

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

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**Product identifier** QMS<sup>®</sup> Everolimus Calibrator Set and Control Set

**Synonyms** 0373860 QMS<sup>®</sup> Everolimus Calibrator Set  
0380005 QMS<sup>®</sup> Everolimus Calibrator Set  
0373878 QMS<sup>®</sup> Everolimus Control Set  
0380010 QMS<sup>®</sup> Everolimus Control Set  
10017386, Everolimus Calibrator SEK  
10017387, Everolimus Control Set SEK

**Trade names** QMS<sup>®</sup> Everolimus Calibrator Set  
QMS<sup>®</sup> Everolimus Control Set

**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.

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**SECTION 2 - HAZARDS IDENTIFICATION**

**Classification of the substance or mixture**

**Regulation (EC) 1272/2008 [GHS]** Aquatic toxicity (chronic) - Category 3. Mixture not yet fully tested.

**Directive 67/548/EEC or 1999/45/EC** R52/53. Mixture not yet fully tested.

**Label elements**

**CLP/GHS hazard pictogram** None required

**CLP/GHS signal word** Warning

## SECTION 2 - HAZARDS IDENTIFICATION ...continued

<b>CLP/GHS hazard statements</b>	H412 - Harmful to aquatic life with long lasting effects.
<b>CLP/GHS precautionary statements</b>	P273 - Avoid release to the environment. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.
<b>EU symbol/indication of danger</b>	None required
<b>Risk (R) Phrase(s)</b>	R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
<b>Safety Advice</b>	S23 - Do not breathe vapor/spray. S29 - Do not empty into drains. S61 - Avoid release to the environment.
<b>Other hazards</b>	This product/mixture contains human source material (human serum) 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.
<b>US Signal word</b>	Caution
<b>US Hazard overview</b>	May be harmful to aquatic life with long lasting effects. Mixture not yet fully tested. This product contains human source material and should be treated/handled as a potential biohazard.
<b>Note</b>	This mixture does not meet criteria for classification according to Directive 1999/45/EC and Regulation EC No 1272/2008 (EU CLP). Nevertheless, it should be regarded as hazardous as it is potentially biohazardous. 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 and on the revised OSHA hazard communication standard. 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	99.9-99.99%	Not classified	Not classified
3:1 Mixture: 5-chloro-2-methyl-4-isothiazoli n-3-one + 2-methyl-4-isothiazolin-3-one	55965-84-9	613-167-00-5	≤0.05%	Toxic - T: R23/24/25, R43; Corrosive - C: R34; Dangerous for the Environment - N: R50/53	ATO3: H301; ATD3: H311; ATI3: H331; SC1B: H314; SS1: H317; AA1: H400; CA1: H410

### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS ...continued

**Note** The ingredient(s) listed above are considered hazardous. Human source material is listed because it is a potential biohazard. The remaining components are non-hazardous and/or present at amounts below reportable limits. Product contains trace levels of active pharmaceutical ingredient ( $\leq 20$  ppb). The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.

### SECTION 4 - FIRST AID MEASURES

#### Description of first aid measures

<b>Immediate Medical Attention Needed</b>	No. If exposed or concerned: Get medical advice/attention.
<b>Eye Contact</b>	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.
<b>Skin Contact</b>	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Inhalation</b>	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.
<b>Ingestion</b>	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.
<b>Protection of first aid responders</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed</b>	See Sections 2 and 11
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	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.

## SECTION 5 - FIREFIGHTING MEASURES ...continued

**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-based 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** Surround spill with absorbents and place a damp cloth or towel over the area to minimize entry into the air. Add excess liquid to allow the material to enter into solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container for 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** Store at -20°C away from incompatible materials.

**Specific end use(s)** No information identified.

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control

#### Parameters/Occupational

#### Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Human Source Material	--	--	--
3:1 Mixture: 5-chloro-2-methyl-4-isothiazoli n-3-one + 2-methyl-4-isothiazolin-3-one	--	--	--

#### 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.

#### Respiratory protection

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.

#### Hand protection

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.

#### 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. 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

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

<b>Color</b>	Colorless
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	5.0-8.0
<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.
<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 in 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>	No information identified.
<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 temperatures $\geq 25^{\circ}$ C.
<b>Incompatible materials</b>	None reported.
<b>Hazardous decomposition products</b>	No information identified.

## SECTION 11 - TOXICOLOGICAL INFORMATION

**Note** No data for this product/mixture were identified. The following data describe the active ingredient and/or the individual ingredients where applicable.

### 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	--	--	--	--
3:1 Mixture: 5-chloro-2-methyl-4-isothiazoli n-3-one + 2-methyl-4-isothiazolin-3-one	--	--	--	--

**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 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 studies identified

**SECTION 11 - TOXICOLOGICAL INFORMATION ...continued****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	--	--	--
3:1 Mixture: 5-chloro-2-methyl-4-isothiazoli n-3-one + 2-methyl-4-isothiazolin-3-one	EC <sub>50</sub> /120h (5-chloro-2-met hyl-4-isothiazol in-3-one)	Anabaena flos-aquae	0.31 mg/L
	EC <sub>50</sub> /72h (5-chloro-2-met hyl-4-isothiazol in-3-one)	Pseudokirchneriella subcapitata	0.11-0.16 mg/L
	EC <sub>50</sub> /96h (5-chloro-2-met hyl-4-isothiazol in-3-one)	Pseudokirchneriella subcapitata	0.03-0.13 mg/L
	LC <sub>50</sub> /96h (5-chloro-2-met hyl-4-isothiazol in-3-one)	Oncorhynchus mykiss	1.6 mg/L
	EC <sub>50</sub> /48h (5-chloro-2-met hyl-4-isothiazol in-3-one)	Daphnia magna	4.71 mg/L

**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.



## SECTION 12 - ECOLOGICAL INFORMATION ...continued

**Note** The environmental characteristics of this product/mixture have not been fully investigated. 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.

## SECTION 15 - REGULATORY INFORMATION ...continued

<b>Chemical safety assessment</b>	Not conducted.
<b>OSHA Hazardous</b>	Caution. May be harmful to aquatic life with long lasting effects. Mixture not fully tested. This product contains human source material and should be treated/handled as a potential biohazard.
<b>WHMIS classification</b>	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.
<b>TSCA status</b>	Not listed
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	Not listed.

## SECTION 16 - OTHER INFORMATION

<b>Full text of R phrases and EU Classifications</b>	T - Toxic. R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed. R43 - May cause sensitization by skin contact. C - Corrosive. R34 - Causes burns. N - Dangerous for the Environment. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R52/53 - Harmful 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>	ATO3 - Acute Toxicity (Oral) Category 3. H301 - Toxic if swallowed. ATD3 - Acute Toxicity (Dermal) Category 3. H311 - Toxic in contact with skin. AT13 - Acute Toxicity (Inhalation) Category 3. H331 - Toxic if inhaled. SC1B - Skin corrosion Category 1. H314 - Causes severe skin burns and eye damage. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction. AA1 - Acute Aquatic Toxicity Category 1. H400 - Very toxic to aquatic life. CA1 - Chronic Aquatic Toxicity Category 1. H410 - Very toxic to aquatic life with long lasting effects. CA3 - Chronic Aquatic Toxicity Category 3. H412 - Harmful to aquatic life with long lasting effects.
<b>Sources of data</b>	Information from published literature and internal company data.
<b>Abbreviations</b>	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 third 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.