

# SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078825891

N/A

Date Prepared: 03/01/2011

Reviewed On: 02/11/2011

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

- **Product Identifier**
- **Product Name:** Azithromycin AZM-15
- **Catalog Number:** 231682
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
BD Diagnostic Systems  
7 Loveton Circle  
Sparks, MD 21152  
Telephone.: (410) 771 - 0100 or (800) 638 – 8663
- **Information Department:** Technical Service
- **Emergency telephone number:**  
In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostic Systems (410) 771-0100 or (800)-638-8663, or ChemTrec at (800) 424-9300.

**2 Composition/information on ingredients**

- **Chemical characterization:** Mixture
- **Description:** Mixture consisting of the following components.
- **Dangerous Components:** Void

**3 Hazards identification**

- **Classification of the substance or mixture**
  - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200, the Canada's Workplace Hazardous Materials Information System (WHMIS) and the European Directive 67/548/EEC and 1999/45/EC.  
Void
  - **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- 
- **Label elements**
  - **Labelling according to EU guidelines:**  
Observe the general safety regulations when handling chemicals  
The product is not subject to identification regulations pertaining to regulations on hazardous materials.
  - **NFPA ratings (scale 0-4)**



- **HMIS ratings (scale 0-4)**
- |            |   |                |
|------------|---|----------------|
| HEALTH     | 0 | Health = 0     |
| FIRE       | 0 | Fire = 0       |
| REACTIVITY | 0 | Reactivity = 0 |

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**Product Name: Azithromycin AZM-15**

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**4 First aid measures**

- **General information** No special measures required.
- **After inhalation** Seek medical treatment in case of complaints.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing** If symptoms persist consult doctor.
- **Information for doctor** Show this product label or this MSDS.

**5 Firefighting measures**

- **Suitable extinguishing agents**  
CO<sub>2</sub>, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:** No special measures required.

**6 Accidental release measures**

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Wipe up with damp sponge or mop.
- **Methods and material for containment and cleaning up:** No special measures required.
- **Reference to other sections** No dangerous substances are released.

**7 Handling and storage**

- **Handling**
- **Precautions for safe handling** Store in cool, dry place in tightly closed containers.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Store away from oxidizing agents.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed containers.

**8 Exposure controls/personal protection**

- **Additional information about design of technical systems:** No further data; see Section 7.
- **Components with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Personal Protective Equipment**
- **General protective and hygienic measures**  
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.

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**Product Name: Azithromycin AZM-15**

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**· Protection of hands:**


Chemical resistant gloves (i.e. nitrile, or equivalent).

**· Eye protection:** Safety glasses

**· Body protection:** Protective work clothing (lab coat).

**9 Physical and chemical properties**
**· General Information**
**· Appearance:**

<b>Form:</b>	Solid.
<b>Color:</b>	According to product specification
<b>· Odor:</b>	Characteristic

<b>· Change in condition</b>	Undetermined
<b>· Melting point/Melting range:</b>	Not determined
<b>· Boiling point/Boiling range:</b>	Not determined

<b>· Flash point:</b>	Not applicable
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<b>· Flammability (solid, gaseous)</b>	Product is not flammable.
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<b>· Danger of explosion:</b>	Product does not present an explosion hazard.
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<b>· Density:</b>	Not determined
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<b>· Solubility in / Miscibility with Water:</b>	Soluble
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**· Solvent content:**

<b>Solids content:</b>	100.0 %
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**10 Stability and reactivity**

- Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- Hazardous decomposition products:** No dangerous decomposition products known.

**11 Toxicological information**

- Acute toxicity:**
- Primary irritant effect:**
  - on the skin:** No irritating effect.
  - on the eye:** No irritating effect.
- Sensitization:** Sensitizing effect through inhalation is possible with prolonged exposure.
- Additional toxicological information:**

The product is not subject to OSHA classification according to internally approved calculation methods for preparations.

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**Product Name: Azithromycin AZM-15**

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When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

**12 Ecological information**

- **Acquatic toxicity:** No further relevant information available.
- **Ecotoxicological effects:**
- **Other information:**  
The ecological effects have not been thoroughly investigated, but currently none have been identified.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water.

**13 Disposal considerations**

- **Waste treatment methods**
- **Recommendation**  
Smaller quantities can be disposed of with solid waste.  
Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements.  
This product is not considered a RCRA hazardous waste.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to state and federal regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

**14 Transport information**

- **DOT regulations:**
- **Hazard class:** -
- **Land transport ADR/RID (cross-border)**
- **ADR/RID class:** -
- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -

- **Transport/Additional information:**  
If a dashed line appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.

**15 Regulatory information**

- **SARA Section 355 (extremely hazardous substances)**  
None of the ingredients is listed.
- **SARA Section 313 (specific toxic chemical listings)**  
None of the ingredients is listed.

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· **TSCA (Toxic Substances Control Act)**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause cancer**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.

**16 Other information**

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

· **Department issuing MSDS:**

Environmental, Health & Safety

Created by Michael J. Spinazzola

· **Contact:** Technical Service Representative

USA

**Safety Data Sheet**  
acc. to OSHA HCS

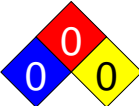
Date Prepared: 10/11/2014

Reviewed On: 08/05/2014

**1 Identification**

- **Product Identifier**
- **Product Name:** Azithromycin AZM-15
- **Catalog Number:** 231682
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** *In-vitro Diagnostics*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
BD Diagnostic Systems  
7 Loveton Circle  
Sparks, MD 21152  
Telephone: (410) 771 - 0100 or (800) 638 – 8663  
Email Address: [Technical\\_Services@bd.com](mailto:Technical_Services@bd.com)
- **Information Department:** Technical Service
- **Emergency telephone number:**  
In case of a chemical emergency, spill, fire, exposure, or accident, contact BD Diagnostic Systems (410) 771-0100 or (800)-638-8663, or ChemTrec at (800) 424-9300.

**2 Hazard(s) identification**

- **Classification of the substance or mixture**  
The product is not classified according to the Globally Harmonized System (GHS).
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200, the Canada's Workplace Hazardous Materials Information System (WHMIS) and the European Directive 67/548/EEC and 1999/45/EC.
- **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **NFPA ratings (scale 0-4)**  
 Health = 0  
Flammability = 0  
Reactivity = 0
- **HMIS ratings (scale 0-4)**  

HEALTH	0
FIRE	0
REACTIVITY	0

 Health = 0  
Flammability = 0  
Reactivity = 0

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**Product Name: Azithromycin AZM-15**

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- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**3 Composition/information on ingredients**

- **Chemical characterization: Mixture**
- **Description:** Mixture consisting of the following components.
- **Dangerous Components:** Void
- **Additional information** Risk phrases refer to section 15.

**4 First-aid measures**

- **Description of first aid measures**
- **General information** No special measures required.
- **After inhalation** Seek medical treatment in case of complaints.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing** If symptoms persist consult doctor.
- **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **Information for doctor** Show this product label or this SDS.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

**5 Fire-fighting measures**

- **Extinguishing media**
- **Suitable extinguishing agents**  
CO<sub>2</sub>, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture**  
No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

**6 Accidental release measures**

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Wipe up with damp sponge or mop.

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**Product Name: Azithromycin AZM-15**

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- **Methods and material for containment and cleaning up:** No special measures required.
- **Reference to other sections** No dangerous substances are released.

**7 Handling and storage**

- **Precautions for safe handling** Store in cool, dry place in tightly closed containers.
- **Information about protection against explosions and fires:**  
No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:**  
Store away from oxidizing agents.
- **Further information about storage conditions:**  
Store in cool, dry conditions in well sealed containers.
- **Specific end use(s)** No further relevant information available.

**8 Exposure controls/personal protection**

- **Additional information about design of technical systems:**  
No further data; see Section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal Protective Equipment**
- **General protective and hygienic measures**  
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Chemical resistant gloves (i.e. nitrile, or equivalent).

- **Eye protection:** Safety glasses
- **Body protection:** Protective work clothing (lab coat).

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**Product Name: Azithromycin AZM-15**

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**9 Physical and chemical properties**· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· <b>Form:</b>	Solid.
· <b>Color:</b>	According to product specification
· <b>Odor:</b>	Characteristic

· **Change in condition** Undetermined· **Melting point/Melting range:** Not determined· **Boiling point/Boiling range:** Not determined· **Flash point:** Not applicable· **Flammability (solid, gaseous)** Product is not flammable.· **Danger of explosion:** Product does not present an explosion hazard.· **Density:** Not determined· **Solubility in / Miscibility with**· **Water:** Soluble· **Solvent content:**· **Solids content:** 100.0 %· **Other information** No further relevant information available.**10 Stability and reactivity**· **Reactivity**· **Chemical stability**· **Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known· **Conditions to avoid** No further relevant information available.· **Incompatible materials:** No further relevant information available.· **Hazardous decomposition products:** No dangerous decomposition products known.**11 Toxicological information**· **Information on toxicological effects**· **Acute toxicity:**· **Primary irritant effect:**· **on the skin:** No irritating effect.· **on the eye:** No irritating effect.· **Sensitization:** Sensitizing effect through inhalation is possible with prolonged exposure.

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**Safety Data Sheet**  
acc. to OSHA HCS

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Reviewed On: 08/05/2014

**Product Name: Azithromycin AZM-15**

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**· Additional toxicological information:**

The product is not subject to OSHA classification according to internally approved calculation methods for preparations.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

**· Carcinogenic categories****· IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

**· NTP (National Toxicology Program)**

None of the ingredients is listed.

**· OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

**12 Ecological information****· Toxicity**

**· Aquatic toxicity:** No further relevant information available.

**· Persistence and degradability** No further relevant information available.

**· Bioaccumulative potential** No further relevant information available.

**· Mobility in soil** No further relevant information available.

**· Ecotoxicological effects:****· Other information:**

The ecological effects have not been thoroughly investigated, but currently none have been identified.

**· Additional ecological information:**

**· General notes:** Generally not hazardous for water.

**· Results of PBT and vPvB assessment**

**· PBT:** Not applicable.

**· vPvB:** Not applicable.

**· Other adverse effects** No further relevant information available.

**13 Disposal considerations****· Waste treatment methods****· Recommendation**

Smaller quantities can be disposed of with solid waste.

Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements.

This product is not considered a RCRA hazardous waste.

**· Uncleaned packagings:**

**· Recommendation:** Disposal must be made according to state and federal regulations.

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**Product Name: Azithromycin AZM-15**

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· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

## 14 Transport information

· **UN-Number**

· **DOT, ADR, ADN, IMDG, IATA** Void

· **UN proper shipping name**

· **DOT, ADR, ADN, IMDG, IATA** Void

· **Transport hazard class(es)**

· **DOT, ADR, ADN, IMDG, IATA**

· **Class** Void

· **Packing group**

· **DOT, ADR, IMDG, IATA** Void

· **Environmental hazards:**

· **Marine pollutant:** No

· **Special precautions for user** Not applicable.

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

· **Transport/Additional information:** If a "void" appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.

· **UN "Model Regulation":** -

## 15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act)**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause cancer**

None of the ingredients is listed.

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**Safety Data Sheet**  
acc. to OSHA HCS

Date Prepared: 10/11/2014

Reviewed On: 08/05/2014

**Product Name: Azithromycin AZM-15**

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**· California Proposition 65 - Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

**· California Proposition 65 - Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

**· California Proposition 65 - Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

**· Carcinogenic categories****· TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

**· GHS label elements** Void**· Hazard pictograms** Void**· Signal word** Void**· Hazard statements** Void**· National regulations****· Water hazard class:** Generally not hazardous for water.**· Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**16 Other information**

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

**· Department issuing SDS:**

Environmental, Health &amp; Safety

Created by Michael J. Spinazzola

**· Date of preparation / last revision** 10/11/2014 / -**· Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

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