

SAFETY DATA SHEET

Luminex

xTAG® Cystic Fibrosis (CFTR) 60 kit v2, xTAG® Cystic Fibrosis (CFTR)
71 kit v2

Section 1. Identification

Product identifier : xTAG® Cystic Fibrosis (CFTR) 60 kit v2, xTAG® Cystic Fibrosis (CFTR) 71 kit v2
Product code :

Other means of identification :

Component 1	xTAG® CFTR PCR Mix v2
Component 2	xTAG® CFTR Bead Mix A v2
Component 3	xTAG® CFTR Bead Mix B v2
Component 4	xTAG® CFTR ASPE Mix A v2
Component 5	xTAG® CFTR ASPE Mix B v2
Component 6	xTAG® Reporter Buffer
Component 7	Platinum Tfi Exo(-) DNA Polymerase
Component 8	Platinum Tfi Reaction Buffer, 5x
Component 9	Tfi 50mM MgCl ₂
Component 10	xTAG® Shrimp Alkaline Phosphatase
Component 11	xTAG® Exonuclease I
Component 12	xTAG® Streptavidin, R-Phycoerythrin Conjugate

Product type : Liquid.

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

Identified uses : For Professional use only. Use as per Product Insert.

Supplier/Manufacturer : Luminex Molecular Diagnostics, Inc.
439 University Avenue
Toronto, Ontario
Canada M5G 1Y8
Tel: 1-512-381-4397
Toll free: 1-877-785-2323 (US and Canada)
Fax: 1-512-219-5114

e-mail address of person responsible for this SDS : Support@Luminexcorp.com

Emergency telephone number (with hours of operation) : 1-512-381-4397
24/7

Section 2. Hazard(s) identification

Classification of the substance or mixture : SKIN CORROSION/IRRITATION - Category 2

GHS label elements for the kit

Hazard pictograms :



Signal word : **WARNING**



Section 2. Hazard(s) identification

Hazard statements : H315 - Causes skin irritation.

Precautionary statements

Prevention : P280 - Wear protective gloves.
P264 - Wash hands thoroughly after handling.

Response : P302 + P352 + P362 + P363 - IF ON SKIN: Wash with plenty of soap and water.
Take off contaminated clothing. Wash contaminated clothing before reuse.
P332 + P313 - If skin irritation occurs: Get medical attention.

Storage : Not applicable.

Disposal : Not applicable.

GHS label elements by component

Hazard pictograms : Component 8



Signal word : Component 1 No signal word.
Component 2 No signal word.
Component 3 No signal word.
Component 4 No signal word.
Component 5 No signal word.
Component 6 No signal word.
Component 7 No signal word.
Component 8 WARNING
Component 9 No signal word.
Component 10 No signal word.
Component 11 No signal word.
Component 12 No signal word.

Hazard statements : Component 1 No known significant effects or critical hazards.
Component 2 No known significant effects or critical hazards.
Component 3 No known significant effects or critical hazards.
Component 4 No known significant effects or critical hazards.
Component 5 No known significant effects or critical hazards.
Component 6 No known significant effects or critical hazards.
Component 7 No known significant effects or critical hazards.
Component 8 H315 - Causes skin irritation.
Component 9 No known significant effects or critical hazards.
Component 10 No known significant effects or critical hazards.
Component 11 No known significant effects or critical hazards.
Component 12 No known significant effects or critical hazards.

Precautionary statements

Section 2. Hazard(s) identification

Prevention	: Component 1	Not applicable.
	Component 2	Not applicable.
	Component 3	Not applicable.
	Component 4	Not applicable.
	Component 5	Not applicable.
	Component 6	Not applicable.
	Component 7	Not applicable.
	Component 8	P280 - Wear protective gloves. P264 - Wash hands thoroughly after handling.
	Component 9	Not applicable.
	Component 10	Not applicable.
	Component 11	Not applicable.
	Component 12	Not applicable.
Response	: Component 1	Not applicable.
	Component 2	Not applicable.
	Component 3	Not applicable.
	Component 4	Not applicable.
	Component 5	Not applicable.
	Component 6	Not applicable.
	Component 7	Not applicable.
	Component 8	P302 + P352 + P362 + P363 - IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing. Wash contaminated clothing before reuse. P332 + P313 - If skin irritation occurs: Get medical attention.
	Component 9	Not applicable.
	Component 10	Not applicable.
	Component 11	Not applicable.
	Component 12	Not applicable.
Storage	: Component 1	Not applicable.
	Component 2	Not applicable.
	Component 3	Not applicable.
	Component 4	Not applicable.
	Component 5	Not applicable.
	Component 6	Not applicable.
	Component 7	Not applicable.
	Component 8	Not applicable.
	Component 9	Not applicable.
	Component 10	Not applicable.
	Component 11	Not applicable.
	Component 12	Not applicable.
Disposal	: Component 1	Not applicable.
	Component 2	Not applicable.
	Component 3	Not applicable.
	Component 4	Not applicable.
	Component 5	Not applicable.
	Component 6	Not applicable.
	Component 7	Not applicable.
	Component 8	Not applicable.
	Component 9	Not applicable.
	Component 10	Not applicable.
	Component 11	Not applicable.
	Component 12	Not applicable.

Section 2. Hazard(s) identification

Supplemental label elements : Not applicable.

Other hazards which do not result in classification : None known.

Section 3. Composition and ingredient information

Substance/mixture : Mixture

Ingredient name	% (w/w)	CAS number
Component 7 Glycerol	≥10 - ≤30	56-81-5
Component 8 Glycerol Potassium hydroxide	≥10 - ≤30 ≥1 - ≤3	56-81-5 1310-58-3
Component 10 Glycerol	≥60 - ≤75	56-81-5
Component 11 Glycerol	≥30 - ≤60	56-81-5

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.
- Inhalation** : Not applicable.
- Skin contact** : Flush contaminated skin with plenty of water. Continue to rinse for at least 20 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Not applicable.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** :
- Component 1** No known significant effects or critical hazards.
 - Component 2** No known significant effects or critical hazards.
 - Component 3** No known significant effects or critical hazards.
 - Component 4** No known significant effects or critical hazards.
 - Component 5** No known significant effects or critical hazards.
 - Component 6** No known significant effects or critical hazards.
 - Component 7** No known significant effects or critical hazards.
 - Component 8** No known significant effects or critical hazards.
 - Component 9** No known significant effects or critical hazards.
 - Component 10** No known significant effects or critical hazards.
 - Component 11** No known significant effects or critical hazards.
 - Component 12** No known significant effects or critical hazards.

Section 4. First aid measures

Inhalation	: Component 1	No known significant effects or critical hazards.
	Component 2	No known significant effects or critical hazards.
	Component 3	No known significant effects or critical hazards.
	Component 4	No known significant effects or critical hazards.
	Component 5	No known significant effects or critical hazards.
	Component 6	No known significant effects or critical hazards.
	Component 7	No known significant effects or critical hazards.
	Component 8	No known significant effects or critical hazards.
	Component 9	No known significant effects or critical hazards.
	Component 10	No known significant effects or critical hazards.
	Component 11	No known significant effects or critical hazards.
	Component 12	No known significant effects or critical hazards.
Skin contact	: Component 1	No known significant effects or critical hazards.
	Component 2	No known significant effects or critical hazards.
	Component 3	No known significant effects or critical hazards.
	Component 4	No known significant effects or critical hazards.
	Component 5	No known significant effects or critical hazards.
	Component 6	No known significant effects or critical hazards.
	Component 7	No known significant effects or critical hazards.
	Component 8	Causes skin irritation.
	Component 9	No known significant effects or critical hazards.
	Component 10	No known significant effects or critical hazards.
	Component 11	No known significant effects or critical hazards.
	Component 12	No known significant effects or critical hazards.
Ingestion	: Component 1	No known significant effects or critical hazards.
	Component 2	No known significant effects or critical hazards.
	Component 3	No known significant effects or critical hazards.
	Component 4	No known significant effects or critical hazards.
	Component 5	No known significant effects or critical hazards.
	Component 6	No known significant effects or critical hazards.
	Component 7	No known significant effects or critical hazards.
	Component 8	No known significant effects or critical hazards.
	Component 9	No known significant effects or critical hazards.
	Component 10	No known significant effects or critical hazards.
	Component 11	No known significant effects or critical hazards.
	Component 12	No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact	:	Adverse symptoms may include the following: pain or irritation watering redness
Inhalation	:	No known significant effects or critical hazards.
Skin contact	:	Adverse symptoms may include the following: irritation redness
Ingestion	:	No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician	:	None identified.
Specific treatments	:	No specific treatment.
Protection of first-aiders	:	No special measures required.



Section 4. First aid measures

See toxicological information (Section 11)

Section 5. Firefighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : Put on appropriate personal protective equipment.

For emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : No special requirements.

Methods and material for containment and cleaning up

Spill : Dilute with water and mop up if water-soluble or absorb with an inert dry material and place in an appropriate waste disposal container.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapour or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

Section 7. Handling and storage

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations.
 Component 1-11: Store at -25°C to -15°C.
 Component 12: Store at 2°C to 6°C.

Section 8. Exposure controls and personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Component 7 Glycerol	Safe Work Australia (Australia, 4/2018). TWA: 10 mg/m ³ 8 hours.
Component 8 Glycerol Potassium hydroxide	Safe Work Australia (Australia, 4/2018). TWA: 10 mg/m ³ 8 hours. Safe Work Australia (Australia, 4/2018). PEAK: 2 mg/m ³ 8 hours.
Component 10 Glycerol	Safe Work Australia (Australia, 4/2018). TWA: 10 mg/m ³ 8 hours.
Component 11 Glycerol	Safe Work Australia (Australia, 4/2018). TWA: 10 mg/m ³ 8 hours.

Appropriate engineering controls : No special ventilation requirements.

Environmental exposure controls : No special measures required.

Individual protection measures

Hygiene measures : Follow good industrial hygiene practice.

Eye/face protection : Not required under normal conditions of use.

Skin protection

Hand protection : Not required under normal conditions of use.

Body protection : Not required under normal conditions of use.

Other skin protection : Not required under normal conditions of use.

Respiratory protection : Not required under normal conditions of use.

Section 9. Physical and chemical properties

Appearance

Physical state : **Component 1** Liquid.
Component 2 Liquid.
Component 3 Liquid.
Component 4 Liquid.
Component 5 Liquid.
Component 6 Liquid.
Component 7 Liquid.
Component 8 Liquid.
Component 9 Liquid.
Component 10 Liquid. [Clear. Viscous.]

Section 9. Physical and chemical properties

	Component 11	Liquid. [Clear. Viscous.]
	Component 12	Liquid.
Colour	: Component 1	Colourless.
	Component 2	Colourless.
	Component 3	Colourless.
	Component 4	Colourless.
	Component 5	Colourless.
	Component 6	Colourless.
	Component 7	Colourless.
	Component 8	Colourless.
	Component 9	Colourless.
	Component 10	Colourless.
	Component 11	Colourless.
	Component 12	Pink. [Light]
Odour	: Component 1	Odourless.
	Component 2	Odourless.
	Component 3	Odourless.
	Component 4	Odourless.
	Component 5	Odourless.
	Component 6	Odourless.
	Component 7	Odourless.
	Component 8	Odourless.
	Component 9	Odourless.
	Component 10	Odourless.
	Component 11	Odourless.
	Component 12	Odourless.
Odour threshold	: Not available.	
pH	: Component 1	Not available.
	Component 2	Not available.
	Component 3	Not available.
	Component 4	Not available.
	Component 5	Not available.
	Component 6	Not available.
	Component 7	Not available.
	Component 8	6 to 8
	Component 9	Not available.
	Component 10	Not available.
	Component 11	Not available.
	Component 12	Not available.
Melting point	: Not available.	
Boiling point	: Component 1	Not available.
	Component 2	Not available.
	Component 3	Not available.
	Component 4	Not available.
	Component 5	Not available.
	Component 6	Not available.
	Component 7	Not available.
	Component 8	Not available.
	Component 9	Not available.
	Component 10	Not available.
	Component 11	Not available.
	Component 12	Not available.

Section 9. Physical and chemical properties

Flash point	: Component 1	Not available.
	Component 2	Not available.
	Component 3	Not available.
	Component 4	Not available.
	Component 5	Not available.
	Component 6	Not available.
	Component 7	Not available.
	Component 8	Not available.
	Component 9	Not available.
	Component 10	Not available.
	Component 11	Not available.
	Component 12	Not available.
Evaporation rate	: Not available.	
Flammability (solid, gas)	: Not available.	
Lower and upper explosive (flammable) limits	: Not available.	
Vapour pressure	: Component 1	Not available.
	Component 2	Not available.
	Component 3	Not available.
	Component 4	Not available.
	Component 5	Not available.
	Component 6	Not available.
	Component 7	Not available.
	Component 8	Not available.
	Component 9	Not available.
	Component 10	Not available.
	Component 11	Not available.
	Component 12	Not available.
Vapour density	: Component 1	Not available.
	Component 2	Not available.
	Component 3	Not available.
	Component 4	Not available.
	Component 5	Not available.
	Component 6	Not available.
	Component 7	Not available.
	Component 8	Not available.
	Component 9	Not available.
	Component 10	Not available.
	Component 11	Not available.
	Component 12	Not available.
Relative density	: Component 1	Not available.
	Component 2	Not available.
	Component 3	Not available.
	Component 4	Not available.
	Component 5	Not available.
	Component 6	Not available.
	Component 7	Not available.
	Component 8	Not available.
	Component 9	Not available.
	Component 10	Not available.
	Component 11	Not available.
	Component 12	Not available.

Section 9. Physical and chemical properties

Solubility : **Component 1** Not available.
Component 2 Not available.
Component 3 Not available.
Component 4 Not available.
Component 5 Not available.
Component 6 Not available.
Component 7 Not available.
Component 8 Not available.
Component 9 Not available.
Component 10 Not available.
Component 11 Not available.
Component 12 Not available.

Solubility in water : Not available.

Partition coefficient: n-octanol/water : Not available.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : **Component 1** Not available.
Component 2 Not available.
Component 3 Not available.
Component 4 Not available.
Component 5 Not available.
Component 6 Not available.
Component 7 Not available.
Component 8 Not available.
Component 9 Not available.
Component 10 Not available.
Component 11 Not available.
Component 12 Not available.

Flow time (ISO 2431) : Not available.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : **Component 1** The product is stable.
Component 2 The product is stable.
Component 3 The product is stable.
Component 4 The product is stable.
Component 5 The product is stable.
Component 6 The product is stable.
Component 7 The product is stable.
Component 8 The product is stable.
Component 9 The product is stable.
Component 10 The product is stable.
Component 11 The product is stable.
Component 12 The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Section 10. Stability and reactivity

Conditions to avoid	: Component 1 Component 2 Component 3 Component 4 Component 5 Component 6 Component 7 Component 8 Component 9 Component 10 Component 11 Component 12	No specific data. No specific data. No specific data. No specific data. No specific data. No specific data. No specific data. No specific data. No specific data. No specific data. No specific data. No specific data.
Incompatible materials	: Component 1 Component 2 Component 3 Component 4 Component 5 Component 6 Component 7 Component 8 Component 9 Component 10 Component 11 Component 12	Reactive or incompatible with the following materials: oxidising materials. Reactive or incompatible with the following materials: oxidising materials. Reactive or incompatible with the following materials: oxidising materials. Reactive or incompatible with the following materials: oxidising materials. Reactive or incompatible with the following materials: oxidising materials. Reactive or incompatible with the following materials: oxidising materials. Reactive or incompatible with the following materials: oxidising materials. Reactive or incompatible with the following materials: oxidising materials. Reactive or incompatible with the following materials: oxidising materials. Reactive or incompatible with the following materials: oxidising materials. Reactive or incompatible with the following materials: oxidising materials. Reactive or incompatible with the following materials: oxidising materials. Reactive or incompatible with the following materials: oxidising materials.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Component 7 Glycerol	LD50 Oral	Rat	12600 mg/kg	-
Component 8 Glycerol	LD50 Oral	Rat	12600 mg/kg	-
Component 10 Glycerol	LD50 Oral	Rat	12600 mg/kg	-
Component 11				

Section 11. Toxicological information

Glycerol	LD50 Oral	Rat	12600 mg/kg	-
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Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Component 8 Potassium hydroxide	Eyes - Moderate irritant Skin - Severe irritant Skin - Severe irritant	Rabbit Guinea pig Rabbit	- - -	24 hours 1 mg 24 hours 50 mg 24 hours 50 mg	- - -

Sensitisation

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Causes skin irritation.
- Ingestion** : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No known significant effects or critical hazards.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Section 11. Toxicological information

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Component 8 Oral	33333.33 mg/kg

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Component 8 Potassium hydroxide	Acute LC50 80 ppm Fresh water	Fish - Gambusia affinis - Adult	96 hours

Persistence and degradability

There is no data available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Component 7 Glycerol	-1.76	-	low
Component 8 Glycerol	-1.76	-	low
Component 10 Glycerol	-1.76	-	low
Component 11 Glycerol	-1.76	-	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Section 12. Ecological information

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimised wherever possible. No specific disposal consideration.

Section 14. Transport information

	ADG	ADR/RID	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-
Transport hazard class(es)	-	-	-	-
Packing group	-	-	-	-
Environmental hazards	No.	No.	No.	No.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15. Regulatory information

Standard Uniform Schedule of Medicine and Poisons

Not regulated.

Model Work Health and Safety Regulations - Scheduled Substances

No listed substance

Australia inventory (AICS) : Not determined.

Section 16. Any other relevant information

Procedure used to derive the classification

Classification	Justification
Component 8 SKIN CORROSION/IRRITATION - Category 2	Calculation method

History

Date of issue : 15/08/2019
Date of previous issue : Not applicable.
Version : 1
Prepared by : KMK Regulatory Services Inc.

Section 16. Any other relevant information

Key to abbreviations

: ADG = Australian Dangerous Goods
ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
NOHSC = National Occupational Health and Safety Commission
SUSMP = Standard Uniform Schedule of Medicine and Poisons
UN = United Nations

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