SAFETY DATA SHEET

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

Contact information

General

Thermo

SCIENTIFIC Microgenics Corporation

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Emergency telephone number

Chemtrec (24-hour availability): +1 (800) 424-9300 (USA and Canada)

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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.

Issue Date 14 August 2015

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 <u>CAS #</u> <u>EINECS/ELIN</u> <u>Amount</u> <u>GHS</u>

Non-Hazardous N/A N/A ~100% Classification Not classified

Reagent(s)

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

No specific first aid measures required. If irritation occurs or persists, notify **Skin Contact**

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

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.

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

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.

No information identified. Specific end use(s)

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control

Parameters/Occupational **Exposure Limit Values**

> Compound **OEL** Issuer 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.

No special precautions required. Choice of respiratory protection should be **Respiratory protection**

appropriate to the task and the level of existing engineering controls.

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

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.

Controls

Environmental Exposure 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.

No information identified. **Odor threshold**

pН No information identified.

Melting point/freezing

point

No information identified.

Initial boiling point and

boiling range

No information identified.

No information identified. Flash point

No information identified. **Evaporation rate**

Flammability (solid, gas) No information identified.

Upper/lower No information identified.

flammability or explosive

limits

No information identified. Vapor pressure

No information identified. Vapor density

Relative density No information identified.

Miscible in water Water solubility

No information identified. Solvent solubility

Partition coefficient

(n-octanol/water)

No information identified.

Auto-ignition

temperature

No information identified.

Decomposition

temperature

No information identified.

Viscosity No information identified.

No information identified. **Explosive properties**

No information identified. **Oxidizing properties**

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

<u>Compound</u> <u>Type</u> <u>Route</u> <u>Species</u> <u>Dose</u> 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

<u>Compound</u> <u>Type</u> <u>Species</u> <u>Concentration</u>

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 Not applicable.

to Annex II of

MARPOL73/78 and the IBC

Code

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental

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.

regulations/legislation

specific for the substance or

mixture

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

Issue Date

Revisions

Disclaimer

14 August 2015

This is the first version of this SDS.

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.