

SAFETY DATA SHEET

according to 29CFR1910.1200 (OSHA HCS) and Regulation (EC) No. 1907/2006

Date of Compilation/Revision Date: 2023-06-30

Revision Number: 004

Replaces Revision: 003

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name/Designation of the mixture: Linearity FD Bilirubin Roche Systems

Product code: K886M-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Intended Use: For use as in vitro diagnostic quality control material.

Uses advised against: Not for use in/on humans or animals. Not for use in the manufacture of products to be used in/on humans or animals.

1.3 Details of the supplier of the safety data sheet

Supplier:
Aalto Scientific, Ltd.
230 Technology Parkway
Eatonton, GA 31024
USA

Customer service telephone: (760) 431-7922

Email (Competent Person): ehs@aaltoscientific.com

1.4 Emergency telephone number 1-800-748-6674

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture

This product does not meet the criteria for classification in accordance with 29CFR1910.1200 (OSHA HCS).

This product meets the criteria for classification in accordance with Regulation (EC) No. 1272/2008 (CLP). This product is classified as Skin Sensitization 1A and Hazardous to the aquatic environment – Chronic, category 3. Once diluted, as it is intended to be used, this product does not meet the criteria for classification

as Hazardous to the aquatic environment – Chronic, category 3 in accordance with Regulation (EC) No. 1272/2008 (CLP).

The most important adverse physicochemical, human health and environmental effects

No additional information available.

2.2 Label elements

Hazard pictogram(s)



Signal word(s)

Warning

Hazard statement(s)

H317 May cause an allergic 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

P302+P352 IF ON SKIN: Wash with plenty of water

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents in accordance with local, state, federal and international regulations.

2.3 Other hazards

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, this material should be considered potentially infectious. Contains materials that could be toxic in large doses.

PBT criteria of REACH Annex XIII

Substance/mixture does not meet the PBT criteria of REACH regulation, Annex XIII

vPvB criteria of REACH Annex XIII

Substance/mixture does not meet the vPvB criteria of REACH regulation, Annex XIII

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier (CAS-No.) (EC No.)	Concentration (%w)	Classification of substance according to Regulation (EC) no. 1272/2008 and hazard statement(s)
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS No.: 55965-84-9 EC No.: 911-418-6	0.00015 – 0.020	Skin Sensitization 1A H317: May cause an allergic skin reaction
Kanamycin sulphate	CAS No.: 25389-94-0 EC No.: 246-933-9	< 0.3%	Category 1B reproductive toxicant H360: May damage fertility or the unborn child

Substances indicated in 3.2 (additional information)

Name	Specific concentration Limit/M- factor(s)	Acute Toxicity Estimate	Reason for indicating the substance
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	M=100 M=100	–	Not applicable.
Kanamycin sulphate	–	–	REACH threshold

For full hazard and supplemental hazard statements refer to Section 16 of this SDS.

SECTION 4: First aid measures

4.1 Description of first aid measures

First-aid measures general

Seek medical advice/attention if you feel unwell.

In case of eye contact:

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Continue rinsing eyes during transport to hospital.

In case of skin contact:

Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician

In case of ingestion:

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

In case of inhalation:

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

Protection of first-aid providers

Wear suitable gloves and eye/face protection.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labeling (see Section 2.2) and/or Section 11 of this SDS.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Extinguishing media which must not be used for safety reasons None to our knowledge.

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases: None to our knowledge.

Combustion products or resulting gases: None.

5.2 Special hazards arising from the substance or mixture

None to our knowledge.

5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective suit.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For emergency responders and non-emergency personnel

Wear suitable gloves and eye/face protection. Handle all blood and materials in contact with blood as if capable of transmitting infectious agents. It is recommended that blood and materials in contact with blood be handled using established good laboratory practices.

6.2 Environmental precautions

Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.

6.3 Methods and material for containment and cleaning up

Containment techniques

Use appropriate adsorbent material.

Spill clean-up

Use appropriate adsorbent material.

6.4 Reference to other sections

See Sections 8 and 13 for Exposure controls/personal protection and waste handling.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations for safe handling

Avoid contact with skin and eyes. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Wear appropriate personal protective equipment - see Section 8.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully

resealed and kept upright to prevent leakage.

7.3 Specific end use(s)

For professional use only.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.2.2 Individual protection measures

Eye/face protection

Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Hand protection

Wear suitable gloves resistant to chemical penetration. Nitrile rubber gloves. Layer thickness : 0.11mm. Breakthrough time : 60 min.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multipurpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Body protection

Wear clothing suitable for a laboratory environment including (but not limited to) a lab coat and closed toed shoes.

Ingredients with workplace control parameters (US)

No occupational exposure limit values.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:	Solid.	Decomposition temperature:	No information available.
Colour:	No information available.	pH:	No information available.
Odour:	No information available.	Kinematic viscosity:	No information available.
Melting point/freezing point:	No information available.	Solubility:	No information available.

Boiling point:	No information available.	Partition coefficient n-octanol/water (log value):	No information available.
Flammability:	No information available.	Vapour pressure:	No information available.
Lower and upper explosion limit:	No information available.	Density/relative density:	No information available.
Flash point:	No information available.	Relative vapour density:	No information available.
Autoignition temperature:	No information available.	Particle characteristics:	No information available.

9.2 Other Information

No other information available.

SECTION 10: Stability and reactivity

10.1 Reactivity	Stable under normal conditions.
10.2 Chemical stability	Stable under normal conditions.
10.3 Possibility of hazardous reactions	No information available.
10.4 Conditions to avoid	Temperatures outside of the specified storage range.
10.5 Incompatible materials	Strong oxidizing agents, Reducing agents, Amines, Mercaptans
10.6 Hazardous decomposition products	Other decomposition products - No data available In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity:	Not classified. Based on available data, classification criteria are not met.
Skin corrosion/irritation:	Not classified. Based on available data, classification criteria are not met.
Serious eye damage/irritation:	Not classified. Based on available data, classification criteria are not met.
Respiratory or skin sensitization:	Not classified. Based on available data, classification criteria are not met.
Germ cell mutagenicity:	Not classified. Based on available data, classification criteria are not met.
Carcinogenicity:	Not classified. Based on available data, classification criteria are not met.
Reproductive toxicity:	Not classified. Based on available data, classification criteria are not met.

STOT-single exposure:	Not classified. Based on available data, classification criteria are not met.
STOT-repeated exposure:	Not classified. Based on available data, classification criteria are not met.
Aspiration hazard:	Not classified. Based on available data, classification criteria are not met.
11.2 Information on other hazards	Not established as having endocrine disrupting properties.

SECTION 12: Ecological information

12.1 Toxicity

Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1) (CAS No. 55965-84-9)	
Toxicity to fish (acute)	flow-through test LC50 - Oncorhynchus mykiss (rainbow trout) – 0.19 mg/L - 96 h (US-EPA)
Toxicity to daphnia and other aquatic invertebrates	flow-through test LC50 - Daphnia magna (Water flea) - 0.18 mg/l - 48 h (US-EPA)
Toxicity to bacteria	static test EC50 - activated sludge - 4.5 mg/l - 3 h (OECD Test Guideline 209)
Toxicity to fish (Chronic toxicity)	semi-static test NOEC - Oncorhynchus mykiss (rainbow trout) - 0.098 mg/l - 35 d (OECD Test Guideline 215)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	flow-through test NOEC - Daphnia magna (Water flea) - 0.1 mg/l - 21 d (US-EPA)

12.2 Persistence and degradability	No data available.
12.3 Bioaccumulative potential	No data available.
12.4 Mobility in soil	No data available.
12.5 Results of PBT and vPvB assessment	Substance/mixture does not meet the PBT or vPvB criteria of REACH regulation, Annex XIII
12.6 Endocrine disrupting properties	Not established as having endocrine disrupting properties.
12.7 Other adverse effects	No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods	Dispose of contents/container in accordance with licensed collector's sorting instructions. Sewage disposal is discouraged. Handle product as if it is capable of transmitting infectious disease.
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SECTION 14: Transport information

ADR	IMDG	IATA	ADN	RID
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14.1 UN number/ID number				
Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.
14.2 UN proper shipping name				
Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.
14.3 Transport hazard class				
Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.
14.4 Packing group				
Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.

14.5 Environmental hazards Not regulated for transportation

14.6 Special precautions for user: None.

14.7 Maritime transport in bulk according to IMO instruments: Not applicable.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Restrictions according to REACH, Annex XVII: Not listed

15.2 Chemical safety assessment No chemical safety assessment has been carried out.

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

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

2.1
3.2

Restrictions on use:

This product is not for human consumption. This product is not for use in/on humans or animals.

Additional advice:

None.

Full text of H- and EUH- statements not written out in full under Sections 2 to 15:

None.

Data Sources:

Component manufacturer, 1907/2006/EC (REACH), 1272/2008/EC (CLP)

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End of Safety Data Sheet