td>Autoignition Temperature (°C/°F):</td>
<td>Melting point/range(°C/°F):</td>
<td>Boiling point/range(°C/°F):</td>
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<tr>
<td>Not applicable</td>
<td>No information available</td>
<td>196-197 °C/384.8-386.6 °F</td>
<td>No information available</td>
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<td>pH:</td>
<td>Decomposition temperature(°C/°F):</td>
<td>Specific gravity:</td>
<td>Density (g/cm3):</td>
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<tr>
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<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
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<td>Evaporation rate:</td>
<td>Vapor pressure @ 20°C (kPa):</td>
<td>Vapor density:</td>
<td>Bulk density:</td>
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<tr>
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<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
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<td>VOC content (g/L):</td>
<td>Partition coefficient (n-octanol/water):</td>
<td>Odor threshold (ppm):</td>
<td>Miscibility:</td>
</tr>
<tr>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
</tr>
</tbody>
</table>

Solubility: Freely soluble in Chloroform
Freely soluble in alcohol
Solubility in Water: 10.84 mg/l @ 25 °C

Section 10 Stability and reactivity

Reactivity: Reactive with oxidizing agents

Chemical stability
Stability: Stable at normal conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur.

Conditions to avoid: Heat. Ignition sources. Avoid dust formation. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Incompatible Materials: Oxidizing agents.


Other Information
Corrosivity: No information available
Special Remarks on Corrosivity: No information available
Amitriptyline Hydrochloride, USP

SDS Preparation Date (10/17/2016)

SAFETY DATA SHEET

Section 11 Toxicological information

Information on likely routes of exposure
Principal Routes of Exposure: None
Acute Toxicity

Component Information
Amitriptyline Hydrochloride – 549-18-8
LD50/oral/rat = 240 mg/kg
LD50/oral/mouse = 140 mg/kg
LD50/dermal/rat = No information available
LD50/dermal/rabbit = 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
LC50/inhalation/rat No information available
LC50/Inhalation/mouse No information available
LD50/dermal/rabbit No information available
LD50/dermal/rat No information available
LD50/oral/mouse = 140mg/kg
LD50/oral/rat 240 mg/kg

Symptoms
Skin Contact: May cause skin irritation. Contact with eyes may cause irritation.
Eye Contact: May cause irritation of respiratory tract.
Inhalation: May cause irritation of respiratory tract. Harmful if swallowed.
Ingestion: May cause dry mouth, thirst. Ingestion may cause nausea, vomiting. May cause constipation. May cause diarrhea. May cause loss of appetite. May affect the cardiovascular system (vasodilation, hypotension, tachycardia, chest pain). May affect the cardiovascular system (cardiac arrhythmias). May affect respiration (difficult or labored breathing resulting in shortness of breath). May affect respiration (respiratory depression). May cause mydriasis (dilated pupils). May cause urinary retention.
Amitriptyline Hydrochloride, USP

SDS Preparation Date (10/17/2016):

SAFETY DATA SHEET

Section 11 Toxicological information (continued)

Ingestion (continued):

- May cause headache
- May cause blurred vision
- May affect behavior/central nervous system (dizziness, drowsiness)
- May affect behavior/central nervous system (somnolence, convulsions, tremor, ataxia)
- May affect behavior/central nervous system (fatigue, weakness)
- May affect behavior/central nervous system (agitation, disorientation, hallucinations, delusion, anxiety, insomnia, trouble concentrating, nightmares, confusion, irritability, restlessness, tremor, problems with speech, impaired consciousness, fainting, coma)
- May cause dystonia, which is defined as prolonged or abnormal contractions of muscle groups. Symptoms may include: spasm of the neck muscles, sometimes progressing tightness of the throat, difficulty swallowing, difficulty breathing, and/or protrusion of the tongue
- May cause Parkinson's-like symptoms (Pseudo-parkinsonism). They may include: mask-like facies, shuffling gait, cogwheel rigidity, pill-rolling motion, drooling, tremors)
- May affect the peripheral nervous system (paresthesia - tingling, pricking, or numbness of the skin (known as the feeling of "pins and needles) generally of the hands and feet (extremities)).
- May cause hyperglycemia
- May cause hypoglycemia (low blood sugar)
- May cause tinnitus

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

Chronic Toxicity:

- May cause Tardive Dyskinesia. It most commonly occurs in patients which psychiatric conditions who are treated with antipsychotic drugs for many months or years. This is a disorder that involves involuntary movements, especially of the lower face. Symptoms include facial grimacing, finger movement, jaw swinging, repetitive chewing and tongue thrusting. Prolonged or repeated ingestion may affect the liver (jaundice, liver function tests impaired). Prolonged or repeated ingestion may cause menstrual irregularities or loss of menstrual periods women, abnormal production of breast milk in non-breast feeding women, breast enlargement in men, ejaculatory disorders/impotence in men. Prolonged or repeated ingestion may cause spontaneous flow of milk from the breast, breast enlargement, absence of menstrual period. Prolonged or repeated ingestion may affect the blood (leukopenia, agranulocytosis, eosinophilia, pancytopenia, thrombocytopenic purpura, bone marrow depression). Prolonged or repeated ingestion may affect the thyroid. Prolonged or repeated ingestion may affect the urinary system. Prolonged or repeated skin contact may cause allergic reaction. Prolonged or repeated inhalation may cause allergic reaction.

Sensitization:

- No information available

Mutagenic Effects:

- May affect genetic material. Animal experiments showed mutagenic effects.
Amitriptyline Hydrochloride, USP

SDS Preparation Date (10/17/2016):

SAFETY DATA SHEET

Section 11 Toxicological information (continued)

Reproductive Effects: May cause adverse reproductive effects. Experiments have shown reproductive toxicity effects on laboratory animals. There are no adequate and well-controlled studies in humans. Data in humans were insufficient to evaluate the effects on reproduction.

Teratogenic Effects: May cause birth defects (teratogenic effects). Possible risk of harm to the unborn child.

Target Organs: Central nervous system. Cardiovascular system.

Carcinogenic effects: Not considered carcinogenic.

<table>
<thead>
<tr>
<th>Components</th>
<th>ACGIH-Carcinogens</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA HCS-Carcinogens</th>
<th>Australia-Prohibited Carcinogenic Substances</th>
<th>Australia-Notifiable Carcinogenic Substances</th>
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</thead>
<tbody>
<tr>
<td>Amitriptyline Hydrochloride</td>
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<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

Section 12 Ecological information

Ecotoxicity

Toxicity to terrestrial and aquatic plants and animals: No information available

Ecotoxicity effects: No data available

Aquatic toxicity: No information available

Mobility: No information available

Persistence and degradability: No information available

Bioaccumulative potential: Potential for bioconcentration in aquatic organisms is very high.

Section 13 Disposal considerations

Disposal Instruction

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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</tr>
</thead>
<tbody>
<tr>
<td>Amitriptyline HCL</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
Amitriptyline Hydrochloride, USP

Section 14 Transport information

DOT
UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s.
Hazard Class: 6.1
Packing Group: III
Subsidiary Risk: Not applicable
Marine Pollutant: No data available
ERG No: 154
DOT RQ (lbs): No information available

IMO / IMDG continued
Subsidiary Risk: No information available
Description: No information available
IMDG Page: No information available
Marine Pollutant: No information available
EMS: F-A
MFAG: No information available
Maximum Quantity: No information available

TDG (Canada)
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: III
Subsidiary Risk: No information available
Description: No information available

RID
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: III
Subsidiary Risk: 6.1
Classification Code: No information available
Description: No information available

ICAO
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: III
Subsidiary Risk: No information available
Description: No information available

IATA
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: III
Subsidiary Risk: No information available
ERG Code: 6L
Description: No information available

ADR
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: III
Subsidiary Risk: No information available
Classification Code: No information available
Description: No information available
CEFIC Tremcard No: No information available

CEFIC Tremcard No: No information available

IMO / IMDG
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: III
Subsidiary Risk: No information available
ERG Code: 6L
Description: No information available
Amitriptyline Hydrochloride, USP

SAFETY DATA SHEET

Section 15 Regulation information

International Inventories

<table>
<thead>
<tr>
<th>Components</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>
<td>Amitriptyline Hydrochloride</td>
<td>Present</td>
<td>Present KE - 10614</td>
<td>Present</td>
<td>Not present</td>
<td>Not present</td>
<td>Present</td>
<td>Present 208-964-6</td>
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</tbody>
</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>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity</th>
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CERCLA/SARA

<table>
<thead>
<tr>
<th>Components</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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U.S. TSCA

<table>
<thead>
<tr>
<th>Components</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>Amitriptyline Hydrochloride</td>
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<td>Not applicable</td>
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Canada

WHMIS hazard class: D1B 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.
Amitriptyline Hydrochloride, USP

SDS Preparation Date (10/17/2016):

SAFETY DATA SHEET

Section 15 Regulation information (continued)

Inventory

<table>
<thead>
<tr>
<th>Components</th>
<th>Canada (DSL)</th>
<th>Canada (NDSL)</th>
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<table>
<thead>
<tr>
<th>Components</th>
<th>CEPA Schedule I – Toxic Substances</th>
<th>CEPA – 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
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<tbody>
<tr>
<td>Amitriptyline Hydrochloride</td>
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<td>Not listed</td>
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EU Classification

R-phrase(s): R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.
S-phrase(s): S46 - If swallowed, seek medical advice immediately and show this container or label.

The Product is classified in accordance with Annex VI to Directive 67/548/EEC
Indication of Danger: Xn – Harmful

Xn

Section 16 Other information

Further information: This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

Notice to reader:
Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.