

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

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**Product identifier** DRI™ Thyroxine (T4) Calibrators, QMS™ Serum-based Calibrators and Controls – Group 1

**Synonyms**

10012088, DRI HS Thyroxine (T4) Calibrators Set  
0476, DRI Thyroxine (T4) Calibrator Kit  
0374173, QMS Topiramate Immunoassay Calibrator Set  
0374181, QMS Topiramate Immunoassay Control Set  
10018469, Topiramate Immunoassay Control Set SEK  
0373902, QMS Gentamicin Immunoassay Calibrator Set  
0374165, QMS Quinidine Immunoassay Calibrator Set  
0374678, QMS Lidocaine Immunoassay Calibrator Set  
0374637, QMS Digitoxin Immunoassay Calibrator Set  
0374652, QMS Teicoplanin Immunoassay Calibrator Set  
0374660, QMS Teicoplanin Immunoassay Control Set  
10019371, Teicoplanin Calibrator Set SEK  
10019378, Teicoplanin Control Set SEK  
0374157, QMS Amikacin Immunoassay Calibrator Set  
10015260, Arbekacin Immunoassay Calibrator Set SEK  
10015261, Arbekacin Immunoassay Control Set SEK  
0373597, QMS Vancomycin Immunoassay Calibrator Set  
0374116, QMS Tobramycin Immunoassay Calibrator Set  
MKIST551AS, Phenobarbital Calibrator Set  
MKIST541AS, Phenytoin Calibrator Set  
MKIST571AS, Carbamazepine Calibrator Set  
MCCST531AS, Theophylline Calibrator Set  
MKIST561AS, Valproic Acid Calibrator Set  
MKIRM73S872LS, Digoxin Calibrator Set  
10023684, QMS Plazomicin Immunoassay Calibrator Set  
10023697, QMS Plazomicin Immunoassay Control Set

**Trade names** DRI Thyroxine (T4) Calibrators, QMS Topiramate Calibrators, QMS Topiramate Controls, QMS Gentamicin Calibrators, QMS Quinidine Calibrators, QMS Lidocaine Calibrators, QMS Digitoxin Calibrators, QMS Teicoplanin Calibrators, QMS Teicoplanin Controls, QMS Amikacin Calibrators, QMS Arbekacin Calibrators, QMS Vancomycin Calibrators, QMS Tobramycin Calibrators, QMS Plazomicin Calibrators, QMS Plazomicin Controls

**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.

## 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 1999/45/EC** Mixture not yet fully tested.

### Label elements

**CLP/GHS hazard pictogram** None required

**CLP/GHS signal word** Warning

**CLP/GHS hazard statements** EUH032 - Contact with acids liberates very toxic gas.

**CLP/GHS precautionary statements** None required

**EU symbol/indication of danger**



Xn - Harmful

**Risk (R) Phrase(s)** R32 - Contact with acids liberates very toxic gas.

**Safety Advice** S2 - Keep out of reach of children. S23 - Do not breathe vapor/spray. S24 - Avoid contact with skin. S37 - Wear suitable protective gloves. S50 - Do not mix with acids.

### Other hazards

No data specific for the mixture were identified. This product contains human source material and should be treated/handled as a potential biohazard. All such human source material has been derived from donors tested individually and shown by FDA approved methods to be free from antibodies to Human Immune Deficiency Virus and Hepatitis B and C. As no test method can offer complete assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions.

**US Signal word** Caution

**US Hazard overview** Mixture not yet fully tested. This product contains human source material and should be treated/handled as a potential biohazard.

**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>	<u>CAS #</u>	<u>EINECS/ELIN CS#</u>	<u>Amount</u>	<u>EU Classification</u>	<u>GHS Classification</u>
Human Source Material	N/A	N/A	97-99%	Not classified	Not classified
Sodium azide	26628-22-8	247-852-1	≤0.10%	Very Toxic - T+: R28, R32; N: R50/53	ATO2: H300; AA1: H400 , CA1: H410; EUH032

**Note** The ingredient(s) listed above are considered hazardous. Human source material (human serum) is listed as it is a potential biohazard. Products contains trace levels of various active pharmaceutical ingredients (≤0.01%). The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of EU and 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

#### SECTION 4 - FIRST AID MEASURES ...continued

**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). Disinfect the area twice with an appropriate solvent, such as 5% chlorine bleach solution.

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

## SECTION 7 - HANDLING AND STORAGE

### Precautions for safe handling

This material should be handled at the Biosafety Level 2 (BSL2) consistent with the U.S. Department of Health and Human Services, the U.S. Public Health Service, Centers for Disease Control (CDC), and National Institute of Health (NIH) Guidelines "Biosafety in Microbiological and Biomedical Laboratories" (December 2009, HHS Publication No. (CDC) 21-1112).

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

### Conditions for safe storage including any incompatibilities

See product packaging for specific storage temperature requirements. Store away from incompatible materials. Keep container upright and tightly closed.

Bacterial contamination produces an increase in turbidity and/or a characteristic odor. Discard vial if evidence of microbial contamination is observed.

### Specific end use(s)

No information identified.

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

### Note

Dispose of broken vials/syringes in a sharps container.



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

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

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Sodium azide	ACGIH,	OEL-TWA	0.1 mg/m <sup>3</sup>
	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		
	NIOSH,	Ceiling	0.3 mg/m <sup>3</sup>
	U.S.-California		
	OSHA		
	Germany	OEL-STEL	0.4 mg/m <sup>3</sup>
	Germany	OEL-TWA	0.2 mg/m <sup>3</sup>

**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. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling.



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

<b>Respiratory protection</b>	Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine handling tasks, an approved and properly fitted air purifying respirator should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls.
<b>Hand protection</b>	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
<b>Skin protection</b>	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.
<b>Eye/face protection</b>	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.
<b>Environmental Exposure Controls</b>	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.
<b>Other protective measures</b>	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

<b>Appearance</b>	Clear liquid
<b>Color</b>	Colorless
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	No information identified.
<b>Melting point/freezing point</b>	No information identified.
<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	No information identified.
<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	Miscible with water.
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (n-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular weight</b>	Not applicable (Mixture)
<b>Molecular formula</b>	Not applicable (Mixture)

## SECTION 10 - STABILITY AND REACTIVITY

<b>Reactivity</b>	Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.
<b>Chemical stability</b>	Stable when stored as recommended.
<b>Possibility of hazardous reactions</b>	Not expected to occur.
<b>Conditions to avoid</b>	Avoid extreme temperatures.
<b>Incompatible materials</b>	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

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Human Source Material	--	--	--	--
Sodium azide	LD <sub>50</sub>	Oral	Rat	27 mg/kg
	LD <sub>50</sub>	Oral	Mouse	27 mg/kg
	LD <sub>50</sub>	Dermal	Rabbit	20 mg/kg

**Irritation/Corrosion** No studies identified.

**Sensitization** No studies identified.

**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.

**Genotoxicity** No studies identified.

**Carcinogenicity** No studies identified. None of the components of this mixture 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 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

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Human Source Material	--	--	--
Sodium azide	LC <sub>50</sub> /96h	Oncorhynchus mykiss	0.8 mg/L
	LC <sub>50</sub> /96h	Lepomis macrochirus	0.7 mg/L
	LC <sub>50</sub> /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** Not performed.

**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.

## SECTION 14 - TRANSPORT INFORMATION ...continued

<b>Transport hazard classes and packing group</b>	None assigned.
<b>Environmental hazards</b>	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
<b>Special precautions for users</b>	Mixture not fully tested - avoid exposure.
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

## SECTION 15 - REGULATORY INFORMATION

<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	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.
<b>Chemical safety assessment</b>	Not conducted.
<b>OSHA Hazardous</b>	Caution. Mixture not fully tested. Product contains human source material and should be treated/handled as a potential biohazard.
<b>WHMIS classification</b>	This product 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.
<b>TSCA status</b>	All components of mixture are on TSCA Inventory or are exempt
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	Not listed.
<b>Additional Information</b>	Federal German Government Water Hazard Classification: WHC 1

## SECTION 16 - OTHER INFORMATION

<b>Full text of R phrases and EU Classifications</b>	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.
<b>Full text of H phrases, P phrases and GHS classification</b>	ATO2 - Acute Toxicity (Oral) Category 2. H300 - Fatal if swallowed. AA1 - Aquatic toxicity (acute) - Category 1. H400 - Very toxic to aquatic life. CA1 - Aquatic toxicity (chronic) - Category 1. H410 - Very toxic to aquatic life with long lasting effects. EUH032 - Contact with acids liberates very toxic gas.

## 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.