

## SAFETY DATA SHEET

**Issuing Date:** 2021-02-19  
**Revision Date:** 2021-02-19  
**Revision:** New

### SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

**Supplier:**

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

**Product name:** Linearity FD iPTH for Roche Systems  
**Product code:** K934M-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 of the substance or mixture**

**GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) and Regulation (EC) No 1272/2008 (CLP)**

Skin Sensitization (Category 1), H317

For the full text of the H-statements mentioned in this section, see section 16

**2.2 GHS label elements, including precautionary statements**

Hazard pictograms



Signal word(s)

Warning

## Hazard statement(s)

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317 May cause an allergic skin reaction.

## Precautionary statement(s)

P261 Avoid breathing dust / fume / gas / mist / vapours / spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

## 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 considered potentially infectious. Contains anti-microbial materials that could be toxic in large doses.

## Carcinogenicity rating

**IARC:** Not classified.

**European Union:** Not classified.

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Component(s)	CAS Number	Classification	Concentration
Human Plasma/Bovine Serum Albumin (BSA)	N/A	N/A	99%
2-methylisothiazol-3(2H)-one	2682-20-4	Skin Sens. 1A	≥ 0.0015 - < 0.1%
Sodium Azide	26628-22-8	N/A	<0.1%

## SECTION 4 – FIRST AID MEASURES

### 4.1 Description of first aid measures

#### General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

### **If inhaled**

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

### **In case of skin contact**

Flush eyes with water as a precaution

### **If swallowed**

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

### **4.2 Most important symptoms and effects, both acute and delayed**

The most important known symptoms and effects are described in section 2.

### **4.3 Indication of any immediate medical attention and special treatment needed**

No data available

## **SECTION 5 – FIRE FIGHTING MEASURES**

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

## **SECTION 6 – ACCIDENTAL RELEASE MEASURES**

<b>Personal precautions:</b>	Wear suitable gloves and eye/face protection.
<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.

**Specific use(s):** 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**

<b>Physical state:</b>	Freeze-dried powder.	<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>	Keep away from heat and sources of ignition.
<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 skin and eye contact and inhalation. Material may be absorbed through the skin.
<b>Symptoms of overexposure:</b>	No information available.
<b>Eye contact:</b>	No information available.
<b>Skin contact:</b>	No information available.
<b>Ingestion:</b>	No information available.
<b>Inhalation:</b>	No information available.
<b>Target organ(s):</b>	No information available.
<b>Reproductive effects:</b>	No information available.
<b>Developmental effects:</b>	No information available.
<b>Carcinogenicity:</b>	No information available.

**Genotoxic effects:** No information available.

## SECTION 12 – ECOLOGICAL INFORMATION

### Ecotoxicity

**Ecotoxicity effects:** No information available.  
**Aquatic toxicity effects:** No information available.  
**Mobility:** No information available.  
**Persistence/degradability:** No information available.  
**Bioaccumulation:** No information available.  
**Degradation:** No information 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

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

## SECTION 16 – OTHER INFORMATION

Company: Aalto Scientific, Ltd.

Product name: Linearity FD iPTH for Roche Systems

Product code: K934M-5

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

N/A.

**Restrictions on use:** This product is not for human consumption. In vitro diagnostic use only.

**Additional advice:** None.

**Full text of H-Statements referred to under sections 2 and 3**

H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction
Respiratory Sens.	Respiratory sensitization
Skin Sens.	Skin sensitization

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**End of Safety Data Sheet**