Section 1. Product and Company Identification

Product Name: Macitentan
Product ID: M0009
Chemical Name (Synonyms): ACT-064992, Actelion-1

Supplier: LKT Laboratories, Inc
545 Phalen Blvd.
St. Paul, MN 55130 USA
Ph: 651-644-8424 Fax: 651-644-8357
www.lktlabs.com - getinfo@lktlabs.com

Emergency Phone #: 1-800-424-9300

Section 2. Hazards Identification

GHS Classification: Not a hazardous substance or mixture.

GHS Label elements including precautionary statements

Pictogram

Signal word

Hazard and precautionary statements

Hazard statement: Not a hazardous substance or mixture.
Precautionary statement: Not a hazardous substance or mixture.

HMIS Classification
Health hazard: 0
Chronic health hazard: *
Flammability: 0
Physical hazard: 0

NFPA Rating
Health hazard: 0
Fire hazard: 0
Reactivity hazard: 0

Potential Health Effects
Inhalation - May be harmful if inhaled. May cause respiratory tract irritation.
Skin - May be harmful if absorbed through skin. May cause skin irritation.
Eyes - May cause eye irritation.
Flash Point
Not available.

Extinguishing Media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Firefighting Procedures
Wear self-contained breathing apparatus for firefighting if necessary.

Unusual Fire Hazards
Carbon oxides, nitrogen oxides (NOx).

Eye Contact
Flush eyes with water as a precaution.

Skin Contact
Wash off with soap and plenty of water.

Inhalation
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Ingestion
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Section 4. First Aid Measures
General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

Eye Contact
Flush eyes with water as a precaution.

Skin Contact
Wash off with soap and plenty of water.

Inhalation
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Ingestion
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Section 5. Firefighting Measures
Flash Point
Not available.

Extinguishing Media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Firefighting Procedures
Wear self-contained breathing apparatus for firefighting if necessary.

Unusual Fire Hazards
Carbon oxides, nitrogen oxides (NOx).

Section 6. Accidental Release Measures
Personal Precautions
Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist, or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental Precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods and materials for containment and cleanup
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Section 7. Handling and Storage
Handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

Storage Conditions
Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature: Ambient

Hazardous Decomposition Products
Not available.

Other Remarks
Section 8. Exposure Controls/Personal Protection

**Personal protective equipment**

**EXPOSURE CONTROLS**
Contains no substances with occupational exposure limit values.

**GENERAL HYGIENE**
General industrial hygiene practice.

**PERSONAL PROTECTION**

**Eye/face protection:** Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

**Skin protection:** Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove’s outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

**Body protection:** Choose body protection in relation to its type, to the concentration and amount of dangerous substances and to the specific workplace. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Respiratory protection:** Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

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Section 9. Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid</td>
<td>White to off-white powder</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Solubility</td>
<td>33mg/ml in DMSO and DMF</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Lower explosion limit</td>
<td>Not available.</td>
</tr>
<tr>
<td>Upper explosion limit</td>
<td>Not available.</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Not available.</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not available.</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>Not available.</td>
</tr>
<tr>
<td>pH</td>
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</tr>
<tr>
<td>Ignition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Autoignition temperature</td>
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</tr>
<tr>
<td>Vapor pressure</td>
<td>Not available.</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available.</td>
</tr>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

Section 10. Stability and Reactivity

**Stability**

Stable under recommended storage conditions.

**Materials To Avoid**

Strong oxidizing agents.

**Hazardous Decomposition Products**

Not available.
Section 11. Toxicological Information

Oral LD50 Not available.  
Inhalation LC50 Not available.  
Dermal LD50 Not available.  
Other information on acute toxicity Not available.  
Skin corrosion/irritation Not available.  
Serious eye damage/irritation Not available.  
Respiratory or skin sensitization Not available.  
Germ cell mutagenicity Not available.  
Reproductive Toxicity Not available.  
Aspiration Hazard Not available.  
Specific organ toxicity single exposure (GHS) Not available.  
Synergistic effects Not available.  
Specific organ toxicity repeated exposure (GHS) Not available.  
Additional Information Not available.  
Teratogenicity Not available.  
Signs and symptoms of exposure Not available.  

Potential Health Effects  
Inhalation - May be harmful if inhaled. May cause respiratory tract irritation.
Skin - May be harmful if absorbed through skin. May cause skin irritation.
Eyes - May cause eye irritation.
Ingestion - May be harmful if swallowed.

Carcinogenicity  
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by IARC.
ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Section 12. Ecological Information

Toxicity Not available.  
Mobility in soil Not available.  
PBT and vPvB assessment Not available as chemical safety assessment not required/not
Persistence and degradability  Not available.

Bioaccumulative potential  Not available.

Other adverse effects  Not available.

Section 13. Disposal Considerations

Waste Disposal
Dispose of material according to all federal, state and local regulations. Offer material to a licensed, professional waste disposal company to dispose of as unused product.

Section 14. Transport Information

DOT (US)  Not dangerous goods.

IATA  Not dangerous goods.

IMDG  Not dangerous goods.

Further Information

Section 15. Regulatory Information

Reach No.

SARA 302 Components  SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components  SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Components  No SARA hazards.

Massachusetts Right To Know Components  No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components  Macitentan  CAS #: 441798-33-0  Revision Date:

New Jersey Right To Know Components  Macitentan  CAS #: 441798-33-0  Revision Date:

California Prop 65 Components  This product does not contain any chemicals known to the State of California to cause cancer, birth defects or any other reproductive harm.

Section 16. Other Information

Other information  The information in this document is believed to be correct but is not necessarily complete. LKT does not guarantee the accuracy of the information. The burden of verifying the information in this document rests solely upon the user.