

## SAFETY DATA SHEET

**Issuing Date:** 2019-07-09  
**Revision Date:** 2019-07-09  
**Revision:** New

### SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

**Supplier:**

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

**Product name:** Linearity FLQ Fertility for Roche Systems

**Product code:** K927M-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 Fertility 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

<b>Personal precautions:</b>	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.
<b>Environmental precautions:</b>	Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.
<b>Methods for cleaning up:</b>	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.
<b><u>Specific use(s):</u></b>	In vitro diagnostic use only.

## SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

### **Exposure limits:**

No information available.

### **Exposure controls / personal protection**

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

## SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

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

## SECTION 10 – STABILITY AND REACTIVITY

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

## SECTION 11 – TOXICOLOGICAL INFORMATION

<b>Primary routes of exposure:</b>	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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<b>Symptoms of overexposure:</b>	No specific symptoms identified
<b>Eye contact:</b>	May cause eye irritation.
<b>Skin contact:</b>	May cause skin irritation.
<b>Ingestion:</b>	Not expected to be toxic if swallowed.
<b>Inhalation:</b>	Not expected to be toxic if inhaled.
<b>Target organ(s):</b>	Not available.
<b>Reproductive effects:</b>	Not available.
<b>Developmental effects:</b>	Not available.
<b>Carcinogenicity:</b>	Not available.
<b>Genotoxic effects:</b>	Not available.

## SECTION 12 – ECOLOGICAL INFORMATION

### Ecotoxicity

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

## SECTION 13– DISPOSAL CONSIDERATIONS

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

<b>U.S. CERCLA/SARA/TSCA Regulatory Information:</b>	<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>
<b>California Proposition 65</b>	<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**