Section 1. Product and Company Identification

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Roxithromycin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product ID</td>
<td>R5992</td>
</tr>
<tr>
<td>Chemical Name</td>
<td>Rulide; Surlid; Rotramin; Claramid; Overal; Rossitrol</td>
</tr>
<tr>
<td>(Synonyms)</td>
<td></td>
</tr>
<tr>
<td>Supplier</td>
<td>LKT Laboratories, Inc</td>
</tr>
<tr>
<td></td>
<td>545 Phalen Blvd.</td>
</tr>
<tr>
<td></td>
<td>St. Paul, MN 55130 USA</td>
</tr>
<tr>
<td></td>
<td>Ph: 651-644-8424 Fax: 651-644-8357</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.lktlabs.com">www.lktlabs.com</a> - <a href="mailto:getinfo@lktlabs.com">getinfo@lktlabs.com</a></td>
</tr>
<tr>
<td>Emergency Phone #</td>
<td>1-800-424-9300</td>
</tr>
</tbody>
</table>

Section 2. Hazards Identification

GHS Classification
Acute toxicity, Oral (Category 4), H302

GHS Label elements including precautionary statements

Pictogram

Signal word
Warning

Hazard and precautionary statements

Hazard statement
H302 - Harmful if swallowed.

Precautionary statements
P264 - Wash skin thoroughly after handling.
P270 - Do not eat, drink, or smoke when using this product.
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P330 - Rinse mouth.
P501 - Dispose of contents/container to an approved waste disposal plant.

HMIS Classification
Health hazard: 1
Chronic health hazard: 0
Flammability: 0
Physical hazard: 0

NFPA Rating
Health hazard: 1
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.
Ingestion - Acute toxicity. Harmful if swallowed.

Section 3. Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Substances</th>
<th>Ingredient: Title Compound</th>
<th>Percent: 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formula</td>
<td>C_{41}H_{76}N_{2}O_{15}</td>
<td>Formula Wt. 837.05</td>
</tr>
<tr>
<td>CAS No.</td>
<td>80214-83-1</td>
<td>EC No.</td>
</tr>
</tbody>
</table>

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. Consult a physician.

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 fire fighting if necessary.

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

Section 6. Accidental Release Measures

Personal Precautions
Use personal protective equipment. Avoid dust formation. Avoid breathing dust, vapors, mist, or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental Precautions
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: 4°C

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.
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

PERSONAL PROTECTION
Eye/face protection: Safety glasses with side-shields conforming to EN 166. 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. Full and Splash contact - Material: Nitrile rubber, Minimum layer thickness: 0.11 mm, Break through time: 480 min, Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M).
Body protection: Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection: For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection, use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

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 crystal powder.</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Melting Point</td>
<td>115-120°C</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in HCl, and NaOH. Slightly soluble in alcohol and water.</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>Slightly soluble in alcohol and water.</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>
<td>Not available.</td>
</tr>
<tr>
<td>Volatility</td>
<td>Not available.</td>
</tr>
<tr>
<td>Density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Ignition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>Not available.</td>
</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>
<td>Not available.</td>
</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**: Rat - 830 mg/kg  Remarks: Behavioral: Change in motor activity (specific assay). Lungs, thorax, or respiration: Other changes. Nutritional and Gross Metabolic: Weight loss or decreased weight gain.

**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.

**Specific organ toxicity repeated exposure (GHS)**: Not available.

**Teratogenicity**: Not available.

**Synergistic effects**: Not available.

**Additional Information**: RTECS: KF4990000  
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

**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 - Acute toxicity. Hazard 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**: PBT/vPvB assessment not available as chemical safety assessment not required/not
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.

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 Acute health hazard.

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

Pennsylvania Right To Know Components Roxithromycin CAS #: 80214-83-1 Revision Date:

New Jersey Right To Know Components Roxithromycin CAS #: 80214-83-1 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.