# SAFETY DATA SHEET



xTAG® Cystic Fibrosis (CFTR) 39 kit v2

# **Section 1. Identification**

**Product identifier** : xTAG® Cystic Fibrosis (CFTR) 39 kit v2

**Product code** 

Other means of identification

: Component 1 xTAG® CFTR PCR Primer Mix v2 Component 2 xTAG® CFTR Bead Mix A v2

Component 3 xTAG® CFTR ASPE Primer Mix A v2

xTAG® Reporter Buffer Component 4

Component 5 Platinum® Tfi Exo(-) DNA Polymerase Platinum® Tfi Reaction Buffer, 5X Component 6

Tfi 50 mM MgCl<sub>2</sub> Component 7

xTAG® Shrimp Alkaline Phosphatase Component 8

xTAG® Exonuclease I Component 9

Component 10 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

: SKIN CORROSION/IRRITATION - Category 2

substance or mixture SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2A

GHS label elements for the kit

**Hazard pictograms** 



Signal word : WARNING

**Hazard statements** : H319 - Causes serious eye irritation.

H315 - Causes skin irritation.

**Precautionary statements** 



**Document No. :** 

### Section 2. Hazard(s) identification

**Prevention**: P280 - Wear protective gloves. Wear eye or face protection.

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.

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 - If eye irritation persists: Get medical attention.

Storage : Not applicable.

Disposal : Not applicable.

#### **GHS label elements by component**

Hazard pictograms : Component 6



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 WARNING **Component 7** No signal word. **Component 8** No signal word. **Component 9** No signal word. **Component 10** No signal word.

**Hazard statements** : **Component 1** No known significant effects or critical hazards.

Component 2

Component 3

Component 4

Component 5

No known significant effects or critical hazards.

**Component 6** H319 - Causes serious eye irritation.

H315 - Causes skin irritation.

Component 7
 Component 8
 Component 9
 Component 10
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.

**Precautionary statements** 

# Section 2. Hazard(s) identification

Prevention	: Component 1 Component 2	Not applicable. Not applicable.
	Component 3	Not applicable.
	Component 4	Not applicable.
	Component 5	Not applicable.
	Component 6	P280 - Wear protective gloves. Wear eye or face protection. P264 - Wash hands thoroughly after handling.
	Component 7	Not applicable.
	Component 8	Not applicable.
	Component 9	Not applicable.
	Component 10	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	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. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with
		water for several minutes. Remove contact lenses, if present
		and easy to do. Continue rinsing.
		P337 + P313 - If eye irritation persists: Get medical attention
	Component 7	Not applicable.
	Component 8	Not applicable.
	Component 9	Not applicable.
	Component 10	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 Component 10	Not applicable.
Dianocal	•	Not applicable.
Disposal	: Component 1 Component 2	Not applicable. 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.
upplemental label lements	: Not applicable.	•••
her hazards which do not	: None known.	

result in classification

### Section 3. Composition and ingredient information

Substance/mixture : Mixture

Ingredient name	% (w/w)	CAS number
Component 5 Glycerol	≥10 - ≤30	56-81-5
Component 6 Glycerol Potassium hydroxide	≥10 - ≤30 ≥1 - <3	56-81-5 1310-58-3
Component 8 Glycerol	≥60 - ≤75	56-81-5
Component 9 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. No known significant effects or critical hazards. **Component 5**

**Component 6** Causes serious eye irritation.

No known significant effects or critical hazards. Component 7 **Component 8** No known significant effects or critical hazards. No known significant effects or critical hazards. Component 9 **Component 10** No known significant effects or critical hazards.

Inhalation : Component 1

No known significant effects or critical hazards. **Component 2** No known significant effects or critical hazards. No known significant effects or critical hazards. Component 3 Component 4 No known significant effects or critical hazards. No known significant effects or critical hazards. Component 5 **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. No known significant effects or critical hazards. Component 9

**Component 10** No known significant effects or critical hazards.



### Section 4. First aid measures

**Skin contact**: **Component 1** No known significant effects or critical hazards.

Component 2

Component 3

Component 4

Component 5

No known significant effects or critical hazards.

**Component 6** Causes skin irritation.

Component 7

Component 8

Component 9

Component 10

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. No known significant effects or critical hazards. **Component 5 Component 6** No known significant effects or critical hazards. No known significant effects or critical hazards. Component 7 No known significant effects or critical hazards. Component 8 Component 9 No known significant effects or critical hazards. **Component 10** 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.

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.

### Section 5. Firefighting measures

**Hazardous thermal** decomposition products Decomposition products may include the following materials: carbon dioxide carbon monoxide metal oxide/oxides

**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.

Conditions for safe storage, including any incompatibilities

: Store in accordance with local regulations. Component 1-9: Store at -25°C to -15°C. Component 10: Store at 2°C to 6°C.

# Section 8. Exposure controls and personal protection

#### **Control parameters**

#### **Occupational exposure limits**

Ingredient name	Exposure limits
Component 5	
Glycerol	Safe Work Australia (Australia, 4/2018). TWA: 10 mg/m³ 8 hours.
Component 6	
Glycerol	Safe Work Australia (Australia, 4/2018). TWA: 10 mg/m³ 8 hours.
Potassium hydroxide	Safe Work Australia (Australia, 4/2018). PEAK: 2 mg/m³ 8 hours.
Component 8	
Glycerol	Safe Work Australia (Australia, 4/2018). TWA: 10 mg/m³ 8 hours.
Component 9	
Glycerol	Safe Work Australia (Australia, 4/2018). TWA: 10 mg/m³ 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
 Body protection
 Other skin protection
 Not required under normal conditions of use.
 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 Component 2 Component 3 Component 4 Component 5 Component 6 Component 7 Component 8 Component 9 Component 10	Liquid. [Clear.] Liquid. [Clear./Viscous.] Liquid. [Clear./Viscous.] Liquid. [Clear.]
Colour	: Component 1 Component 2 Component 3 Component 4 Component 5 Component 6 Component 7 Component 8	Colourless. Colourless. Colourless. Colourless. Colourless. Colourless. Colourless. Colourless.

### Section 9. Physical and chemical properties

	Component 9 Component 10	Colourless. Pink. [Light]
Odour	: Component 1 Component 2	Odourless. 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.

**Odour threshold** 

pН

: Component 1 Not available.

: Not available.

: Not available.

Component 2 Not available. Component 3 Not available. Component 4 Not available. Component 5 Not available.

Component 6 6 to 8 [Conc. (% w/w): 100%]

Component 7 Not available.

**Component 8** 6 to 8 [Conc. (% w/w): 100%]

Not available. Component 9 Not available. Component 10

**Melting point** 

**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.

**Flash point** 

Not available. : Component 1 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.

**Evaporation rate** Flammability (solid, gas) Lower and upper explosive

(flammable) limits

: Not available. : Not available.

**Document No. :** 

: Not available.

# Section 9. Physical and chemical properties

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.
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.
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.
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	Easily soluble in the following materials: cold water and hot water.
	Component 9	Easily soluble in the following materials: cold water and hot water.
	Component 10	Easily soluble in the following materials: cold water and hot water.
Solubility in water	: Not available.	
Partition coefficient: n-	: Not available.	

octanol/water

**Auto-ignition temperature** : Not available. **Decomposition temperature**: Not available.

### Section 9. Physical and chemical properties

**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. Not available. **Component 10** 

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. The product is stable. Component 5 Component 6 The product is stable. Component 7 The product is stable. **Component 8** The product is stable. The product is stable. Component 9 Component 10 The product is stable.

Possibility of hazardous reactions

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

**Conditions to avoid** 

: Component 1 No specific data. Component 2 No specific data. **Component 3** No specific data. **Component 4** No specific data. **Component 5** No specific data. Component 6 No specific data. Component 7 No specific data. **Component 8** No specific data. No specific data. **Component 9** Component 10 No specific data.

**Incompatible materials** 

: **Component 1** Reactive or incompatible with the following materials:

oxidising materials.

**Component 2** Reactive or incompatible with the following materials:

oxidising materials.

**Component 3** Reactive or incompatible with the following materials:

oxidising materials.

**Component 4** Reactive or incompatible with the following materials:

oxidising materials.

**Component 5** Reactive or incompatible with the following materials:

oxidising materials.

**Component 6** Reactive or incompatible with the following materials:

oxidising materials.

Document No. : 10/15

### Section 10. Stability and reactivity

**Component 7** Reactive or incompatible with the following materials:

oxidising materials.

**Component 8** Reactive or incompatible with the following materials:

oxidising materials.

**Component 9** Reactive or incompatible with the following materials:

oxidising materials.

**Component 10** 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 5 Glycerol	LD50 Oral	Rat	12600 mg/kg	-
Component 6 Glycerol	LD50 Oral	Rat	12600 mg/kg	-
Component 8 Glycerol	LD50 Oral	Rat	12600 mg/kg	-
Component 9 Glycerol	LD50 Oral	Rat	12600 mg/kg	-

#### **Irritation/Corrosion**

Product/ingredient name	Result	Species	Score	Exposure	Observation
Component 5					
Glycerol	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
•	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-
Component 6					
Glycerol	Eyes - Mild irritant	Rabbit	_	24 hours 500 mg	-
•	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	
Potassium hydroxide	Eyes - Moderate irritant	Rabbit	-	24 hours 1 mg	-
•	Skin - Severe irritant	Guinea pig	-	24 hours 50 mg	-
	Skin - Severe irritant	Rabbit	-	24 hours 50 mg	-
Component 8					
Glycerol	Eyes - Mild irritant	Rabbit	_	24 hours 500 mg	_
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	
Component 9					
Glycerol	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	1-
,	Skin - Mild irritant	Rabbit	-	24 hours 500 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.

Document No. : 11/15

### Section 11. Toxicological information

#### **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** : Causes serious eye irritation.

**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**

Potential immediate : No known significant effects or critical hazards.

effects

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

Long term exposure

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

effects

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

#### Potential chronic health effects

General
 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.
 No known significant effects or critical hazards.

**Document No. :** 

# **Section 11. Toxicological information**

#### **Numerical measures of toxicity**

#### **Acute toxicity estimates**

Route	ATE value
Component 6	20000 00 #
Oral	33333.33 mg/kg

# Section 12. Ecological information

#### **Toxicity**

Product/ingredient name	Result	Species	Exposure
Component 6 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	LogPow	BCF	Potential
Component 5 Glycerol	-1.76	-	low
Component 6 Glycerol	-1.76	-	low
Component 8 Glycerol	-1.76	-	low
Component 9 Glycerol	-1.76	-	low

#### **Mobility in soil**

Soil/water partition coefficient (Koc)

: Not available.

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 6 SKIN CORROSION/IRRITATION - Category 2 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2A	Calculation method Calculation method

**History** 

**Date of issue** : 15/06/2019 **Date of previous issue** : Not applicable.

**Version** : 1

**Prepared by** : KMK Regulatory Services Inc.

**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,



14/15 **Document No. :** 

# Section 16. Any other relevant information

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

#### Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.