

SAFETY DATA SHEET

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

Contact information

General

Thermo

SCIENTIFIC

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| | |
|--|---|
| Product identifier | QMS™ Lamotrigine Assay, QMS™ Zonisamide Assay, QMS™ Vancomycin Assay |
| Synonyms | 0373795, QMS Lamotrigine Assay 0373571, QMS Zonisamide Assay 10017230, QMS Zonisamide Assay 10019419, Zonisamide Antibody Reagent – SEK 10019420, Zonisamide Microparticle Reagent – SEK 0373589, QMS Vancomycin Assay 10017224, QMS Vancomycin Assay 0373605, QMS Vancomycin Antibody Reagent 0373613, QMS Vancomycin Microparticle Reagent 0234934, Vancomycin Antibody Reagent 0234918, Vancomycin Microparticle Reagent |
| Trade names | QMS Lamotrigine Assay, QMS Zonisamide Assay SDS, QMS Vancomycin Assay |
| Chemical family | Mixture |
| Relevant identified uses of the substance or mixture and uses advised against | <i>In vitro</i> diagnostic kit. |
| Note | The pharmacological, toxicological, and ecological properties of this product/mixture have not been fully characterized. This data sheet will be updated as more data become available. |

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

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| Globally Harmonized System [GHS] | Respiratory sensitizer - Category 1. Skin sensitizer - Category 1. |
| Other/Supplemental Label elements | Mixture not yet fully tested. |

SECTION 2 - HAZARDS IDENTIFICATION ...continued

GHS hazard pictogram



GHS signal word

Danger

GHS hazard statements

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

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.

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 source material (human serum albumin) and should be treated/handled as a potential biohazard. 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 assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions.

As the mixture contains a protein 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 protein particles are fairly large in size, it is not known if systemic effects can occur following accidental inhalation.

Note

This mixture is classified as hazardous according to Regulation EC No 1272/2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA). The pharmacological, toxicological and ecological properties of this mixture have not been fully characterized.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

| <u>Ingredient</u> | <u>CAS #</u> | <u>EINECS/ELIN CS#</u> | <u>Amount</u> | <u>GHS Classification</u> |
|----------------------------|--------------|----------------------------|---------------|--|
| Choline salt | Proprietary | Proprietary | ≤6.4% | SI2: H315; EI2: H319 |
| Bis-Tris | 6976-37-0 | 230-237-7 | ≤5.2% | SI2: H315; EI2: H319; STOT-SE3: H335 |
| Drug-specific antibody | N/A | N/A | ≤5.0% | SS1: H317; RS1: H334 |
| Human Serum Albumin | 70024-90-7 | 274-272-6 | ≤2.0% | RS1: H334; SS1: H317 |
| Carbodiimide Hydrochloride | Proprietary | Proprietary | ≤1.9% | SI2: H315; EI2: H319; STOT-SE3: H335 |
| Sodium azide | 26628-22-8 | 247-852-1 | ≤0.09% | ATO2: H300; AA1: H400 , CA1: H410; EUH032 |

Note The ingredient(s) listed above are considered hazardous. Human serum albumin is a potential biohazard. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications. Product contains low levels of active pharmaceutical ingredients (≤0.5%). The GHS classification is based on Regulation (EC) 1272/2008 and Hazard Communication Standard No. 1910.1200.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

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| 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

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| 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

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| 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

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| 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

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| 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 | -- | -- | -- |
| Drug-specific antibody | -- | -- | -- |
| Human Serum Albumin | -- | -- | -- |
| Carbodiimide Hydrochloride | -- | -- | -- |

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 |

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

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| 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. Laboratory operations should be conducted within a laboratory hood or biological safety cabinet if feasible. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling. |
| Respiratory protection | Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. If handling outside of containment device, an approved and properly fitted air-purifying respirator with HEPA filters should be considered to provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with HEPA filters or combination filters or 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. |
| 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

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| Appearance | Clear to cloudy liquid |
| Color | Off-white to slightly yellow |

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

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| 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. |
| 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

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| 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 $\geq 32^{\circ}$ C. Do not freeze. |
| Incompatible materials | None reported. |
| 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 | -- | -- | -- | -- |
| Drug-specific antibody | -- | -- | -- | -- |
| Human Serum Albumin | -- | -- | -- | -- |
| Carbodiimide Hydrochloride | LD ₅₀ | Intravenous | Mouse | 56 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 |

Irritation/Corrosion No studies identified.

Sensitization As human serum albumin is a protein, there is potential for the material to cause an allergic response in humans. Proteins, in general, can cause skin and/or respiratory sensitization.

STOT-single exposure No studies identified.

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

Reproductive toxicity No studies identified.

SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

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| 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 | -- | -- | -- |
| Drug-specific antibody | -- | -- | -- |
| Human Serum Albumin | -- | -- | -- |
| Carbodiimide Hydrochloride | -- | -- | -- |
| 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.

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 generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.

Chemical safety assessment Not conducted.

WHMIS classification RS1: H334; SS1: H317. This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations and the SDS contains all of the information required by those regulations.

SECTION 15 - REGULATORY INFORMATION ...continued

| | |
|----------------------------------|--|
| TSCA status | Not listed |
| SARA section 313 | Not listed. |
| California proposition 65 | Not listed. |
| Additional information | Federal German Government Water Hazard Classification: WHC2. |

SECTION 16 - OTHER INFORMATION

Full text of H phrases and GHS classifications 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

Issue Date 01 January 2019

Revisions This is the second version of this SDS.

SECTION 16 - OTHER INFORMATION ...continued

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.