Date : 28/02/2021

Version : 2

SAFETY DATA SHEET



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

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

1.1 Product identifier

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

UFI : Component 8: DUAJ-360G-210Y-XFXF

Product code :

Product description : Not available.

Component name : **Component 1** xTAG® CFTR PCR Mix v2

Component 2xTAG® CFTR Bead Mix A v2Component 3xTAG® CFTR Bead Mix B v2Component 4xTAG® CFTR ASPE Mix A v2Component 5xTAG® 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 MqCl2

Component 10 xTAG® Shrimp Alkaline Phosphatase

Component 11 xTAG® Exonuclease I

Component 12 xTAG® Streptavidin, R-Phycoerythrin Conjugate

Product type : Liquid.

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

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

1.3 Details of the supplier of the safety data sheet

Supplier's details : 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

1.4 Emergency telephone number

National advisory body/Poison Centre

Telephone number :

Emergency telephone number (with hours of

: 1-512-381-4397

24/7

operation)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition: Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Component 8 Skin Irrit. 2, H315 Eye Irrit. 2, H319

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

GHS label elements for the kit

Hazard pictograms



Signal word : Warning

Hazard statements : H319 - Causes serious eye irritation.

H315 - Causes skin irritation.

Precautionary statements

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

P264 - Wash hands thoroughly after handling.

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

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

Storage : Not applicable.

Disposal : Not applicable.

GHS label elements by component

Hazard pictograms : Component 8



SECTION 2: Hazards identification

SECTION 2: Hazards	identification	
Signal word Hazard statements	: Component 1 Component 2 Component 3 Component 4 Component 5 Component 6 Component 7 Component 8 Component 9 Component 10 Component 11 Component 12 : Component 1 Component 2 Component 3	No signal word. Warning No signal word. No known significant effects or critical hazards. No known significant effects or critical hazards.
	Component 4 Component 5 Component 6 Component 7 Component 8 Component 9 Component 10 Component 11 Component 12	No known significant effects or critical hazards. H319 - Causes serious eye irritation. H315 - Causes skin irritation. 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	Component 12	No known significant choose of childer hazards.
Prevention	: Component 1 Component 2 Component 3 Component 4 Component 5 Component 6 Component 7 Component 8 Component 9 Component 10 Component 11 Component 12	Not applicable. P280 - Wear protective gloves. Wear eye or face protection. P264 - Wash hands thoroughly after handling. Not applicable. Not applicable. Not applicable. Not applicable.
Response	Component 1 Component 2 Component 3 Component 4 Component 5 Component 6 Component 7 Component 8 Component 9 Component 10 Component 11 Component 12	Not applicable. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Not applicable. Not applicable. Not applicable. Not applicable.

SECTION 2: Hazards identification

Storage

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

Disposal

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

Supplemental label

elements

: Not applicable.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

: Not applicable.

Special packaging requirements

Containers to be fitted with child-resistant

: Not applicable.

fastenings

Tactile warning of danger : Not applicable.

2.3 Other hazards

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

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SECTION 3: Composition/information on ingredients

Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]	Type
Component 7				
Glycerol	REACH #: Annex V EC: 200-289-5 CAS: 56-81-5	≥10 - ≤25	Not classified.	[2]
Component 8				
Glycerol	REACH #: Annex V EC: 200-289-5 CAS: 56-81-5	≥10 - ≤25	Not classified.	[2]
Potassium hydroxide	EC: 215-181-3 CAS: 1310-58-3 Index: 019-002-00-8	≥1 - <2	Met. Corr. 1, H290 Acute Tox. 4, H302 Skin Corr. 1A, H314 Eye Dam. 1, H318	[1] [2]
Component 10				
Glycerol	REACH #: Annex V EC: 200-289-5 CAS: 56-81-5	≥50 - ≤75	Not classified.	[2]
Component 11				
Glycerol	REACH #: Annex V EC: 200-289-5 CAS: 56-81-5	≥50 - ≤75	Not classified.	[2]
			See Section 16 for the full text of the H statements declared above.	

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, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

<u>Type</u>

- [1] Substance classified with a health or environmental hazard
- [2] Substance with a workplace exposure limit
- [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
- [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII
- [5] Substance of equivalent concern
- [6] Additional disclosure due to company policy

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

SECTION 4: First aid measures

4.1 Description of 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.

minutes. Get medicar atter

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.

Protection of first-aiders : No special measures required.

4.2 Most important symptoms and effects, both acute and delayed Potential acute health effects

SECTION 4: First aid measures

	10000100	
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	Causes serious eye 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.
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	Irritating to skin.
	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/sympton	ns	

Over-exposure signs/symptoms

Eye contact

: Adverse symptoms may include the following: pain or irritation watering



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redness

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SECTION 4: First aid measures

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.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : None identified.

Specific treatments : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing

media

: Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing

media

: None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture

: No specific fire or explosion hazard.

Hazardous combustion

products

: Decomposition products may include the following materials:

carbon dioxide carbon monoxide

5.3 Advice for firefighters

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. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 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".

6.2 Environmental precautions

: No special requirements.

6.3 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.

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SECTION 6: Accidental release measures

6.4 Reference to other sections

: See Section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment.

See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures

: Put on appropriate personal protective equipment (see Section 8).

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.

7.2 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.

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific : Not available.

solutions

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
Component 7	
Glycerol	EH40/2005 WELs (United Kingdom (UK), 8/2018). TWA: 10 mg/m³ 8 hours. Form: Mist
Component 8	
Glycerol	EH40/2005 WELs (United Kingdom (UK), 8/2018). TWA: 10 mg/m³ 8 hours. Form: Mist
Potassium hydroxide	EH40/2005 WELs (United Kingdom (UK), 8/2018). STEL: 2 mg/m³ 15 minutes.
Component 10	
Glycerol	EH40/2005 WELs (United Kingdom (UK), 8/2018). TWA: 10 mg/m³ 8 hours. Form: Mist
Component 11	
Glycerol	EH40/2005 WELs (United Kingdom (UK), 8/2018). TWA: 10 mg/m³ 8 hours. Form: Mist

SECTION 8: Exposure controls/personal protection

procedures

Recommended monitoring: If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

Product/ingredient name	Type	Exposure	Value	Population	Effects
Component 8 Potassium hydroxide	DNEL	Long term Inhalation	1 mg/m³	General population	Local
	DNEL	Long term Inhalation	1 mg/m³	Workers	Local

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls

: No special ventilation requirements.

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.

Environmental exposure

controls

: No special measures required.

SECTION 9: Physical and chemical properties

9.1 Information on basic 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.

Liquid. [Clear. Viscous.] Component 10 Component 11 Liquid. [Clear. Viscous.]

SECTION 9: Physical and chemical properties

_		-	-	
		Component 12	Li	quid.
Colour	:	Component 1	С	olourless.
		Component 2	С	olourless.
		Component 3	С	olourless.
		Component 4	С	olourless.
		Component 5	С	olourless.
		Component 6	С	olourless.
		Component 7	С	olourless.
		Component 8	С	olourless.
		Component 9	С	olourless.
		Component 10	С	olourless.
		Component 11	С	olourless.
		Component 12	Ρ	ink. [Light]
Odour	÷	Component 1	0	dourless.
		Component 2	0	dourless.
		Component 3	0	dourless.
		Component 4	0	dourless.
		Component 5	0	dourless.
		Component 6	0	dourless.
		Component 7	0	dourless.
		Component 8	0	dourless.
		Component 9	0	dourless.
		Component 10	_	dourless.
		Component 11	0	dourless.
		Component 12	0	dourless.
Odour threshold	:	Not available.		
рН	:	Component 1	Ν	ot available.
•		Component 2	Ν	ot available.
		Component 3	Ν	ot available.
		Component 4	Ν	ot available.
		Component 5	Ν	ot available.
		Component 6	Ν	ot available.
		Component 7	Ν	ot available.
		Component 8	6	to 8
		Component 9	Ν	ot available.
		Component 10	Ν	ot available.
		Component 11	Ν	ot available.
		Component 12	Ν	ot available.
Melting point/freezing point	:	Not available.		
Initial boiling point and boiling	:	Component 1	Ν	ot available.
range		Component 2	Ν	ot available.
•		Component 3	Ν	ot available.
		Component 4	Ν	ot available.
		Component 5	Ν	ot available.
		Component 6	Ν	ot available.
		Component 7	Ν	ot available.
		Component 8	Ν	ot available.
		Component 9	Ν	ot available.
		Component 10	Ν	ot available.
		Component 11		ot available.
		Component 12	Ν	ot available.

SECTION 9: Physical	and	chemical pro	operties
Flash point	:		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. Not available.
		Component 8 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.	
Upper/lower flammability or explosive limits	:	Not available.	
Vapour pressure	:	Component 1	Not available.
vapour pressure	•	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.
Vapour density	:	Component 12 Component 1	Not available. Not available.
vapour density		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 Component 12	Not available. Not available.
Relative density		Component 1	Not available.
Tiolan to donoity		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. Not available.
		Component 11	Not available.

Component 12

Not available.

SECTION 9: Physical and chemical properties

Solubility(ies) : 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.

Partition coefficient: n-octanol/ : Not available.

water

Auto-ignition temperature Decomposition temperature

Viscosity

: Not available. : Not available.

: 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.

Not available.

Component 12 : Not available.

Explosive properties Oxidising properties

: Not available.

SECTION 10: Stability and reactivity

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

10.2 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. The product is stable. **Component 10 Component 11** The product is stable. **Component 12** The product is stable.

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

SECTION 10: Stability and reactivity

0.4 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.
	Component 9	No specific data.
	Component 10	No specific data.
	Component 11	No specific data.

Component 12

10.5 Incompatible materials

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

oxidising materials.

No specific data.

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.

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.

Component 11 Reactive or incompatible with the following materials:

oxidising materials.

Component 12 Reactive or incompatible with the following materials:

oxidising materials.

10.6 Hazardous decomposition products

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

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

There is no data available.

Acute toxicity estimates

Route	ATE value
Component 8 Oral	33333.33 mg/kg

Irritation/Corrosion

SECTION 11: Toxicological information

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.

of exposure

Information on likely routes: Dermal contact. Eye contact. Inhalation. 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	Causes serious eye 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 2 Component 3 Component 4 Component 5 Component 6 Component 7 Component 8 Component 9 Component 10

	Component 12	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.
	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

Document No. :

Component 11 No known significant effects or critical hazards.Component 12 No known significant effects or critical hazards.

No known significant effects or critical hazards.

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SECTION 11: Toxicological information

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

Component 2
 Component 3
 Component 4
 Component 5
 Component 6
 Component 7
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.

Component 8 Irritating to skin.

Component 9
 Component 10
 Component 11
 Component 11
 Component 12
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.

Ingestion : Component 1 No known significant effects or critical hazards.

No known significant effects or critical hazards. **Component 2 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. 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. **Component 11** No known significant effects or critical hazards. No known significant effects or critical hazards. Component 12

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 : 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.

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SECTION 11: Toxicological information

Developmental effectsNo known significant effects or critical hazards.Fertility effectsNo known significant effects or critical hazards.

Other information : Not available.

SECTION 12: Ecological information

12.1 Toxicity

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

12.2 Persistence and degradability

There is no data available.

12.3 Bioaccumulative potential

There is no data available.

12.4 Mobility in soil

Soil/water partition coefficient (Koc)

: Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

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

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal

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

Hazardous waste

: The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal

: The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions

: This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.

user

14.6 Special precautions for : 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

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions : Not applicable.

on the manufacture,

placing on the market

and use of certain

dangerous substances,

mixtures and articles

Other EU regulations

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

15.2 Chemical safety assessment

: This product contains substances for which Chemical Safety Assessments are still required.

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

SECTION 16: Other information

Abbreviations and acronyms : ATE = Acute Toxicity Estimate

CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No.

1272/2008]

DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level

EUH statement = CLP-specific Hazard statement PBT = Persistent, Bioaccumulative and Toxic PNEC = Predicted No Effect Concentration RRN = REACH Registration Number

vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification	
Component 8 Skin Irrit. 2, H315 Eye Irrit. 2, H319	Calculation method Calculation method	

Full text of abbreviated H statements

Component 8	
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.

Full text of classifications [CLP/GHS]

Component 8	
Acute Tox. 4, H302	ACUTE TOXICITY (oral) - Category 4
Eye Dam. 1, H318	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Eye Irrit. 2, H319	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2
Met. Corr. 1, H290	CORROSIVE TO METALS - Category 1
Skin Corr. 1A, H314	SKIN CORROSION/IRRITATION - Category 1A
Skin Irrit. 2, H315	SKIN CORROSION/IRRITATION - Category 2

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Prepared by : KMK Regulatory Services Inc.

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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.