

## Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

Issue date 02/09/2016

Reviewed on 02/09/2016

### 1 Identification

· **Product Identifier**

· **Trade name: Primsol® Solution**

· **CAS Number:**

60834-30-2

· **Relevant identified uses of the substance or mixture and uses advised against:**

No further relevant information

· **Product Description**

PRIMSOL (trimethoprim hydrochloride oral solution) is a solution of the synthetic antibacterial trimethoprim in water prepared with the aid of hydrochloric acid. Each 5 mL for oral administration contains trimethoprim hydrochloride equivalent to 50 mg trimethoprim and the inactive ingredients bubble gum flavor, fructose, glycerin, methylparaben, monoammonium glycyrrhizinate, povidone, propylparaben, propylene glycol, saccharin sodium, sodium benzoate, sorbitol, water and hydrochloric acid and/or sodium hydroxide to adjust pH to a range of 3.0 - 5.0. Trimethoprim is 2,4-diamino-5-(3,4,5-trimethoxybenzyl) pyrimidine. Trimethoprim is a white to cream-colored, odorless, bitter compound with a molecular formula of C<sub>14</sub>H<sub>18</sub>N<sub>4</sub>O<sub>3</sub> and a molecular weight of 290.32.

· **Details of the Supplier of the Safety Data Sheet:**

· **Manufacturer/Supplier:**

Aytu BioScience, Inc.

373 Inverness Parkway, Suite 206

Englewood, CO 80112

Phone: 1(855) aytubio or 1(855) 298-8246

www.aytubio.com

· **Emergency telephone number:** 1 (855) 298-8246

### 2 Hazard(s) Identification

· **Classification of the substance or mixture:**

The product does not need classification according to OSHA HazCom Standard 29 CFR paragraph (d) of §1910.1200(g) and GHS Rev 03.

· **Label elements:**

· **GHS label elements** Non-Regulated Material

· **Hazard pictograms:** Non-Regulated Material

· **Signal word:** Non-Regulated Material

· **Hazard statements:** Non-Regulated Material

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



· **Hazard(s) not otherwise classified (HNOC):** None known

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### 3 Composition/Information on Ingredients

- **Chemical characterization: Substance**
- **CAS No. Description**  
60834-30-2 5-[(3,4,5-TRIMETHOXYPHENYL)METHYL]PYRIMIDINE-2,4-DIAMINE  
HYDROCHLORIDE

### 4 First-Aid Measures

- **Description of first aid measures:**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If swallowed and symptoms occur, consult a doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed:** No further relevant information available.
- **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>, extinguishing powder 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:**  
As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures:** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (i.e. sand, diatomite, acid binders, universal binders, sawdust).  
Dispose of the collected material according to regulations.
- **Reference to other sections:**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and Storage

- **Handling**
- **Precautions for safe handling:** No special measures required.
- **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:** Not required.
- **Further information about storage conditions:** None.

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- **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 occupational exposure limits:**
- **Additional information:** The lists that were valid during the creation of this SDS 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:** Not required.
- **Material of gloves:**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material:** Not applicable.
- **Eye protection:** Not required.

### \* 9 Physical and Chemical Properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

· <b>Form:</b>	Liquid
· <b>Color:</b>	White to cream
· <b>Odor:</b>	Odorless
· <b>Odor threshold:</b>	Not determined.
· <b>pH-value:</b>	3-5
- **Change in condition**

· <b>Melting point/Melting range:</b>	Not determined.
· <b>Boiling point/Boiling range:</b>	Not determined.
- **Flash point:** None
- **Flammability (solid, gaseous):** Not applicable.
- **Ignition temperature:** Not determined
- **Decomposition temperature:** Not determined.
- **Auto igniting:** Not determined.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
- **Vapor pressure:** Not determined.
- **Density:**

· <b>Relative density:</b>	Not determined.
· <b>Vapor density:</b>	Not determined.

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- Evaporation rate:** Not determined.
- **Solubility in / Miscibility with:**
- Water:** Not miscible or difficult to mix.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
- Dynamic:** Not determined.
- Kinematic:** Not determined.
- Organic solvents:** 0.0 %
- **Other information:** No further relevant information available.

### 10 Stability and Reactivity

- **Reactivity:** No further relevant information available.
- **Chemical stability:** Stable under normal conditions.
- **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.
- **Additional toxicological information:**  
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.  
The substance is not subject to classification.
- **Carcinogenic categories:**

· <b>IARC (International Agency for Research on Cancer):</b>
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Substance is not listed.
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· <b>NTP (National Toxicology Program):</b>
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Substance is not listed.
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· <b>OSHA-Ca (Occupational Safety &amp; Health Administration):</b>
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Substance is not listed.
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### 12 Ecological Information

- **Toxicity:**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability:** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential:** No further relevant information available.
- **Mobility in soil:** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water.

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- **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 household waste.  
Observe all federal, state and local environmental regulations when disposing of this material.
- **Uncleaned packagings**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport Information

- **UN-Number:** Non-Regulated Material
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name:** Non-Regulated Material
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es):**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **Class:** Non-Regulated Material
- **Packing group:**
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:** Not applicable.
- **Special precautions for user:** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.
- **UN "Model Regulation":** Non-Regulated Material

### 15 Regulatory Information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture:**
- **SARA (Superfund Amendments and Reauthorization):**

<b>Section 355 (extremely hazardous substances):</b>	Substance is not listed.
<b>Section 313 (Specific toxic chemical listings):</b>	Substance is not listed.
<b>TSCA (Toxic Substances Control Act):</b>	Substance is not listed.
<b>California Proposition 65:</b>	
<b>Chemicals known to cause cancer:</b>	Substance is not listed.
<b>Chemicals known to cause reproductive toxicity for females:</b>	Substance is not listed.
<b>Chemicals known to cause reproductive toxicity for males:</b>	Substance is not listed.

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· <b>Chemicals known to cause developmental toxicity:</b>
Substance is not listed.
· <b>Carcinogenic categories:</b>
· <b>EPA (Environmental Protection Agency):</b>
Substance is not listed.
· <b>TLV (Threshold Limit Value established by ACGIH):</b>
Substance is not listed.
· <b>NIOSH-Ca (National Institute for Occupational Safety and Health):</b>
Substance is not listed.
· <b>GHS label elements</b> Non-Regulated Material
· <b>Hazard pictograms:</b> Non-Regulated Material
· <b>Signal word:</b> Non-Regulated Material
· <b>Hazard statements:</b> Non-Regulated Material
· <b>National regulations:</b>
Non-Regulated Material
· <b>State Right to Know:</b>
None of the ingredients are listed
· <b>Chemical safety assessment:</b> A Chemical Safety Assessment has not been carried out.

### 16 Other Information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· **Date of preparation / last revision:** 02/09/2016 / 1

· **Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road  
 ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways  
 IMDG: International Maritime Code for Dangerous Goods  
 DOT: US Department of Transportation  
 IATA: International Air Transport Association  
 ACGIH: American Conference of Governmental Industrial Hygienists  
 CAS: Chemical Abstracts Service (division of the American Chemical Society)  
 NFPA: National Fire Protection Association (USA)  
 HMIS: Hazardous Materials Identification System (USA)  
 PBT: Persistent, Bioaccumulative and Toxic  
 vPvB: very Persistent and very Bioaccumulative  
 NIOSH: National Institute for Occupational Safety  
 OSHA: Occupational Safety & Health  
 TLV: Threshold Limit Value  
 PEL: Permissible Exposure Limit  
 REL: Recommended Exposure Limit

· **\* Data compared to the previous version altered.**

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