**SAFETY DATA SHEET**

MICROGENICS
Part of Thermo Fisher Scientific

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


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**Product identifier** DRI® Endocrine Assays SDS

**Synonyms**
0454 DRI® Thyroxine (T4) Assay
10013070 DRI® Thyroxine (T4) Assay
0723 DRI® T-Uptake Assay

**Trade names** DRI® Thyroxine (T4) Assay, DRI® T-Uptake Assay

**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** 22 May 2015

## SECTION 2 - HAZARDS IDENTIFICATION

**Classification of the substance or mixture**

**Regulation (EC) 1272/2008 [GHS]** Respiratory Sensitizer - Category 1. Skin Sensitizer - Category 1. Mixture not yet fully tested.

**Directive 67/548/EEC or 1999/45/EC** Xn - R42 (Respiratory Sens.), R43 (Skin Sens.). Mixture not yet fully tested.

**Label elements**

## SECTION 2 - HAZARDS IDENTIFICATION …continued

**CLP/GHS hazard pictogram**

**CLP/GHS signal word**

Danger

**CLP/GHS hazard statements**

H317 - May cause allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**CLP/GHS precautionary statements**

P261 - Avoid breathing mist or vapor. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/eye protection/ face protection. P285 - In case of inadequate ventilation wear respiratory protection. P302 + P352 - If on skin: Wash with plenty of soap and water. P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

**EU symbol/indication of danger**

Xn - Harmful

**Risk (R) Phrase(s)**

R42/43 - May cause sensitization by inhalation and skin contact.

**Safety Advice**

S2 - Keep out of reach of children. S23 - Do not breathe spray. S24 - Avoid contact with skin. S37 - Wear suitable protective gloves. S63 - In case of accident by inhalation: remove casualty to fresh air and keep at rest.

**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.

Because the mixture contains a protein (bovine serum albumin) it may cause an allergic skin or respiratory reaction (e.g., potential to cause anaphylaxis). In a workplace setting, the likelihood of systemic effects following accidental ingestion is low, due to the rapid breakdown of proteins in the digestive tract. Bovine serum albumin has been associated with occupational sensitization. Although antibody particles are fairly large proteins, it is not known if systemic effects can occur following accidental inhalation. Proteins, in general, can cause skin and/or respiratory sensitization. Material produced in compliance with USDA and/or CPMP/BWP/1230/98 (Guidance on Minimizing the Risk of Transmitting Animal

## SECTION 2 - HAZARDS IDENTIFICATION …continued

**Other hazards** …continued

Spongiform Encephalopathy Agents via Medicinal Products). This is a CPMP/BWP/1230/98 Category IV material: it does not contain nor is it derived from specified risk materials as defined in Commission decision 97/534/EC (or successive amendments).

**US Signal word**

Danger

**US Hazard overview**

May cause allergic respiratory reaction. May cause allergic skin reaction. 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

| Ingredient | CAS # | EINECS/ELINCS# | Amount | EU Classification | GHS Classification |
|---|---|---|---|---|---|
| Tris-Hydrochloride | 1185-53-1 | 214-684-5 | 1–2% | Irritant - Xi: R36/R37/R38 | SI2: H315; EI2: H319; STOT-SE3: H335 |
| Tromethamine (Tris {hydroxymethyl} aminomethane) | 77-86-1 | 201-064-4 | 1-2% | Irritant - Xi: R36/37/38 | SI2: H315; EI2: H319; STOT-S3: H335 |
| Barbital buffer | N/A | N/A | ≤0.2% | Harmful - Xn: R22 | ATO4: H302 |
| Drug-specific antibody | N/A | N/A | ≤0.1% | Harmful - Xn: R42/R43 | SS1: H317; RS1: H334 |
| Bovine serum albumin | 9048-46-8 | N/A | ≤0.1% | Harmful - Xn: R42/R43 | SS1: H317, RS1: H334 |
| Sodium azide | 26628-22-8 | 247-852-1 | ≤0.09% | Very Toxic - T+: R28, R32; N: R50/53 | ATO2: H300; AA1: H400 , 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 also contains trace amounts of drug-specific antibody conjugates (≤0.08%). 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**

| | |
|---|---|
| **Immediate Medical Attention Needed** | Yes |
| **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. |
| **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**

| Compound | Issuer | Type | OEL |
|---|---|---|---|
| Tris-Hydrochloride | -- | -- | -- |
| Tromethamine (Tris {hydroxymethyl} aminomethane) | -- | -- | -- |
| Barbital buffer | -- | -- | -- |
| Drug-specific antibody | -- | -- | -- |
| Bovine serum albumin | -- | -- | -- |

**Control Parameters/Occupational Exposure Limit Values**
…continued

| Compound | Issuer | Type | OEL |
|---|---|---|---|
| Sodium azide | ACGIH, Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, U.S.-California OSHA, United Kingdom | OEL-STEL | 0.3 mg/m³ |
| | New Zealand, Portugal | Ceiling | 0.29 mg/m³ |

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION …continued

**Control Parameters/Occupational Exposure Limit Values**
…continued

| Compound | Issuer | Type | OEL |
|---|---|---|---|
| Sodium azide | ACGIH, Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, U.S.-California OSHA, United Kingdom | OEL-TWA | 0.1 mg/m³ |
| | NIOSH, U.S.-California OSHA | Ceiling | 0.3 mg/m³ |
| | Germany | OEL-STEL | 0.4 mg/m³ |
| | Germany | OEL-TWA | 0.2 mg/m³ |

**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. |
| **Eye/face protection** | Wear safety glasses with side shields, chemical splash goggles, or full face shield, 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. |
| **Environmental Exposure Controls** | 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. |
| **Odor threshold** | No information identified. |
| **pH** | 5-8 |
| **Melting point/freezing point** | No information identified. |
| **Initial boiling point and boiling range** | No information identified. |
| **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 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**

| | |
|---|---|
| **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 ≥ 25° C. |
| **Incompatible materials** | No information identified. |

## SECTION 10 - STABILITY AND REACTIVITY …continued

**Hazardous decomposition products** No information identified.

## 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 |
|---|---|---|---|---|
| Tris-Hydrochloride | -- | -- | -- | -- |
| Tromethamine (Tris {hydroxymethyl} aminomethane) | $LD_{50}$ | Oral | Rat | 5900 mg/kg |
| | $LD_{50}$ | Intravenous | Rat | 1800 mg/kg |
| | $LD_{50}$ | Intravenous | Mouse | 1210 mg/kg |
| Barbital buffer | $LD_{50}$ | Oral | Mouse | 800 mg/kg |
| | $LD_{50}$ | Oral | Rat | 600 mg/kg |
| | $LD_{50}$ | Intravenous (IV) | Mouse | 830 mg/kg |
| | $LD_{50}$ | Intravenous (IV) | Rat | 230 mg/kg |
| Drug-specific antibody | -- | -- | -- | -- |
| Bovine serum albumin | -- | -- | -- | -- |
| Sodium azide | $LD_{50}$ | Oral | Rat | 27 mg/kg |
| | $LD_{50}$ | Oral | Mouse | 27 mg/kg |
| | $LD_{50}$ | Dermal | Rabbit | 20 mg/kg |

**Additional acute toxicity information** No studies identified.

**Irritation/Corrosion** No studies identified.

**Sensitization** No studies identified. As bovine serum albumin (BSA) is derived from animal (foreign) protein, there is potential for the material to cause an allergic response in humans. Occupational exposure to BSA has caused some cases of allergic sensitization in workers handling this material.

**STOT-single exposure** No studies identified.

**STOT-repeated exposure/Repeat-dose toxicity** No studies identified.

**Reproductive toxicity** No studies identified.

**Developmental toxicity** No studies identified.

## SECTION 11 - TOXICOLOGICAL INFORMATION …continued

| | |
|---|---|
| **Genotoxicity** | No studies identified. |
| **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**

| Compound | Type | Species | Concentration |
|---|---|---|---|
| Tris-Hydrochloride | -- | -- | -- |
| Tromethamine (Tris {hydroxymethyl} aminomethane) | -- | -- | -- |
| Barbital buffer | -- | -- | -- |
| Drug-specific antibody | -- | -- | -- |
| Bovine serum albumin | -- | -- | -- |
| Sodium azide | $LC_{50}$/96h | Oncorhynchus mykiss | 0.8 mg/L |
| | $LC_{50}$/96h | Lepomis macrochirus | 0.7 mg/L |
| | $LC_{50}$/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** | No data available. |
| **Bioaccumulative potential** | No data available. |
| **Mobility in soil** | 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. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility. |

## 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. |
| **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 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 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. |
| **Chemical safety assessment** | Not conducted. |
| **OSHA Hazardous** | Yes. Danger. May cause allergic respiratory reaction. May cause allergic skin reaction. Mixture not fully tested. |

## SECTION 15 - REGULATORY INFORMATION …continued

| | |
|---|---|
| **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** | Not listed |
| **SARA section 313** | Not listed. |
| **California proposition 65** | Not listed. |

## SECTION 16 - OTHER INFORMATION

| | |
|---|---|
| **Full text of R phrases and EU Classifications** | Xn - Harmful. R22- Harmful if swallowed. R42 - May cause sensitization by inhalation. R43 - May cause sensitization by skin contact. 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. Xi - Irritant. R36/37/38 - Irritating to eyes, respiratory system and skin. |
| **Full text of H phrases, P phrases and GHS classification** | ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction. RS1 - Respiratory Sensitizer Category 1. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled. 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. SI2 - Skin irritant Category 2. H315 - Causes skin irritation. H319 - Causes serious eye irritation. EI2 - Eye irritant Category 2. STOT-SE3 - Specific Target Organ Toxicity Following Single Exposure Category 3. H335 - May cause respiratory irritation. |
| **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

## SECTION 16 - OTHER INFORMATION …continued

**Abbreviations** …continued

of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

**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.