Safety Data Sheet (SDS)

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

Issue date 10/22/2015 Reviewed on 10/22/2015

1 Identification

· **Product identifier**

· **Trade name: MiOXSYS Sensor**
· **Relevant identified uses of the substance or mixture and uses advised against**
In vitro diagnostic reagent
· **Product description**
The MiOXSYS™ System measures the amount of oxidative stress in biological samples by measuring oxidation-reduction potential (reported as “static ORP”). The biologic sample is applied to a MiOXSYS™ Sensor inserted into a galvanostat-based analyzer. The test starts when the sample fills the reference electrode, thereby completing the electrochemical circuit. After an initial ORP reading is recorded, the reader applies a small current sweep to the sample, resulting in the exhaustion of important antioxidant species. As a result, the antioxidant capacity of the sample is calculated and reflects the amount of electrons applied to the sample that causes this exhaustion of antioxidants in the sample reported as “capacity ORP”).

Oxidation-reduction potential (ORP) in biological systems has been described as an integrated measure of the balance between total oxidants (ie, oxidized thiols, superoxide radicals, hydroxyl radicals, hydrogen peroxide, nitric oxide, peroxynitrite, transition metal ions, etc) and total reductants (ie, free thiols, ascorbate, α-tocopherol, β-carotene, uric acid, etc). Therefore, the amount of oxidative or reductive stress (redox balance) present can be monitored with a MiOXSYS Sensor using the MiOXSYS™ System.
· **Application of the substance / the mixture** Chemical component of the in vitro diagnostic test strip (sensor)

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Aytu Bioscience, Inc.
373 Inverness Pkwy, Suite 206
Englewood, CO 80112
Phone (720) 437-6580
Fax (720) 437-6501
· **Emergency telephone number:** (720) 437-6580

* 2 Hazard(s) identification

· **Classification of the substance or mixture**


GHS05 Corrosion

Skin Corr. 1C H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.


GHS07

STOT SE 3 H335 May cause respiratory irritation.

· **Label elements**
· **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
· **Hazard pictograms**


GHS05 GHS07

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Trade name: MiOXSYS Sensor

· ***Signal word*** Danger

· ***Hazard-determining components of labeling:***
silver chloride
Silver
Hydroxyethyl Cellulose

· ***Hazard statements***
Causes severe skin burns and eye damage.
May cause respiratory irritation.

· ***Precautionary statements***
Do not breathe dusts or mists.
Avoid breathing dust/fume/gas/mist/vapors/spray.
Use only outdoors or in a well-ventilated area.
Wear eye protection / face protection.
Wash thoroughly after handling.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
Continue rinsing.
Immediately call a poison center/doctor.
Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Call a poison center/doctor if you feel unwell.
Wash contaminated clothing before reuse.
If swallowed: Rinse mouth. Do NOT induce vomiting.
Store locked up.
Store in a well-ventilated place. Keep container tightly closed.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· ***Unknown acute toxicity:***
49 percent of the mixture consists of ingredient(s) of unknown toxicity.

· ***Classification system:***

· ***NFPA ratings (scale 0 - 4)***

Health = 3
Fire = 0
Reactivity = 0

· ***HMIS-ratings (scale 0 - 4)***

Health = 4
Fire = 0
Reactivity = 0

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

*
3 Composition/information on ingredients

7447-40-7	Potassium Chloride	25-50%
39346-81-1	2-Hydroxyethyl agarose	2-12%

· ***Chemical characterization: Mixtures***
· ***Description:*** Mixture of substances listed below with nonhazardous additions.

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· **Dangerous Components:**		
CAS: 7440-22-4	Silver STOT SE 3, H335	15-35%
CAS: 34590-94-8 RTECS: JM 1575000	(2-methoxymethylethoxy)propanol Flam. Liq. 4, H227	15-35%
CAS: 9004-62-0	Hydroxyethyl Cellulose STOT SE 3, H335; Eye Irrit. 2B, H320; Combustible Dust	5-10%
CAS: 7783-90-6	silver chloride Skin Corr. 1C, H314	5-10%

*

4 First-aid measures

· ***Description of first aid measures***
· ***General information:*** Immediately remove any clothing soiled by the product.
· ***After inhalation:***
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness, place patient securely on side position for transportation.
· ***After skin contact:***
Immediately wash with water and soap and rinse thoroughly.
If skin irritation occurs, consult a doctor.
· ***After eye contact:*** Rinse opened eye for several minutes under running water. Then consult a doctor.
· ***After swallowing:*** Drink copious amounts of water and provide fresh air. Immediately call 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_2, 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***
Wear protective equipment. Keep unprotected persons away.
· ***Environmental precautions:***
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
· ***Methods and material for containment and cleaning up:***
Absorb with liquid-binding material (ie. sand, diatomite, acid binders, universal binders, sawdust).
Use neutralizing agent.
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
Dispose of the collected material according to regulations.
· ***Reference to other sections***
See Section 7 for information on safe handling.

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See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Handling:**
· **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
· **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:** Keep receptacle tightly sealed.
· **Specific end use(s)** No further relevant information available.

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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**
· **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

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Select glove material based on penetration times, rates of diffusion and degradation.
· **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. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material**
The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.

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· **Eye protection:**

Tightly sealed goggles

9 Physical and chemical properties

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

Form:	Solid
Color:	Layered gray-clear-white
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
Melting point/Melting range:	Not determined.
Boiling point/Boiling range:	Not determined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not applicable.
· **Ignition temperature:**	
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:**	Not determined.
· **Density:**	
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.
· **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.

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· **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:**		
7440-22-4 Silver		
Oral	LD50	>5000 mg/kg (rat)
34590-94-8 (2-methoxymethylethoxy)propanol		
Oral	LD50	5135 mg/kg (rat)
Dermal	LD50	>19000 mg/kg (rab)
Inhalative	LC50/96 hours	>10.000 mg/l (Pimephales)
7447-40-7 Potassium Chloride		
Oral	LD50	2600 mg/kg (rat)

· **Primary irritant effect:**
· **on the skin:** Strong caustic effect on skin and mucous membranes.
· **on the eye:**
Strong irritant with the danger of severe eye injury.
Corrosive effect.
Causes serious eye irritation.
· **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Corrosive
Irritant
Swallowing will lead to a corrosive effect on mouth and throat and to the danger of perforation of esophagus and stomach.

· **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:** Must not reach bodies of water or drainage ditch undiluted or unneutralized.

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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:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
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, IMDG, IATA** Non-Regulated Material
· **UN proper shipping name**
· **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
· **Transport hazard class(es)**

· **DOT, ADR, ADN, IMDG, IATA**
· **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":** -

* 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 are listed.

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

7783-90-6	silver chloride

· **TSCA (Toxic Substances Control Act):**
All ingredients are listed.

· **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.

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· **Chemicals known to cause developmental toxicity:**
None of the ingredients are listed.

· **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 product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**

GHS05 GHS07

· **Signal word** Danger

· **Hazard-determining components of labeling:**
silver chloride
Silver
Hydroxyethyl Cellulose

· **Hazard statements**
Causes severe skin burns and eye damage.
May cause respiratory irritation.

· **Precautionary statements**
Do not breathe dusts or mists.
Avoid breathing dust/fume/gas/mist/vapors/spray.
Use only outdoors or in a well-ventilated area.
Wear eye protection / face protection.
Wash thoroughly after handling.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a poison center/doctor.
Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Call a poison center/doctor if you feel unwell.
Wash contaminated clothing before reuse.
If swallowed: Rinse mouth. Do NOT induce vomiting.
Store locked up.
Store in a well-ventilated place. Keep container tightly closed.
Dispose of contents/container in accordance with local/regional/national/international regulations.

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

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· ***State Right to Know***		
CAS: 7447-40-7	Potassium Chloride	25-50%
CAS: 7440-22-4	Silver STOT SE 3, H335	15-35%
CAS: 34590-94-8 RTECS: JM 1575000	(2-methoxymethylethoxy)propanol Flam. Liq. 4, H227	15-35%
CAS: 7783-90-6	silver chloride Skin Corr. 1C, H314	5-10%
CAS: 9004-62-0	Hydroxyethyl Cellulose STOT SE 3, H335; Eye Irrit. 2B, H320; Combustible Dust	5-10%
CAS: 39346-81-1	2-Hydroxyethyl agarose	2-12%
All ingredients are listed.		

· ***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*** 10/22/2015 / 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)
Flam. Liq. 4: Flammable liquids, Hazard Category 4
Skin Corr. 1C: Skin corrosion/irritation, Hazard Category 1C
Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
Eye Irrit. 2B: Serious eye damage/eye irritation, Hazard Category 2B
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

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

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