

SAFETY DATA SHEET

MICROGENICS

Part of Thermo Fisher Scientific

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

Microgenics Corporation 46500 Kato Road

Fremont, CA 94538 Main: (510) 979-5000

Fax: (510) 979-5002

E-mail:

techservice.mgc@thermofisher.com

Emergency telephone 1-(800) 424-9300 (US and

number (Chemtrec): Canada)

1-(703) 527-3887

International access (collect

calls accepted)

1-(202) 483-7616 Europe

Product identifier DRI[®] Ethyl Alcohol Calibrators and Controls

DRI® Acetaminophen Serum Tox Calibrators

0311 DRI® Ethyl Alcohol Negative Calibrator **Synonyms**

1405 DRI[®] Ethyl Alcohol Negative Calibrator 0241 DRI[®] Ethyl Alcohol 100 mg/dL Calibrator 1406 DRI[®] Ethyl Alcohol 100 mg/dL Calibrator 0239 DRI[®] Ethyl Alcohol 50 mg/dL Control 0243 DRI[®] Ethyl Alcohol 300 mg/dL Control 1091 DRI[®] Acetaminophen Serum Tox Calibrators

DRI[®] Ethyl Alcohol Calibrators and Controls Trade names

DRI® Acetaminophen Serum Tox Calibrators

Chemical family Mixture

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

In vitro diagnostic kit.

Note The pharmacological, toxicological, and ecological properties of this product/

mixture have not been fully characterized. This data sheet will be updated as more

data become available.

Issue Date 5 January 2016

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

> **Regulation (EC)** 1272/2008 [GHS]

Mixture not yet fully tested.

Directive 67/548/EEC or Mixture not yet fully tested.

1999/45/EC

Label elements

CLP/GHS hazard

pictogram

None required

10006103SDS DRI® Ethyl Alcohol Cals and Controls, DRI® Acetaminophen Tox Cals Revision date: 5 January 2016, Version: 3

SECTION 2 - HAZARDS IDENTIFICATION ... continued

CLP/GHS hazard

statements

None required

CLP/GHS precautionary None required

statements

EU symbol/indication of None required

danger

Risk (R) Phrase(s)

None required

Safety Advice

None required

Other hazards

The potential health hazards associated with exposure/handling of this mixture are unknown; no data specific for the mixture were identified. The following data

describe the hazards of individual ingredients, where applicable.

US Signal word

Caution

US Hazard overview

Mixture not yet fully tested.

Note

This mixture is classified as hazardous according to Directive 1999/45/EC, Regulation EC No 1272/2008 (EU CLP) and applicable US regulations. The pharmacological, toxicological, and ecological properties of this mixture have not been fully characterized. The CLP/GHS classifications are based on Regulation (EC) 1272/2008. The EU symbol/indicator of danger, R Phrases and Safety

Advice are based on Directive 1999/45/EC.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	CAS#	EINECS/ELIN	Amount	<u>EU</u>	GHS
		CS#		Classification	Classification
Sodium azide	26628-22-8	247-852-1	≤0.09%	Very Toxic -	ATO2: H300;
				T+: R28, R32;	AA1: H400,
				N: R50/53	CA1: H410;

EUH032

Note The ingredient(s) listed above are considered hazardous. The remaining

> components are non-hazardous and/or present at amounts below reportable limits. Product contains trace amounts of ethanol (≤0.03%) and active pharmaceutical ingredient (≤0.0002%). See Section 16 for full text of EU and CLP/GHS classifications. The EU classification is based on Directive 67/548/EEC and the

CLP/GHS classification is based on Regulation (EC) 1272/2008.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

SECTION 4 - FIRST AID MEASURES ...continued

Immediate Medical Attention Needed No. If exposed or concerned: Get medical advice/attention.

Eye Contact

If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify

medical personnel and supervisor.

Skin Contact

Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

Inhalation

Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical

personnel and supervisor.

Ingestion

If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

oid

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

Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for

surrounding fire and materials.

Specific hazards arising from the substance or mixture

No information identified. May emit toxic gases of carbon monoxide, carbon

dioxide, and oxides of nitrogen.

Flammability/Explosivity No explosivity or flammability data identified. As product is 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

Do not empty into drains. Avoid release to the environment.

Methods and material for containment and cleaning up

DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9).

Reference to other sections

See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling

Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing mist/spray.

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

 $\begin{array}{ccc} \underline{Compound} & \underline{Issuer} & \underline{Type} & \underline{OEL} \\ Sodium \ azide & ACGIH, & OEL-STEL & 0.3 \ mg/m^3 \end{array}$

Australia, Austria, Belgium, Bulgaria, Croatia,

Cyprus, Czech Republic, Estonia, Finland,

France, Greece,

Hungary, Ireland, Italy, Latvia,

Latvia, Lithuania, Malta, Netherlands, Poland, Romania,

Slovakia,

Slovenia, Spain, Sweden, U.S.-California OSHA, United

Kingdom

New Zealand, Ceiling

 0.29 mg/m^3

Portugal

 $10006103SDS\ DRI^{\oplus}$ Ethyl Alcohol Cals and Controls, DRI^{\oplus} Acetaminophen Tox Cals Revision date: 5 January 2016, Version: 3

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ... continued

Control

Parameters/Occupational Exposure Limit Values

...continued

 $\begin{array}{ccc} \underline{Compound} & \underline{Issuer} & \underline{Type} & \underline{OEL} \\ Sodium \ azide & ACGIH, & OEL-TWA & 0.1 \ mg/m^3 \end{array}$

Australia, Austria, Belgium, Bulgaria, Croatia,

Cyprus, Czech Republic, Denmark, Estonia, Finland,

France, Greece,

Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands,

Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden,

Spain, Sweden, U.S.-California OSHA, United Kingdom

NIOCH

NIOSH, Ceiling 0.3 mg/m³

U.S.-California

OSHA

 $\begin{array}{lll} \text{Germany} & \text{OEL-STEL} & 0.4 \text{ mg/m}^3 \\ \text{Germany} & \text{OEL-TWA} & 0.2 \text{ mg/m}^3 \end{array}$

Exposure/Engineering controls

Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at aerosol/mist-generating points.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ... continued

Respiratory protection Choice of respiratory protection should be appropriate to the task and the level of

> existing engineering controls. An approved and properly fitted air-purifying respirator with HEPA filters should provide ancillary protection based on the

known or foreseeable limitations of existing engineering controls.

Hand protection Wear nitrile, rubber or other impervious gloves if skin contact is possible. If the

material is dissolved or suspended in an organic solvent, wear gloves that provide

protection against the solvent.

Skin protection Wear appropriate gloves, lab coat, or other protective overgarment if skin contact

is likely. Base the choice of skin protection on the job activity, potential for skin

contact and solvents and reagents in use.

Wear safety glasses with side shields, chemical splash goggles, or full face shield, Eye/face protection

> if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Controls

Environmental Exposure Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of

contamination and to prevent inadvertent contact by personnel.

Other protective

measures

Wash hands in the event of contact with this product/mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective

equipment following use.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

> **Appearance** Clear liquid

Color Colorless

Odor No information identified.

No information identified. Odor threshold

pН 5-8

Melting point/freezing

point

No information identified.

Initial boiling point and No information identified.

boiling range

Flash point No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ... continued

Evaporation rate No information identified.

Flammability (solid, gas) No information identified.

Upper/lower No information identified.

flammability or explosive

limits

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

 $(n ext{-}octanol/water)$

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

Molecular weight No information identified.

Molecular formula No information identified.

SECTION 10 - STABILITY AND REACTIVITY

Reactivity Sodium azide may react with lead or copper plumbing to form highly explosive

metal azides.

Chemical stability Stable when stored as recommended.

Possibility of hazardous

reactions

Not expected to occur.

Conditions to avoid Avoid temperatures $\geq 25^{\circ}$ C.

Incompatible materials No information identified.

SECTION 10 - STABILITY AND REACTIVITY ... continued

Hazardous decomposition

No information identified.

products

SECTION 11 - TOXICOLOGICAL INFORMATION

Information on toxicological effects

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

Acute toxicity

Compound Type Route Species Dose Sodium azide LD_{50} Oral 27 mg/kg Rat Oral Mouse 27 mg/kg LD_{50} LD_{50} Dermal Rabbit 20 mg/kg

Additional acute toxicity No studies identified.

information

Irritation/Corrosion No studies identified. Sensitization No studies identified. **STOT-single exposure** No studies identified. No studies identified.

STOT-repeated

exposure/Repeat-dose

toxicity

Reproductive toxicity No studies identified. **Developmental toxicity** No studies identified. No studies identified. Genotoxicity

Carcinogenicity No studies identified. This mixture is not listed by NTP, IARC, ACGIH or OSHA

as a carcinogen.

Aspiration hazard No data available.

Human health data See "Section 2 - Other Hazards"

Additional information The toxicological properties of this mixture have not been fully characterized.

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

 $\begin{array}{c|cccc} \underline{Compound} & \underline{Type} & \underline{Species} & \underline{Concentration} \\ Sodium azide & LC_{50}/96h & Oncorhynchus mykiss & 0.8 mg/L \\ & LC_{50}/96h & Lepomis macrochirus & 0.7 mg/L \\ \end{array}$

 LC_{50} /96h Pimephales promelas 5.46 mg/L

Additional toxicity

information

Sodium azide is toxic to aquatic organisms and should not be allowed to accumulate in metal piping as it has the potential to form explosive mixtures.

Persistence and Degradability

Mobility in soil

No data available.

Bioaccumulative potential

No data available.

No data available.

Results of PBT and vPvB

assessment

No data available.

Other adverse effects

No data available.

Note

The environmental characteristics of this product/mixture have not been fully investigated. The above data are for the active ingredient and/or any other ingredient(s) where applicable. Although present at low concentrations, disposal should consider that sodium azide is present. Releases to the environment should

be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods

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. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner.

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

Mixture not fully tested - avoid exposure.

Transport in bulk according Not applicable. **to Annex II of**

MARPOL73/78 and the IBC

Code

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental

regulations/legislation specific for the substance or This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local or regional

authorities for more information.

mixture

Chemical safety assessment Not conducted.

OSHA Hazardous Yes. Caution. Mixture not fully tested.

WHMIS classification This product/mixture has been classified in accordance with the hazard criteria of

the Controlled Products Regulations and the SDS contains all of the information

required by those regulations.

TSCA status All components of mixture are on TSCA Inventory or are exempt

SARA section 313 Not listed.

California proposition 65 Ethyl alcohol (ethanol) as contained in alcoholic beverages (and consumed) is

listed as a reproductive toxicant, but this is not applicable with normal use of this

product.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications

T+ - Very toxic. R28 - Very toxic if swallowed. R32 - Contact with acids liberates very toxic gas. N - Dangerous for the Environment. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Full text of H phrases, P phrases and GHS classification

ATO2 - Acute Toxicity (Oral) Category 2. H300 - Fatal if swallowed. AA1-Aquatic toxicity (acute) - Category 1. H400 - Very toxic to aquatic life. CA1 - Chronic Aquatic Toxicity Category 1. H410 - Very toxic to aquatic life with long lasting effects. EUH032 - Contact with acids liberates very toxic gas.

10006103SDS DRI® Ethyl Alcohol Cals and Controls, DRI® Acetaminophen Tox Cals Revision date: 5 January 2016, Version: 3

SECTION 16 - OTHER INFORMATION ... continued

Sources of data

Information from published literature and internal company data.

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; 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

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.