

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

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Product identifier QMS[®] Tacrolimus Assay, Reagent 1 and Reagent 2

Synonyms 10015556, QMS[®] Tacrolimus Assay
10019478, Tacrolimus Antigen Reagent
10019479, Tacrolimus Microparticle Reagent

Trade names QMS[®] Tacrolimus 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 28 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/R43. 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 vapor/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.

Product/mixture contains human serum albumin, a protein, and thus 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 protein particles are fairly large in size, it is not known if systemic effects can occur following accidental inhalation. Proteins, in general, can cause skin and/or respiratory sensitization.

All 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

SECTION 2 - HAZARDS IDENTIFICATION ...continued

Other hazards ...continued assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions.

US Signal word Danger

US Hazard overview May cause allergic respiratory/skin reaction. 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

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN CS#</u>	<u>Amount</u>	<u>EU Classification</u>	<u>GHS Classification</u>
Choline salt	Proprietary	Proprietary	6-7%	Irritant - Xi: R36/38	SI2: H315; EI2: H319
Bis-Tris	6976-37-0	230-237-7	5-6%	Irritant - Xi: R36/37/38	SI2: H315; EI2: H319; STOT-SE3: H335
Human Serum Albumin	70024-90-7	274-272-6	1-3%	Harmful - Xn: R42/43	RS1: H334; SS1: H317
Carbodiimide Hydrochloride	Proprietary	Proprietary	1-2%	Irritant - Xi: R36/37/38	SI2: H315; EI2: H319; STOT-SE3: H335
Drug-specific antibody	N/A	N/A	0.1-1%	Harmful - Xn: R42/R43	SS1: H317; RS1: H334
Sodium azide	26628-22-8	247-852-1	0.05-0.09%	Very Toxic - T+: R28, R32; N: R50/53	ATO2: H300; AA1: H400 , CA1: H410; EUH032

Note The ingredient(s) listed above are considered hazardous. Human source material (human serum albumin) is a potential biohazard. The remaining components are non-hazardous and/or present at amounts below reportable limits. Product contains trace amounts of active pharmaceutical ingredients ($\leq 0.03\%$). 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
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, oxides of nitrogen, and chlorine-containing compounds.
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.

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	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

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Choline salt	--	--	--
Bis-Tris	--	--	--
Human Serum Albumin	--	--	--
Carbodiimide Hydrochloride	--	--	--
Drug-specific antibody	--	--	--

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, 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/m ³
	NIOSH, U.S.-California OSHA	Ceiling	0.3 mg/m ³
	Germany	OEL-STEL	0.4 mg/m ³
	Germany	OEL-TWA	0.2 mg/m ³

**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. For routine handling tasks, an approved and properly worn air-purifying respirator equipped with HEPA filters or combination 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. 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 to cloudy liquid
Color	Off-white to slightly yellow
Odor	No information identified.
Odor threshold	No information identified.
pH	6.0-7.0
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	Not applicable (Mixture)
Molecular formula	Not applicable (Mixture)

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.
Chemical stability	Stable when stored as recommended.
Possibility of hazardous reactions	Not expected to occur.
Conditions to avoid	Avoid temperatures $\geq 25^{\circ}$ C. Do not freeze.
Incompatible materials	None reported.

SECTION 10 - STABILITY AND REACTIVITY ...continued

Hazardous decomposition products 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>
Choline salt	LD ₅₀	Oral	Rat	3400 mg/kg
	LD ₅₀	Oral	Mouse	3900 mg/kg
Bis-Tris	--	--	--	--
Human Serum Albumin	--	--	--	--
Carbodiimide Hydrochloride	LD ₅₀	Intravenous	Mouse	56 mg/kg
Drug-specific antibody	--	--	--	--
Sodium azide	LD ₅₀	Oral	Rat	27 mg/kg
	LD ₅₀	Oral	Mouse	27 mg/kg
	LD ₅₀	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 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

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>
Choline salt	--	--	--
Bis-Tris	--	--	--
Human Serum Albumin	--	--	--
Carbodiimide Hydrochloride	--	--	--
Drug-specific antibody	--	--	--
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 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.

SECTION 14 - TRANSPORT INFORMATION ...continued

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. Product contains human source material and should be treated/handled as a potential biohazard. May cause allergic respiratory/skin reaction. Mixture not fully tested.
WHMIS classification	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.
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

T+ - Very toxic. R28 - Very toxic if swallowed. N - Dangerous for the Environment. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R32 - Contact with acids liberates very toxic gas. Xi - Irritant. R36/38 - Irritating to eyes and skin. R36/37/38 - Irritating to eyes, respiratory system and skin. Xn - Harmful. R42/43 - May cause sensitization by inhalation and skin contact.

Full text of H phrases, P phrases and GHS classification

ATO2 - Acute Toxicity (Oral) Category 2. H300 - Fatal if swallowed. 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. SI2 - Skin irritant Category 2. H315 - Causes skin irritation. EI2 - Eye irritant Category 2. H319 - Causes serious eye irritation. STOT-SE3 - Specific Target Organ Toxicity Following Single Exposure Category 3. H335 - May cause respiratory irritation. SS1 - Skin sensitizer Category 1. RS1 - Respiratory Sensitizer Category 1. H317 - May cause an allergic skin reaction. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled. 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 second 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

SECTION 16 - OTHER INFORMATION ...continued

Disclaimer ...continued

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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Product identifier QMS[®] Tacrolimus Assay – Extraction Reagent

Synonyms 10015556, QMS[®] Tacrolimus Assay
10019480, Tacrolimus Extraction Reagent

Trade names QMS[®] Tacrolimus Assay

Chemical family Mixture

Relevant identified uses of the substance or mixture and uses advised against *In vitro* diagnostic kit

Note The 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 18 May 2015

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Regulation (EC) 1272/2008 [GHS] Corrosive (eye) - Category 1. Aquatic toxicity (chronic) - Category 2. Mixture not yet fully tested.



Directive 67/548/EEC or 1999/45/EC Xi: R41; N: R51/53 Mixture not yet fully tested.

Label elements

CLP/GHS hazard pictogram



SECTION 2 - HAZARDS IDENTIFICATION ...continued

CLP/GHS signal word	Danger
CLP/GHS hazard statements	H318 - Causes serious eye damage. H411 - Toxic to aquatic life with long-lasting effects.
CLP/GHS precautionary statements	P273 - Avoid release to the environment. P280 - Wear protective gloves/eye protection/face protection. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a Poison Center or doctor/physician. 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  Xi - Irritant
Risk (R) Phrase(s)	R41 - Risk of serious damage to eyes. R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Safety Advice	S7 - Keep container tightly closed. S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S29 - Do not empty into drains. S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection. S57 - Use appropriate container to avoid environmental contamination. S61 - Avoid release to the environment. Refer to special instructions/safety data sheets.
Other hazards	Information specific for the mixture was not identified. Data presented below are for the ingredients, where applicable. Zinc sulfate is irritating to eyes and skin - eye redness and persistent discomfort occur after exposure to concentrated solutions. Exposure to mists containing zinc sulfate during electrolytic manufacturing of zinc has been reported to produce irritation of respiratory and digestive systems and dental deterioration. Impaired immune response to excess zinc in diet has also been reported. Oral exposure to zinc at the level of 150 mg zinc sulfate twice a day for six weeks resulted in a reduction in lymphocyte stimulation.
US Signal word	Danger
US Hazard overview	Causes eye burns. May be toxic to aquatic life with long lasting effects. Mixture not yet fully tested.

SECTION 2 - HAZARDS IDENTIFICATION ...continued

Note This mixture is classified as hazardous according to Directive 1999/45/EC and Regulation EC No 1272/2008 (EU CLP), and applicable US regulations. 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>
Zinc sulfate	7733-02-0	231-793-3	8-9%	Harmful - Xn: R22; R41; N: R50/R53	ATO4: H302; ED1: H318; AA1: H400; CA1: H410

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 GHS classifications. The EU classification is based on Directive 1999/45/EC 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.

SECTION 4 - FIRST AID MEASURES ...continued

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 and carbon dioxide, and sulfur-containing compounds.
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 a fire, keep containers cool with water and remove from fire area. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Wash all equipment thoroughly 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. Avoid breathing mist/spray. Keep container tightly closed. Wash thoroughly after handling. Wear appropriate protective equipment when handling.
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

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Zinc sulfate	Germany	MAK-TWA (8-Hr)	0.1 mg/m ³
	Switzerland	MAK-W	0.1 mg/m ³
	Switzerland	KZG-W	0.4 mg/m ³

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. High-energy operations should be done within an approved emission control or containment system.
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 with appropriate HEPA or combination filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.
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.

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

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.
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.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

Partition coefficient (<i>n</i>-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	Not applicable (Mixture)
Molecular formula	Not applicable (Mixture)

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Stable
Possibility of hazardous reactions	Not expected to occur.
Conditions to avoid	No information identified.
Incompatible materials	No information identified.
Hazardous decomposition products	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>
Zinc sulfate	LD ₅₀	Oral	Rat	623 mg/kg
	LD ₅₀	Oral	Rat (male)	920 mg/kg

Irritation/Corrosion Zinc sulfate is irritating to eyes and skin.

SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

Sensitization	No studies identified.
STOT-single exposure	<p>Zinc sulfate administration caused severe ocular irritation in rabbits. In animal studies, dermal administration of zinc sulfate induced marginal epidermal hyperplasia.</p> <p>At an oral dose of 2,000 mg/kg in rats, clinical signs included hunched posture, lethargy, ataxia, piloerection, decreased respiration rate, labored respiration, emaciation, and diarrhea. Necropsy in animals that died revealed hemorrhagic lungs, dark liver and kidneys, white/green colored and thickened gastric mucosa and hemorrhagic small intestine. At a lower dose of 200 mg/kg, no death or clinical signs were observed.</p>
STOT-repeated exposure/Repeat-dose toxicity	Mice and rats were dosed with zinc sulfate at oral (gavage) dose levels of 0.3, 3.0, and 30 mg/kg in their feed for 13 weeks. The maximum dose caused decreased body weight gain, reduction in food and water consumption (mice), erythrocyte count, enzyme activity cholesterol and glucose content. Gross pathology examination revealed morphology changes in the gastrointestinal tract, spleen and kidneys, and decreased relative weights of visceral organs. NOAELs were 458 mg/kg in male mice, 479 mg/kg in female mice, and 240 mg/kg in rats.
Reproductive toxicity	No studies identified.
Developmental toxicity	The oral administration of up to 42.5 mg/kg of zinc sulfate via gavage had no adverse effects on adult rats and their fetuses.
Genotoxicity	Zinc sulfate was negative in the Ames bacterial cell mutagenicity assay, in a mouse micronucleus test, and in a chromosomal aberration assay in rats.
Carcinogenicity	<p>In long term studies, mice were administered 1250-5000 ppm of zinc sulfate in drinking water for a period of one year. Apart from severe anemia in animals receiving 5000 ppm, there were no adverse effects observed. Tumor incidence was not significantly different from that seen in controls.</p> <p>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.</p>
Aspiration hazard	No studies identified
Human health data	See "Section 2 - Other Hazards"
Additional information	The ecological and 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>
Zinc sulfate	LC ₅₀ /96h	Oncorhynchus mykiss (rainbow trout)	2.4 mg/L
	LC ₅₀ /96h	Pimephales promelus (fathead minnow)	0.6 mg/L
	LC ₅₀ /48h	Philodina acuticornis (rotifer)	0.5 mg/L
	LC ₅₀ (48h)	Oncorhynchus mykiss (rainbow trout)	4.76 mg/L
	LC ₅₀ /96h	Oncorhynchus mykiss (rainbow trout)	4.6 ppm
	LC ₅₀ (24h)	Lepomis macrochirus (bluegill sunfish)	8.85 ppm
	LC ₅₀ (24h)	Carassius auratus (fresh water fish)	24 ppm
	LC50 (24 h)	Acrossocheilus paradoxus (minnow)	1422.9 µg/L
	LC ₅₀ /48h	Acrossocheilus paradoxus (minnow)	1066.4 µg/L
	LC ₅₀ (96 h)	Acrossocheilus paradoxus (minnow)	813.3 µg/L

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 the formulated product 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 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 zinc sulfate)
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	Avoid release to the environment.
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. Causes eye burns. May be toxic to aquatic life with long-lasting effects.
WHMIS classification	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.
TSCA status	Not listed
SARA section 313	Zinc sulfate is listed.
California proposition 65	Not listed

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	Xi - Irritant. Xn - Harmful. R22 - Harmful if swallowed. R41 - Risk of serious damage to eyes. N - Dangerous for the Environment. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Full text of H phrases, P phrases and GHS classification	ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. ED1 - Eye Damage Category 1. H318 - Causes serious eye damage. 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. H411 - Toxic to aquatic life with long lasting effects.
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.