

SAFETY DATA SHEET

Issuing Date: 2021-02-16
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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 Siemens Centaur
Product code: K813M-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

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.
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.

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

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

U.S. Federal Regulations:	
U.S. CERCLA/SARA/TSCA Regulatory Information:	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.
California Proposition 65	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 Siemens Centaur

Product code: K813M-5

Page 6 of 7

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