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

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Product identifier

QMS® Everolimus Immunoassay – Reagent 1 and Reagent 2

Synonyms

0373852, QMS® Everolimus Immunoassay
10015993, QMS® Everolimus Immunoassay
0380000, QMS® Everolimus Immunoassay
10015987, QMS® Everolimus Immunoassay
10017261, QMS® Everolimus Anti-Reagent
10017262, QMS® Everolimus MicroReagent

Trade names

QMS® Everolimus Reagents

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

27 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 - R42/43. Mixture not yet fully tested.

Label elements

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.

This product/mixture contains human serum albumin 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.

Because the mixture contains foreign protein (IgM goat antisera) 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. Although

SECTION 2 - HAZARDS IDENTIFICATION …continued

Other hazards …continued

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 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. This product contains human source material and should be treated/handled as a potential biohazard. 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 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

Ingredient	CAS #	EINECS/ELINCS#	Amount	EU Classification	GHS Classification
IgM Antisera (Goat)	N/A	N/A	≤3.5%	Harmful - Xn: R42/43	RS1: H334; SS1: H317
Human Serum Albumin	70024-90-7	274-272-6	≤1.0%	Harmful - Xn: R42/43	RS1: H334; SS1: H317
Antibody (Animal)	N/A	N/A	≤1.0%	Harmful - Xn: R42/43	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 low levels (<0.6%) of active pharmaceutical ingredient. 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 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 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
IgM Antisera (Goat)	--	--	--
Human Serum Albumin	--	--	--
Antibody (Animal)	--	--	--

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

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

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 or other impervious gloves if skin contact is possible. Double gloves should be considered. 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. 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	Liquid
Color	Yellow to opaque-white
Odor	No information identified.
Odor threshold	No information identified.
pH	6-8
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
IgM Antisera (Goat)	--	--	--	--
Human Serum Albumin	--	--	--	--
Antibody (Animal)	--	--	--	--
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 IgM goat antisera is derived from animal (foreign) protein, there is potential for the material to cause an allergic response in humans.

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. 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
IgM Antisera (Goat)	--	--	--
Human Serum Albumin	--	--	--
Antibody (Animal)	--	--	--
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.

SECTION 14 - TRANSPORT INFORMATION …continued

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. This product contains human source material and should be treated/ handled as a potential biohazard. 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	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. 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.

SECTION 16 - OTHER INFORMATION …continued

Full text of H phrases, P phrases and GHS classification	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.
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
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.

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

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International access (collect calls accepted)
1-(202) 483-7616 Europe

Product identifier QMS® Everolimus Reagent – Precipitant Reagent

Synonyms 0373852, QMS® Everolimus Immunoassay
10015993, QMS® Everolimus Immunoassay
0380000, QMS® Everolimus Immunoassay
10017333, QMS® Precipitation Reagent

Trade names QMS® Everolimus

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 27 May 2015

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Regulation (EC) 1272/2008 [GHS] Aquatic toxicity (acute) - Category 1. Aquatic toxicity (chronic) - Category 1. Mixture not yet fully tested.

Directive 67/548/EEC or 1999/45/EC N: R50; R50/53. Mixture not yet fully tested.

Label elements

CLP/GHS hazard pictogram

CLP/GHS signal word Warning

CLP/GHS hazard statements H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long-lasting effects.

CLP/GHS precautionary statements P273 - Avoid release to the environment. P391 - Collect spillage. P501 - Dispose of contents/container to location in accordance with local/regional/national/ international regulations.

EU symbol/indication of danger

N - Dangerous for the environment

Risk (R) Phrase(s) R50 - Very toxic to aquatic organisms. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety Advice S7 - Keep container tightly closed. S29 - Do not empty into drains. S35 - This material and its container must be disposed of in a safe way. S57 - Use appropriate container to avoid environmental contamination. S61 - Avoid release to the environment. Refer to special instructions/safety data sheets.

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 May be very toxic to aquatic life (acute). May be very toxic to aquatic life with long lasting effects. 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 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

Ingredient	CAS #	EINECS/ELINCS#	Amount	EU Classification	GHS Classification
Copper (II) Sulfate	7758-98-7	231-847-6	≤6.4%	Harmful - Xn: R22; R36/38; N: R50/53	ATO4: H302; SI2: H315; EI2: H319; AA1: H400; CA1: H410
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. 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

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). 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

Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). 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
Copper (II) Sulfate	ACGIH	TLV-TWA 8-Hr	0.2 mg(Cu)/m³ (fume)
	Finland, Hungary	TWA-8 HR	1 mg(Cu)/m³
	Germany	MAK-TWA (8-Hr)	0.1 mg(Cu)/m³
	Hungary	STEL	4 mg(Cu)/m³
	Sweden	TWA-8 HR	1 mg(Cu)/m³
	Sweden	TWA 8-HR	0.2 mg(Cu)/m³ (respirable dust)
	US-OSHA	PEL-TWA (8-HR)	1 mg(Cu)/m³ (dust)
	US-OSHA	PEL-TWA (8-HR)	1 mg(Cu)/m³ (fume)

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

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

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	No information identified.
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
Copper (II) Sulfate	LD_{50}	Oral	Rat	960 mg/kg
	LD_{50}	Oral	Mouse	379 mg/kg
	LD_{50}	Intravenous (IV)	Rat	48.9 mg/kg
	LD_{50}	Intravenous (IV)	Mouse	23.3 mg/kg
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.

STOT-single exposure In animals, ingestion of three ounces of a 1% solution of copper sulfate produces intense inflammation of the gastrointestinal tract, with abdominal pain, vomiting, and diarrhea.

STOT-repeated exposure/Repeat-dose toxicity Administration of copper ("cupric") sulfate to rats in feed or drinking water resulted in significant gastric changes and hepatic and renal damage. The primary effect in rats was an increase in the size and number of proteinaceous droplets in the epithelial cytoplasm and lumen of the proximal convoluted tubule of the kidney.

For rats in a 13-week study, the no-observed-adverse-effect level (NOAEL) for evidence of histologic injury to the kidney was 1000 ppm for males and 500 ppm for females, while the NOAEL for liver inflammation was 1000 ppm for males and 2000 ppm for females. Hyperplasia with hyperkeratosis of the epithelium on the limiting ridge separating the forestomach from the glandular stomach was also seen in rats of each sex, and the NOAEL for this change was 1000 ppm cupric sulfate in feed.

Additionally, clinical pathology alterations noted in a 13-week study, along with histologic changes in bone marrow noted in a 2-week study, were indicative of a microcytic anemia with a compensatory bone marrow response.

SECTION 11 - TOXICOLOGICAL INFORMATION …continued

STOT-repeated exposure/Repeat-dose toxicity …continued	Mice appeared to be much more resistant to the toxic effects of cupric sulfate than rats. The primary target tissue in mice was the epithelium of the limiting ridge of the forestomach. The NOAEL for the hyperplasia and hyperkeratosis seen at this site in mice was 2000 ppm cupric sulfate in the feed.
Reproductive toxicity	Cupric sulfate produced no adverse effects on any of the reproductive parameters measured in rats or mice of either sex (additional details not identified).
Developmental toxicity	Copper salts administered intravenously to hamsters on Day 8 of gestation induced embryonic resorptions and developmental malformations (e.g., heart defects) in surviving offspring. When supplemented in the diet of mice at doses of 500-1,000 ppm, copper sulfate stimulated embryonic development and increased both litter size and fetal weights. Higher copper doses (>1,000 ppm) increased fetal mortality and decreased litter size. When supplemented in the diet of mice at 3,000 and 4,000 ppm, copper sulfate induced a level (e.g., up to 8% of living fetuses) of various skeletal and other malformations that were absent at lower doses and controls.
Genotoxicity	Mutagenicity of cupric sulfate was evaluated *in vivo* by chromosome aberration, sperm abnormality, and micronucleus tests in mice. Dose, route, and time influenced significantly the frequency of chromosome aberration, incidence of micronucleus and sperm abnormality. Relative sensitivity of the three assays was: sperm abnormality > chromosome aberration > micronucleus formation.
Carcinogenicity	No studies identified. None of the components of the 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

Compound	Type	Species	Concentration
Copper (II) Sulfate	LC_{50} (96 h)	Haliotis cracherodii (abalone)	0.05 mg/L
	LC_{50} (96 h)	Crassostrea gigas (oyster)	0.56 mg/L
	LC_{50} (96 h)	Anguilla rostrata (American eel)	3.2 mg/L
	LC_{50} (96 h)	Oncorhynchus kisutch (coho salmon)	0.286 mg/L
	EC_{50} (72 h)	Thalassiosira pseudonana (algae)	0.005 mg/L
	EC_{50} (96 h)	Nitschia closterium (algae)	0.033 mg/L

SECTION 12 - ECOLOGICAL INFORMATION …continued

Toxicity …continued

Compound	Type	Species	Concentration
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 regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

UN number UN3082

UN proper shipping name Environmentally Hazardous Substance, liquid, n.o.s. (contains cupric sulfate)

SECTION 14 - TRANSPORT INFORMATION …continued

Transport hazard classes and packing group	Hazard Class - 9; Packing Group III.
Environmental hazards	Based on the available data, this product/mixture is 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. Caution. May be very toxic to aquatic life (acute). May be very toxic to aquatic life with long lasting effects. 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	Not listed
SARA section 313	Copper (II) sulfate is listed.
California proposition 65	Not listed.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	T+ - Very toxic. Xn - Harmful. R22 - Harmful if swallowed. R36/38 - Irritating to eyes and skin. R28 - Very toxic if swallowed. R32 - Contact with acids liberates very toxic gas. N - Dangerous for the Environment. R50 - Very toxic to aquatic organisms. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SECTION 16 - OTHER INFORMATION …continued

Full text of H phrases, P phrases and GHS classification	SI2 - Skin irritant Category 2. H315 - Causes skin irritation. EI2 - Eye irritant Category 2. H319 - Causes serious eye irritation. ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. 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.
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
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.