

Safety Data Sheet (SDS)

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

Issue date 02/03/2017

Reviewed on 02/03/2017

* 1 Identification

· **Product Identifier**

· **Trade name: MiOXSYS® High Control Solution**

· **Product Number:** 100277

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

No further relevant information

· **Product Description**

The MiOXSYS® External Control Solutions Kit contains High and Low Control Solutions and is intended to provide for quality control testing on the MiOXSYS System® using the MiOXSYS® Analyzer and the MiOXSYS® Sensor. These external controls are intended to provide the user with a method of detecting issues that may result in erroneous test results.

· **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:**



GHS07

Eye Irrit. 2A H319 Causes serious eye irritation.

· **Label elements:**

· **GHS label elements**

The substance is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms:**



GHS07

· **Signal word:** Warning

· **Hazard statements:**

H319 Causes serious eye irritation.

· **Precautionary statements:**

P280 Wear eye protection / face protection.

P264 Wash thoroughly after handling.

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

· **Unknown acute toxicity:**

This value refers to knowledge of known, established toxicological or ecotoxicological values.

· **Classification system:** NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme

(Contd. on page 2)

Safety Data Sheet (SDS)

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

Issue date 02/03/2017

Reviewed on 02/03/2017

Trade name: MiOXSYS® High Control Solution

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



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

3 Composition/Information on Ingredients

· **Non-hazardous components:**

Water, distilled water, deionized water	90-99%
---	--------

· **Chemical characterization: Substance**

· **CAS No. Description**

60834-30-2 5-[(3,4,5-TRIMETHOXYPHENYL)METHYL]PYRIMIDINE-2,4-DIAMINE
HYDROCHLORIDE

· **Chemical characterization: Mixtures**

· **Description:** Mixture of substances listed below with non-hazardous additions.

· **Dangerous Components:**

CAS: 7558-79-4	Sodium Phosphate, dibasic	≤ 2.5%
RTECS: WC 4500000	⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335-H336	

· **Additional information:**

The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

* 4 First-Aid Measures

· **Description of first aid measures:**

· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

· **After skin contact:** If skin irritation occurs, consult a doctor.

· **After eye contact:**

Rinse opened eye for at least 15 minutes under running water. If symptoms persist, consult a doctor.
If easy to do so, remove contact lenses if worn.

· **After swallowing:** Dilute with water or milk. Call a physician if necessary.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed:**

Does not present any significant health hazards. May cause irritation to those allergic to phosphates. Wash areas of contact with water. EYE CONTACT: May cause slight irritation. SKIN CONTACT: May cause slight irritation to those allergic to phosphates.

· **Indication of any immediate medical attention and special treatment needed:**

No further relevant information available.

5 Fire-Fighting Measures

· **Extinguishing media:**

· **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.

· **Special hazards arising from the substance or mixture:** No further relevant information available.

(Contd. on page 3)

Safety Data Sheet (SDS)

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

Issue date 02/03/2017

Reviewed on 02/03/2017

Trade name: MiOXSYS® High Control Solution

· **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:**

Wear protective equipment. Keep unprotected persons away.

· **Environmental precautions:** Dilute with plenty of water.

· **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.

· **Protective Action Criteria for Chemicals**

· PAC-1:		
1310-73-2	Sodium Hydroxide	0.5 mg/m ³
· PAC-2:		
1310-73-2	Sodium Hydroxide	5 mg/m ³
· PAC-3:		
1310-73-2	Sodium Hydroxide	50 mg/m ³

* **7 Handling and Storage**

· **Handling**

· **Precautions for safe handling:**

As with all chemicals, wash hands thoroughly after handling. Avoid contact with eyes and skin.

· **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:** Protect from freezing and physical damage.

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:** Keep receptacle tightly sealed.

· **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:**

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

1310-73-2 Sodium Hydroxide	
PEL	Long-term value: 2 mg/m ³
REL	Ceiling limit value: 2 mg/m ³
TLV	Ceiling limit value: 2 mg/m ³

(Contd. on page 4)

Safety Data Sheet (SDS)

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

Issue date 02/03/2017

Reviewed on 02/03/2017

Trade name: MiOXSYS® High Control Solution

- **Additional information:** The lists that were valid during the creation of this SDS were used as basis.
- **Exposure controls:**
Ventilation must be adequate to maintain the ambient workplace atmosphere below the exposure limit(s) outlined in the SDS. Where acceptable concentrations cannot be maintained by general mechanical ventilation, local exhaust ventilation is recommended.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing and wash before reuse.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

- **Material of gloves:**
The selection of the suitable gloves depends on the material, and marks of quality, and varies from manufacturer to manufacturer.
- **Penetration time of glove material:**
The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.
- **Eye protection:**



Tightly sealed goggles

* 9 Physical and Chemical Properties

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

Form:	Liquid
Color:	Colorless
Odor:	Odorless
Odor threshold:	Not determined.
- **pH-value @ 20 °C (68 °F):** 11
- **Change in condition**

Melting point/Melting range:	Not determined.
Boiling point/Boiling range:	100 °C (212 °F)
- **Flash point:** None
- **Flammability (solid, gaseous):** Not applicable.
- **Ignition temperature:** Not determined.
- **Decomposition temperature:** Not determined.

(Contd. on page 5)

Safety Data Sheet (SDS)

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

Issue date 02/03/2017

Reviewed on 02/03/2017

Trade name: MiOXSYS® High Control Solution

- **Auto igniting:** Product is not self-igniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
 - Lower:** Not determined.
 - Upper:** Not determined.
- **Vapor pressure @ 20 °C (68 °F):** 23 hPa (17 mm Hg)
- **Density @ 20 °C (68 °F):** 1.01 g/cm³ (8.428 lbs/gal)
- **Relative density:** Not determined.
- **Vapor density:** Not determined.
- **Evaporation rate:** Not determined.
- **Solubility in / Miscibility with:**
 - Water:** Fully miscible.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:** Not determined.
 - Kinematic:** Not determined.
- **Solvent content:**
 - Organic solvents:** 0.0 %
 - Solids content:** 1.1 %
- **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:**

LD/LC50 values that are relevant for classification:		
7558-79-4 Sodium Phosphate, dibasic		
Oral	LD50	17000 mg/kg (Rat)

- **Primary irritant effect:**
- **On the skin:** No irritating effect.
- **On the eye:** Irritating effect.
- **Additional toxicological information:**
 The product shows the following dangers according to internally approved calculation methods for preparations:
 Irritant

(Contd. on page 6)

Safety Data Sheet (SDS)

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

Issue date 02/03/2017

Reviewed on 02/03/2017

Trade name: MiOXSYS® High Control Solution

· **Carcinogenic categories:**

· IARC (International Agency for Research on Cancer):
None of the ingredients are listed.
· NTP (National Toxicology Program):
None of the ingredients are listed.
· OSHA-Ca (Occupational Safety & Health Administration):
None of the ingredients are listed.

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.
- **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:**
Observe all federal, state and local environmental regulations when disposing of this material.
- **Uncleaned packagings**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport Information

- **UN-Number:**
- **DOT, ADR/ADN, ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name:**
- **DOT, ADR/ADN, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es):**
- **DOT, ADR/ADN, ADN, IMDG, IATA**
- **Class:** Non-Regulated Material
- **Packing group:**
- **DOT, ADR/ADN, 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

(Contd. on page 7)

Safety Data Sheet (SDS)

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

Issue date 02/03/2017

Reviewed on 02/03/2017

Trade name: MiOXSYS® High Control Solution

15 Regulatory Information

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

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

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

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

All ingredients are listed or exempt from listing.

· **California Proposition 65:**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed.

· **New Jersey Right-to-Know List:**

7558-79-4 Sodium Phosphate, dibasic

1310-73-2 Sodium Hydroxide

· **New Jersey Special Hazardous Substance List:**

1310-73-2 Sodium Hydroxide

CO, R1

· **Pennsylvania Right-to-Know List:**

7558-79-4 Sodium Phosphate, dibasic

1310-73-2 Sodium Hydroxide

· **Pennsylvania Special Hazardous Substance List:**

7558-79-4 Sodium Phosphate, dibasic

E

1310-73-2 Sodium Hydroxide

E

· **Carcinogenic categories:**

· **EPA (Environmental Protection Agency):**

None of the ingredients are listed.

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

None of the ingredients are listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health):**

None of the ingredients are listed.

· **GHS label elements**

The substance is classified and labeled according to the Globally Harmonized System (GHS).

(Contd. on page 8)

Safety Data Sheet (SDS)

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

Issue date 02/03/2017

Reviewed on 02/03/2017

Trade name: MiOXSYS® High Control Solution

· **Hazard pictograms:**



GHS07

· **Signal word:** Warning

· **Hazard statements:**

H319 Causes serious eye irritation.

· **Precautionary statements:**

P280 Wear eye protection / face protection.

P264 Wash thoroughly after handling.

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

· **National regulations:**

The product is subject to be classified according with the latest version of the regulations on hazardous substances.

· **Chemical safety assessment:** 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:** 02/03/2017 / 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

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety and Health

OSHA: Occupational Safety & Health Administration

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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

SDS created by MSDS Authoring Services www.msdsauthoring.com +1-877-204-9106