

SAFETY DATA SHEET

Issuing Date: 2022-11-14
Revision Date: 2022-11-14
Revision: New

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Supplier:

Aalto Scientific, Ltd.
230 Technology Parkway
Eatonton, GA 31024
U.S.

Product name: Linearity FLQ Anti-Mullerian Hormone for Roche Systems
Product code: K896M-5
Pure substance/preparation: Preparation
Intended Use: For In Vitro Diagnostic use only.
Customer service telephone: (760) 431-7922
Email: ehs@aaltoscientific.com
Emergency telephone number: 1-800-748-6674

SECTION 2 - HAZARDS IDENTIFICATION

2.1 Classification: This product contains no hazardous chemicals in reportable quantities in accordance with 29CFR1910 (OSHA HCS) or Regulation (EC) No 1272/2008 (CLP).

2.2 Label Elements

Product name Linearity FLQ Anti-Mullerian Hormone for Roche Systems
Hazard pictograms None assigned
Signal word(s) None assigned
Hazard statements None assigned
Precautionary statement(s) None assigned

2.3 Other hazard information: Some components of this kit contain human and/or animal blood derivatives. No known test method can offer complete assurance

that products derived from human and/or animal blood will not transmit infectious agents. Therefore, all blood derivatives should be handled using universal precautions and considered potentially infectious.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Component(s)	CAS Number	Weight %	OSHA PEL:	OSHA STEL:
Water/Bovine serum albumin	N/A	99-100%	N/A	N/A

SECTION 4 – FIRST AID MEASURES

- Eye contact:** May Cause irritation. In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical attention.
- Skin contact:** May cause slight skin irritation. If a person feels unwell or symptoms of skin irritation appear, consult a physician. Wash off immediately with soap and plenty of water.
- Ingestion:** May cause gastrointestinal irritation, nausea, vomiting and diarrhea
- Inhalation:** May cause irritation of respiratory tract
- Protection of first-aiders:** Wear suitable gloves and eye/face protection.

SECTION 5 – FIRE FIGHTING MEASURES

- Suitable extinguishing media:** Use any extinguishing media which is suitable for the surrounding fire.
- Extinguishing media which must not be used for safety reasons:** None.
- Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:** None reasonably foreseeable.
- Combustion products or resulting gases:** None.
- Special protective equipment for firefighters:** Wear self-contained breathing apparatus and protective suit.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal precautions:	Wear suitable gloves and eye/face protection. Handle all blood materials as if capable of transmitting infectious agents. It is recommended that blood materials be handled using established good laboratory practices.
Environmental precautions:	Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.
Methods for cleaning up:	Wipe up with absorbent material (e.g. cloth, fleece). Clean with disinfectants. Clean contaminated surface thoroughly.

SECTION 7 – HANDLING AND STORAGE

Handling:

Technical measures/precautions:	Wear protective safety glasses, gloves and clothing.
Safe handling advice:	Always replace cap after use. Wear disposable gloves while handling reagents. Thoroughly wash hands afterwards.

Storage:

Technical measures/storage conditions:	Store opened and unopened containers in accordance with COA or package insert.
Incompatible products:	Keep away from sources of ignition.
<u>Specific use(s):</u>	In vitro diagnostic use only.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits:

No information available.

Exposure controls / personal protection

Engineering controls:	Ensure adequate ventilation.
Respiratory protection:	None required.
Hand protection:	Wear disposable gloves while handling. Thoroughly wash hands afterwards.
Eye protection:	Wear eye/face protection
Skin and body protection:	Wear suitable protective clothing. Wear suitable gloves and eye/face protection.
Environmental exposure controls:	No information available.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Frozen liquid.	Vapor Pressure:	No information available.
Appearance:	No information available.	Specific gravity:	No information available.
Colour:	No information available.	Density (20/4):	No information available.
Odour:	No information available.	Water solubility:	No information available.
Flash Point:	No information available.	Solubility in other solvents:	No information available.
pH:	Neutral.	Partition coefficient:	No information available.
Flammability (solid, gas):	No information available.	Viscosity:	No information available.
Explosive properties:	No information available.	Vapor density:	No information available.
Oxidizing properties:	No information available.	Evaporation rate:	No information available.
Autoignition temperature:	No information available.	Fat solubility (g/l)	No information available.
Miscibility:	No information available.	Gas group:	No information available.
Volume resistivity:	No information available.		

SECTION 10 – STABILITY AND REACTIVITY

Chemical stability:	Stable under recommended storage conditions.
Materials to avoid:	No information available.
Conditions to avoid:	No information available.
Hazardous polymerisation:	No information available.
Possibility of hazardous reactions:	No information available.
Hazardous incompatibilities/decomposition products:	No information available.

SECTION 11 – TOXICOLOGICAL INFORMATION

Primary routes of exposure:	The most likely routes of exposure are ingestion, skin contact, eye contact and inhalation. Material may be absorbed through raw or damaged skin.
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Symptoms of overexposure:	No specific symptoms identified
Eye contact:	May cause eye irritation.
Skin contact:	May cause skin irritation.
Ingestion:	Not expected to be toxic if swallowed.
Inhalation:	Not expected to be toxic if inhaled.
Target organ(s):	Not available.
Reproductive effects:	Not available.
Developmental effects:	Not available.
Carcinogenicity:	Not available.
Genotoxic effects:	Not available.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects:	This product has no known ecological effects.
Aquatic toxicity effects:	No data available.
Mobility:	No data available.
Persistence/degradability:	No data available.
Bioaccumulation:	No data available.
Degradation:	No data available.

SECTION 13– DISPOSAL CONSIDERATIONS

Waste from residues/unused products:	Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.
Contaminated packaging:	Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.

SECTION 14 – TRANSPORT INFORMATION

Product not regulated by DOT, IATA/ICAO, IMO/IMDG, ADR/RID, or TDG.

SECTION 15– REGULATORY INFORMATION

U.S. Federal Regulations:

Company: Aalto Scientific, Ltd.

Product name: Linearity FLQ Anti-Mullerian Hormone for Roche Systems

Product code: K896M-5

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U.S. CERCLA/SARA/TSCA Regulatory Information:	<p>This Product does not contain any chemicals currently listed on the Section 302/312, SARA Title III above the OSHA de minimis concentration.</p> <p>This product does not contain any chemicals currently listed with a CERCLA RQ above the OSHA de minimis concentration.</p>
California Proposition 65	<p>This product contains trace amounts of the following substances known to the State of California to cause Cancer and/or reproductive harm: None</p>

SECTION 16 – OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):

Not applicable.

Restrictions on use:

This product is not for human consumption. In vitro diagnostic use only.

Additional advice:

None.

Full text of R-phrases referred to under sections 2 and 3

Not applicable.

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End of Safety Data Sheet