SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Contact information

General

Microgenics Corporation
46500 Kato Road
Fremont, CA 94538
Main: (510) 979-5000
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Emergency telephone number

Chemtrec *(24-hour availability)*:
+1 (800) 424-9300 (USA and Canada)
+1 (703) 527-3887 (International; Collect calls accepted)
+1 (202) 483-7616 (Europe)

Product identifier

10015654, DRI® pH Detect Test
100054, DRI® pH Detect Test
100284, DRI® pH Detect Test 7.0 Control
100272, DRI®Creatinine-Detect Calibrator Kit
100273, DRI®Creatinine-Detect 1.3 mg/dL Control Kit
100274, DRI®Creatinine-Detect 7.5 mg/dL Control Kit
100275, DRI®Creatinine-Detect 23.0 mg/dL Control Kit
1754, DRI® Specific Gravity, Low Gravity Calibrator
1755, DRI® Specific Gravity, High Gravity Calibrator
1756, DRI® Specific Gravity, Level 1 Gravity Control
1757, DRI® Specific Gravity, Level 2 Gravity Control
10009971, DRI® General Oxidant-Detect Calibrator Kit
10009972, DRI® General Oxidant-Detect Control Kit
0980, DRI® Serum Tox Salicylate Calibrator Set

Synonyms

None identified

Trade names

DRI® pH Detect Test, DRI® pH Detect Test 7.0 Control, DRI® Creatinine Detect Calibrators and Controls, DRI® Specific Gravity Calibrators and Controls, DRI® Oxidant Detect Calibrators and Controls, DRI® Serum Tox Salicylate Cals

Chemical family

Mixture

Relevant identified uses of the substance or mixture and uses advised against

In vitro diagnostic kit

Note

This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product.

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SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Globally Harmonized System [GHS]	None required.
Other/Supplemental	Mixture not yet fully tested.

Label elements

GHS hazard pictogram	None required
GHS signal word	None required
GHS hazard statements	None required
GHS precautionary statements	None required

Other hazards The hazardous properties of this mixture have not been fully investigated. Potential health hazards associated with exposure/handling may be similar to the ingredients, all of which are considered non-hazardous (See note in Section 3).

Note This mixture is not classified as hazardous according to Regulation EC No 1272/ 2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA).

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	EINECS/ELINCS#	Amount	GHS Classification
Non-Hazardous Reagent(s)	N/A	N/A	~100%	Not classified

Note The principal ingredient in this mixture is distilled water. Any remaining components are not hazardous and/or are present at amounts below reportable limits. The GHS classification is based on Regulation (EC) 1272/2008 and Hazard Communication Standard No. 1910.1200.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed	No. If exposed or concerned: Get medical advice/attention.
Eye Contact	Flush with water. If irritation occurs or persists, notify medical personnel and supervisor.

SECTION 4 - FIRST AID MEASURES …continued

Skin Contact	No specific first aid measures required. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation	No specific first aid measures required. In case of accidental inhalation, move exposed subject to fresh air. If signs/symptoms occur of if concerned, get medical attention.
Ingestion	No specific first aid measures required. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. If signs/symptoms occur or if concerned, get medical attention.
Protection of first aid responders	See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	See Sections 2 and 11.
Indication of immediate medical attention and special treatment needed, if necessary	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	In case of fire in the surroundings: Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate.
Specific hazards arising from the substance or mixture	No information identified.
Flammability/Explosivity	No explosivity or flammability data identified. As product is primarily an aqueous solution, it is not expected to be flammable or explosive.
Advice for firefighters	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
Environmental precautions	No special precautions required.

SECTION 6 - ACCIDENTAL RELEASE MEASURES …continued

Methods and material for containment and cleaning up For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area to minimize the spreading of spilled material. Soak up material with absorbent. Wash spill area thoroughly with water if needed.

Reference to other sections See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling No special handling requirements for the normal use of this mixture.

Conditions for safe storage including any incompatibilities Store at 2-8 °C in a well-ventilated area, away from incompatible materials. Keep container upright and tightly closed.

Specific end use(s) No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters/Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Non-Hazardous Reagent(s)	--	--	--

Exposure/Engineering controls No specific controls or precautions required. Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential.

Respiratory protection No special precautions required. Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls.

Hand protection No special precautions required. Wear nitrile or other impervious gloves to avoid mixture contamination.

Skin protection No special precautions required. Base the choice of skin protection (*e.g.*, appropriate gloves, lab coat, or other protective overgarment) on the job activity, potential for skin contact and solvents and reagents in use.

Eye/face protection Base the choice of protection (*e.g.*, chemical splash goggles) on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Environmental Exposure Controls No special precautions required.

Other protective measures Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Liquid
Color	Clear
Odor	No information identified.
Odor threshold	No information identified.
pH	No information identified.
Melting point/freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified.
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	Miscible in water
Solvent solubility	No information identified.
Partition coefficient (*n-octanol/water*)	No information identified.
Auto-ignition temperature	No information identified.
Decomposition temperature	No information identified.
Viscosity	No information identified.
Explosive properties	No information identified.
Oxidizing properties	No information identified.

Other information

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES …continued

Molecular weight Not applicable (Mixture)

Molecular formula Not applicable (Mixture)

SECTION 10 - STABILITY AND REACTIVITY

Reactivity No information identified.

Chemical stability No information identified.

Possibility of hazardous reactions Not expected to occur.

Conditions to avoid Avoid excessive heat.

Incompatible materials No information identified.

Hazardous decomposition products No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Note No data were available for this mixture. The hazards may be similar to the hazards of the ingredient(s), all of which are considered non-hazardous.

Information on toxicological effects

Route of entry May be absorbed by inhalation, skin contact and ingestion.

Acute toxicity

Compound	Type	Route	Species	Dose
Non-Hazardous Reagent(s)	--	--	--	--

Irritation/Corrosion No data on product formulation.

Sensitization No data on product formulation.

STOT-single exposure No data on product formulation.

STOT-repeated exposure/Repeat-dose toxicity No data on product formulation.

Reproductive toxicity No data on product formulation.

Developmental toxicity No data on product formulation.

Genotoxicity No data on product formulation.

SECTION 11 - TOXICOLOGICAL INFORMATION …continued

Carcinogenicity No data on product formulation. None of the components of the product present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

Aspiration hazard No data on product formulation.

Human health data See "Section 2 - Other Hazards"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Non-Hazardous Reagent(s)	--	--	--

Persistence and Degradability No data available.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Results of PBT and vPvB assessment Not performed.

Other adverse effects No data available.

Note Ecological characteristics of this mixture were not available. No special precautions needed.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods No specific waste treatment methods are required. Used product should be disposed of according to local, state, and federal regulations. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines.

SECTION 14 - TRANSPORT INFORMATION

Transport Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

UN number None assigned.

UN proper shipping name None assigned.

SECTION 14 - TRANSPORT INFORMATION …continued

Transport hazard classes and packing group	None assigned.
Environmental hazards	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users	No special precautions needed.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
Chemical safety assessment	Not conducted.
WHMIS classification	This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations and the SDS contains all of the information required by those regulations.
TSCA status	Not listed
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	Not applicable.
Full text of H phrases and GHS classifications	Not applicable.
Sources of data	Information from published literature and internal company data.

SECTION 16 - OTHER INFORMATION …continued

Abbreviations

ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

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Revisions

This is the first version of this SDS.

Disclaimer

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical/diagnostic product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.