



AZITHROMYCIN IMPURITY E SAFETY DATA SHEET

1. IDENTIFICATION

Product Identifier	Azithromycin Impurity E
Product Number	A074
Distributor Name	TOKU-E Company
Distributor Address	715 W Orchard Dr, Suite 3 Bellingham, WA 98225
Phone Number	(360) 734-1789
Emergency Phone Number (International)	+1 (352) 323-3500
Emergency Phone Number (US only)	1 (800) 535-5053
Safety Data Sheet Issued By	TOKU-E USA
CAS-No.	[612069-27-9]
EC/ REACH Number	Not available
Recommended Use	Reference standard for Azithromycin impurity tracing
Restrictions on Use	Not for human or animal use

2. HAZARD(S) IDENTIFICATION

GHS Classification Not classified. Toxicology information unavailable.

To the best of our knowledge, the chemical, physical and toxicological properties of this material have not been thoroughly investigated. Azithromycin Impurity E is an impurity and may share properties with its source material. Please reference an Azithromycin SDS for potential hazards.

GHS Label Elements, Including Precautionary statements	None
Hazard Statements	None
Precautionary Statements	None
Hazards not otherwise classified (HNOC) by GHS	None

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonym(s)	Aminoazithromycin
Formula	$C_{36}H_{68}N_2O_{12}$
Molecular Weight	720.942 g/mol

CAS-No.	[612069-27-9]
EC-No.	Not available
Index-No.	Not available
Hazardous components	None

4. FIRST-AID MEASURES

General Advice	Consult a physician. Show this Safety Data Sheet to the medical provider
If Inhaled	If breathed in, move person to fresh air. If not breathing, give artificial respiration. Consult a doctor
In Case of Skin Contact	Wash thoroughly with plenty of soap and water
In Case of Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes, consult a doctor
If Swallowed	Never give anything by mouth to an unconscious person. Consult a doctor. Rinse mouth with water. Please see Section 2 and/or Section 11
Most important symptoms and effects, both acute and delayed	
Indication of any immediate medical attention and special treatment needed	No data available

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media	Water spray, alcohol-resistant foam, dry chemical, carbon dioxide
Special Protective Equipment for Firefighters	Wear self-contained breathing apparatus
Hazardous Combustion Products	Formed under fire conditions: Carbon and Nitrogen oxides

6. ACCIDENTAL RELEASE MEASURES

General	Evacuate personnel to safe location
Personal Precautions	Wear respiratory protection. Avoid dust formation and breathing vapors/mist/dust/gas. Ensure adequate ventilation
Environmental Precautions	Prevent spillage, do not let product enter drains
Methods of Containment and Cleanup	Place in suitable, closed containers for licensed disposal. Avoid dust formation

7. HANDLING AND STORAGE

Precautions for Safe Handling	Avoid contact with skin and eyes. Provide exhaust ventilation in areas where dust is formed
Precautions for Safe Storage	Keep container tightly closed and in a dry, well-ventilated place. Recommended storage temperature: -20°C
Incompatibilities	None known

8. EXPOSURE CONTROLS/ PERSONAL

PROTECTION

Contains no substances with occupational exposure limit values

PPE: Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate, use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)

PPE: Hand Protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal techniques to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices, and wash and dry hands

PPE: Eye Protection

Use a face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU)

PPE: Skin and Body Protection

Handle with gloves. Wear protective clothing. Choose body protection according to the amount and concentration of the dangerous substance at the work place. When deemed needed according to the concentration and amount of this product, use a complete body suit

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance

Deep yellow powder

pH

8-9

Melting Point/Freezing Point

134.4-136°C

Boiling Point

No data available

Flash Point

No data available

Ignition Temperature

No data available

Autoignition Temperature

No data available

Lower Explosion Limit

No data available

Upper Explosion Limit

No data available

Vapor Pressure

No data available

Density

No data available

Water Solubility

No data available

Solubility in Other Solvents

No data available

Partition Coefficient: n-octanol/water

No data available

Optical Rotation

No data available

Absorbance (290nm, 5% in H₂O)

No data available

Water content (Karl Fisher)

No data available

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under recommended storage conditions
Possibility of Hazardous Reactions	No data available
Conditions to Avoid	No data available
Materials to Avoid	Strong oxidizing agents
Hazardous Decomposition Products	Carbon and Nitrogen oxides formed under fire conditions

11. TOXICOLOGICAL INFORMATION

Oral LD ₅₀	No data available
Inhalation LC ₅₀	No data available
Dermal LD ₅₀	No data available
Intraperitoneal LD ₅₀	No data available
Intravenous LD ₅₀	No data available
Skin Corrosion/Irritation	No data available
Serious Eye Damage/ Eye Irritation	No data available
Respiratory or Skin Sensitization	No data available
Germ Cell Mutagenicity	No data available
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
Reproductive Toxicity	No data available
Specific Target Organ Toxicity: Single Exposure (Globally Harmonized System)	No data available
Specific Target Organ Toxicity: Repeated Exposure (Globally Harmonized System)	No data available
Aspiration Hazard	No data available
Potential Health Effects	See Section 2, Hazard(s) Identification
Signs and Symptoms of Exposure	Effects due to ingestion may include dizziness, drowsiness, chest pain, nausea, diarrhea, nephritis, hyperglycemia, hyperkalemia, and photosensitivity. To the best of our knowledge, the chemical, physical, and toxicological properties of this material have not been thoroughly investigated
Synergistic Effects	No data available
Additional Information	RTECS: Not available

12. ECOLOGICAL INFORMATION

Toxicity	No data available
Persistence and Degradability	No data available
Bioaccumulative Potential	No data available
Mobility in Soil	No data available
PBT and vPvB Assessment	No data available
Treat as if harmful if released into environment	

13. DISPOSAL CONSIDERATIONS

Product	Dispose of product through a licensed disposal company
Contaminated Packaging	Dispose of as unused product

14. TRANSPORTATION INFORMATION

DOT (US)	Not Dangerous Goods
IMDG	Not Dangerous Goods
IATA	Not Dangerous Goods

15. REGULATORY INFORMATION

SARA 302 Components	No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302
SARA 313 Components	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 Hazards	No SARA Hazards
Massachusetts Right to Know Components	No components are subject to the Massachusetts Right to Know Act
Pennsylvania Right to Know Components	No components are subject to the Pennsylvania Right to Know Act
New Jersey Right to Know Components	No components are subject to the New Jersey Right to Know Act
California Prop. 65 Components	This product does not contain any chemicals known to the State of California to cause birth defects, cancer, or any other reproductive harm SDS in accordance with REACH 1907/2006
EU Information	A registration number is not available for this substance or its uses are exempted from registration, the annual tonnage does not require a registration, or the registration is envisaged for a later registration deadline. See GHS Information under Section 2, Hazard Identification

16. OTHER INFORMATION

Date of last revision: 2017-04-20

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. TOKU-E Company, shall not be held liable for any damage resulting from handling or from contact with the above product. Please see reverse side of invoice or packing slip for additional terms and conditions of sale.