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**

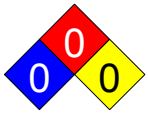
· **Trade name: MiOXSYS® Low Control Solution**
· **Product Number:** 100276
· **Relevant identified uses of the substance or mixture and uses advised against:**
No further relevant information
· **Product Description**
The MiOXSYS® External Control Solutions Kit contains High and Low Control Solutions 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:**
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
· **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
· **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 0
Fire = 0
Reactivity = 0

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

*
3 Composition/Information on Ingredients

· **Non-hazardous components:**		
	Water, distilled water, deionized water	98-100%
7447-40-7	Potassium Chloride	<0.5%

(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® Low Control Solution

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

· **Dangerous Components:**			
1310-73-2	Sodium Hydroxide	Skin Corr. 1A, H314	<0.5%

· **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:**
· **General information:** No special measures required.
· **After inhalation:** Supply fresh air; consult doctor in case of complaints.
· **After skin contact:**
Wash with soap and water.
If skin irritation occurs, consult a doctor.
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:** Dilute with water or milk. Do not induce vomiting. Call a physician if necessary.
· **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:** Use fire fighting measures that suit the environment.
· **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:**
Wear protective equipment. Keep unprotected persons away.
· **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.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**		
1310-73-2	Sodium Hydroxide	0.5 mg/m3

· **PAC-2:**		
1310-73-2	Sodium Hydroxide	5 mg/m3

(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® Low Control Solution

· **PAC-3:**		
1310-73-2	Sodium Hydroxide	50 mg/m3

*
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 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 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.
· **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

(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® Low Control Solution

* 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):** 12

· **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.

· **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: Miscible

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**
Dynamic: Not determined.
Kinematic: Not determined.

· **Solvent content:**
Organic solvents: 0.0 %

Solids content: 0.4 %
· **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.

(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® Low Control Solution

· **Conditions to avoid:** Avoid contact with Bromine Trifluoride, Potassium Permanganate and Sulfuric Acid.
· **Incompatible materials:** Bromine Trifluoride, Potassium Permanganate and Sulfuric Acid.
· **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:**
The product is not subject to 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 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:**
Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.
· **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.

(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® Low Control Solution

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

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:**

1310-73-2	Sodium Hydroxide

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

1310-73-2	Sodium Hydroxide	CO, R1

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

1310-73-2	Sodium Hydroxide

· **Pennsylvania Special Hazardous Substance List:**

1310-73-2	Sodium Hydroxide	E

(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® Low Control Solution

· **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** Non-Regulated Material
· **Hazard pictograms:** Non-Regulated Material
· **Signal word:** Non-Regulated Material
· **Hazard statements:** Non-Regulated Material

· **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 / 2
· **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)
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 Corr. 1A: Skin corrosion/irritation – Category 1A
· ***Data compared to the previous version altered.***
SDS created by MSDS Authoring Services www.msdsauthoring.com +1-877-204-9106