

<b>Luminex®</b>	<b>SAFETY DATA SHEET</b>	
<b>xTAG® Cystic Fibrosis (CFTR) 71 kit v2</b>	09 January 2024	Page 1 of 17

Complying with Regulation (EC) No 1272/2008 (CLP) as amended by Commission Regulation (EU) 2020/878 and GB CLP – (United Kingdom).

**SECTION 1: IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**

**1.1 Product identifier**

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

**Other means of identification:**

**Commercial name(s):** xTAG® Cystic Fibrosis (CFTR) 71 kit v2

**Product Codes:** I024C0185

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

**Relevant identified uses:** For Professional use only. Use as per Product Insert

**Uses advised against:** Uses other than those described above.

**1.3 Details of the supplier of the safety data sheet**

**Company Name:** Luminex Molecular Diagnostics, Inc.

**Company Address:** 439 University Avenue,  
Toronto, Ontario, Canada, M5G 1Y8

**Company Tel (Enquiries):** Tel: 1- (512) 381-4397  
Toll Free: 1-(877)-785-2323 (US and Canada)  
Fax: (512) 219-5114  
<http://www.luminexcorp.com>

**1.4 Emergency telephone number**

**Emergency telephone number (including hours of operation):** 1-(512) 381-4397

**Emergency email:** [support@luminexcorp.com](mailto:support@luminexcorp.com)

**Hours of operations:** 24/7

**Poison Centre Information:**

National Poisons Information Centre, Beaumont Hospital, Dublin 9, Ireland.

Members of the public:

In an emergency, if the patient has collapsed or is not breathing properly, call 999

For medical advice contact:

NHS 111 in England: 111

NHS 24 in Scotland: 111

NHS Direct in Wales: 111 or 0845 4647

In Northern Ireland: contact your local GP or pharmacist during normal hours; click here for GP services Out-of-Hours.

In Ireland: contact NPIC on (01) 809 2166 (8 am to 10 pm); outside of these hours contact your GP or hospital emergency department.

**SECTION 2: HAZARDS IDENTIFICATION**

**2.1 Classification of the substance or mixture**

**Classification in accordance to Regulation (EC) No. 1272/2008 (CLP/GHS)**

**Overall Classification for the kit:**

<b>Product name</b>	<b>GHS Classification</b>
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**xTAG<sup>®</sup> Cystic Fibrosis (CFTR)  
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**xTAG<sup>®</sup> Cystic Fibrosis (CFTR)  
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Not classified as hazardous

**Classification of BOX 1:**

Not classified as hazardous

**Classification of the components of BOX 1:****Component 1: xTAG<sup>®</sup> CFTR PCR Primer Mix v2**

Not classified as hazardous

**Component 2: xTAG<sup>®</sup> CFTR Bead Mix A v2**

Not classified as hazardous

**Component 3: xTAG<sup>®</sup> CFTR Bead Mix B v2**

Not classified as hazardous

**Component 4: xTAG<sup>®</sup> CFTR ASPE Primer Mix A v2**

Not classified as hazardous

**Component 5: xTAG<sup>®</sup> CFTR ASPE Primer Mix B v2**

Not classified as hazardous

**Component 6: xTAG<sup>®</sup> Reporter Buffer**

Not classified as hazardous

**Component 7: Platinum<sup>®</sup> *Tfi* Exo(-) DNA Polymerase**

Not classified as hazardous

**Component 8: Platinum<sup>®</sup> *Tfi* Reaction Buffer, 5x**

Skin irritation, category 2

Eye irritation, category 2

**Component 9: Platinum<sup>®</sup> *Tfi* 50mM MgCl<sub>2</sub>**

Not classified as hazardous

**Component 10: xTAG<sup>®</sup> Shrimp Alkaline Phosphatase**

Not classified as hazardous

**Component 11: xTAG<sup>®</sup> Exonuclease I**

Not classified as hazardous

**Classification of the components of BOX 2:****Component 12: xTAG<sup>®</sup> Streptavidin, R-Phycoerythrin Conjugate**

Not classified as hazardous

**2.2 Label elements****Labelling in accordance with Regulation 1272/2008****Labelling information for the kit:****Hazard pictograms:** None required**Signal word:** None required**Hazard statements:** None required**Precautionary Statements:** None required

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**Supplemental Hazard Statements.** None known

**Labelling information for BOX 1:**

**Hazard pictograms:** None required  
**Signal word:** None required  
**Hazard statements:** None required  
**Precautionary Statements:** None required

**Supplemental Hazard Statements.** None known

**Labelling information for the components of the kit:****Component 1: xTAG<sup>®</sup> CFTR PCR Primer Mix v2**

**Hazard pictograms:** None required  
**Signal word:** None required  
**Hazard statements:** None required  
**Precautionary Statements:** None required

**Supplemental Hazard Statements.** None known

**Component 2: xTAG<sup>®</sup> CFTR Bead Mix A v2**

**Hazard pictograms:** None required  
**Signal word:** None required  
**Hazard statements:** None required  
**Precautionary Statements:** None required

**Supplemental Hazard Statements.** None known

**Component 3: xTAG<sup>®</sup> CFTR Bead Mix B v2**

**Hazard pictograms:** None required  
**Signal word:** None required  
**Hazard statements:** None required  
**Precautionary Statements:** None required

**Supplemental Hazard Statements.** None known

**Component 4: xTAG<sup>®</sup> CFTR ASPE Primer Mix A v2**

**Hazard pictograms:** None required  
**Signal word:** None required  
**Hazard statements:** None required  
**Precautionary Statements:** None required

**Supplemental Hazard Statements.** None known

**Component 5: xTAG<sup>®</sup> CFTR ASPE Primer Mix B v2**

**Hazard pictograms:** None required

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**Signal word:** None required  
**Hazard statements:** None required  
**Precautionary Statements:** None required

**Supplemental Hazard Statements.** None known

**Component 6: xTAG<sup>®</sup> Reporter Buffer**

**Hazard pictograms:** None required  
**Signal word:** None required  
**Hazard statements:** None required  
**Precautionary Statements:** None required

**Supplemental Hazard Statements.** None known

**Component 7: Platinum<sup>®</sup> Tfi Exo(-) DNA Polymerase**

**Hazard pictograms:** None required  
**Signal word:** None required  
**Hazard statements:** None required  
**Precautionary Statements:** None required

**Supplemental Hazard Statements.** None known

**Component 8: Platinum<sup>®</sup> Tfi Reaction Buffer, 5x**

**Hazard pictograms:**



**Signal word:** **WARNING**

**Hazard statements:** H315 – Causes skin irritation  
H319 – Causes serious eye irritation

**Precautionary Statements:** P264 - Wash thoroughly after handling  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P302+P352 - IF ON SKIN: Wash with plenty of water.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P332+P313 - If skin irritation occurs: Get medical advice/attention  
P337+P313 - If eye irritation persists: Get medical advice/attention

**Supplemental Hazard Statements.** None known

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**Component 9: Platinum<sup>®</sup> Tfi 50mM MgCl<sub>2</sub>**

Hazard pictograms: None required  
Signal word: None required  
Hazard statements: None required  
Precautionary Statements: None required

Supplemental Hazard Statements. None known

**Component 10: xTAG<sup>®</sup> Shrimp Alkaline Phosphatase**

Hazard pictograms: None required  
Signal word: None required  
Hazard statements: None required  
Precautionary Statements: None required

Supplemental Hazard Statements. None known

**Component 11: xTAG<sup>®</sup> Exonuclease I**

Hazard pictograms: None required  
Signal word: None required  
Hazard statements: None required  
Precautionary Statements: None required

Supplemental Hazard Statements. None known

**Labelling information for BOX 2:****Component 12: xTAG<sup>®</sup> Streptavidin, R-Phycoerythrin Conjugate**

Hazard pictograms: None required  
Signal word: None required  
Hazard statements: None required  
Precautionary Statements: None required

Supplemental Hazard Statements. None known

**2.3 Other hazards**

This kit contains Poly(oxy-1,2-ethanediyl),  $\alpha$ -[(1,1,3,3-tetramethylbutyl)phenyl]- $\omega$ -hydroxy-which is considered to be an endocrine-disrupting substance at levels below 0.1%.

No components are classified as persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

**3.1 Substances :**  
Not applicable

**3.2 Mixture :**  
**Component 1: xTAG<sup>®</sup> CFTR PCR Primer Mix v2:**

Not classified as a hazardous mixture and therefore does not require reporting in this section.

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**Component 2: xTAG<sup>®</sup> CFTR Bead Mix A v2:**

Product/ Ingredient name	Identifiers	%	Classification 1272/2008/EC	Nano material form	M Factor	Specific conc'n limits (SCL)	Acute toxicity estimate (ATE)
<b>Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-</b>	CAS No 9002-93-1  EC No 618-344-0  REACH No n/a	< 0.1%	Acute Tox. 4, (oral) H302 Skin Irrit 2 H315 Eye Dam 1, H318 Aquatic Chronic 2, H411	No	1	No SCL in Annex VI	No ATE in Annex VI

**Component 3: xTAG<sup>®</sup> CFTR Bead Mix B v2:**

Product/ Ingredient name	Identifiers	%	Classification 1272/2008/EC	Nano material form	M Factor	Specific conc'n limits (SCL)	Acute toxicity estimate (ATE)
<b>Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-</b>	CAS No 9002-93-1  EC No 618-344-0  REACH No n/a	< 0.1%	Acute Tox. 4, (oral) H302 Skin Irrit 2 H315 Eye Dam 1, H318 Aquatic Chronic 2, H411	No	1	No SCL in Annex VI	No ATE in Annex VI

**Component 4: xTAG<sup>®</sup> CFTR ASPE Primer Mix A v2:**

Not classified as a hazardous mixture and therefore does not require reporting in this section.

**Component 5: xTAG<sup>®</sup> CFTR ASPE Primer Mix B v2:**

Not classified as a hazardous mixture and therefore does not require reporting in this section.

**Component 6: xTAG<sup>®</sup> Reporter Buffer**

Product/ Ingredient name	Identifiers	%	Classification 1272/2008/EC	Nano material form	M Factor	Specific conc'n limits (SCL)	Acute toxicity estimate (ATE)
<b>Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-</b>	CAS No 9002-93-1  EC No 618-344-0  REACH No n/a	< 0.1%	Acute Tox. 4, (oral) H302 Skin Irrit 2 H315 Eye Dam 1, H318 Aquatic Chronic 2, H411	No	1	No SCL in Annex VI	No ATE in Annex VI

**Component 7: Platinum<sup>®</sup> Tfi Exo(-) DNA Polymerase**

Not classified as a hazardous mixture and therefore does not require reporting in this section.

**Component 8: Platinum<sup>®</sup> Tfi Reaction Buffer, 5x**

Product/ Ingredient name	Identifiers	%	Classification 1272/2008/EC	Nano material form	M Factor	Specific conc'n limits (SCL)	Acute toxicity estimate (ATE)
<b>Potassium hydroxide</b>	CAS No 1310-58-3  EC No 215-181-3  REACH No 01- 2119487136 -33-XXXX	0.1-1.5%	Acute Tox. 4, (oral) H302 Skin Irrit 1A H314	No	1	Skin Corr 1A H314: C ≥ 5% Skin Corr 1B H314: 2 ≤ C < 5% Skin Irrit. 2 H315: 0.5 ≤ C < 2% Eye Irrit. 2; H319 0.5 ≤ C < 2%	No ATE in Annex VI

**Component 9: Platinum<sup>®</sup> Tfi 50mM MgCl<sub>2</sub>:**

Not classified as a hazardous mixture and therefore does not require reporting in this section.

**Component 10: xTAG<sup>®</sup> Shrimp Alkaline Phosphatase:**

Not classified as a hazardous mixture and therefore does not require reporting in this section.

**Component 11: xTAG<sup>®</sup> Exonuclease I:**

Product/ Ingredient name	Identifiers	%	Classification 1272/2008/EC	Nano material form	M Factor	Specific conc'n limits (SCL)	Acute toxicity estimate (ATE)
<b>2- Mercapto ethanol</b>	CAS No 60-24-2  EC No 215-181-3  REACH No 01- 2119487136- 33-XXXX	0.01-0.1%	Acute Tox 3 (oral) H301 Acute Tox 2 (dermal) H310 Skin Irrit 2 H315 Skin Sens 1A H317 Eye Dam 1 H318 Acute Tox 3 (inhal) H331 Repr 2 H361 STOT RE 2 H373 Aquatic acute 1 H400 Aquatic chronic 2 H411	No	1	No SCL in Annex VI	No ATE in Annex VI

**Component 12: xTAG<sup>®</sup> Streptavidin, R-Phycoerythrin Conjugate:**

Not classified as a hazardous mixture and therefore does not require reporting in this section.

**Nanofoms present in product:** Not applicable

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 .  
See section 16 for the full text of the H and P statements declared above

**SECTION 4: FIRST AID MEASURES**

- Eye contact:** In case of eye contact, remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 mins. Get medical attention if symptoms develop.
- Skin contact:** Wash with water and soap and rinse thoroughly. Seek medical advice if irritation or pain develops.
- Inhalation:** Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Oxygen should only be administered by qualified personnel. Seek medical advice.
- Ingestion:** Do NOT induce vomiting. Get medical attention immediately. If spontaneous vomiting occurs, keep head below hips to avoid breathing the product into the lungs. Never give anything by mouth to an unconscious person.

**4.2 Most important symptoms and effects, both acute and delayed**

- Overall Kit:** None known  
**Box 1:** None known  
**Box 2:** None known

- Component 1: xTAG<sup>®</sup> CFTR PCR Primer Mix v2:** None known  
**Component 2: xTAG<sup>®</sup> CFTR Bead Mix A v2:** None known  
**Component 3: xTAG<sup>®</sup> CFTR Bead Mix B v2:** None known  
**Component 4: xTAG<sup>®</sup> CFTR ASPE Primer Mix A v2:** None known  
**Component 5: xTAG<sup>®</sup> CFTR ASPE Primre Mix B v2:** None known  
**Component 6: xTAG<sup>®</sup> Reporter Buffer:** None known  
**Component 7: Platinum<sup>®</sup> Tfi Exo(-) DNA Polymerase:** None known  
**Component 8: Platinum<sup>®</sup> Tfi Reaction Buffer, 5x:** Causes skin irritation. Causes serious eye irritation.  
**Component 9: Platinum<sup>®</sup> Tfi 50mM MgCl<sub>2</sub>:** None known  
**Component 10: xTAG<sup>®</sup> Shrimp Alkaline Phosphatase:** None known  
**Component 11: xTAG<sup>®</sup> Exonuclease I:** None known  
**Component 12: xTAG<sup>®</sup> Streptavidin, R-Phycoerythrin Conjugate:** None known

**4.3 Indication of any immediate medical attention and special treatment needed**

If any symptoms are observed, contact a physician and give them this SDS sheet. Provide general supportive measures and treat symptomatically:

**SECTION 5: FIREFIGHTING MEASURES****5.1 Extinguishing media**

Suitable extinguishing media: In case of fire: Use water spray (fog), carbon dioxide (CO<sub>2</sub>), dry chemical powder or foam to extinguish. Use an extinguishing agent suitable for the surrounding area.

Unsuitable extinguishing media: None known.

**5.2 Special hazards arising from the substance or mixture**

No specific fire or explosion hazard.



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Hazardous combustion products:

Carbon dioxide, carbon monoxide, metal oxide/oxides.

### **5.3 Advice for firefighters**

Move containers from fire area if you can do it without risk. Cool containers with flooding quantities of water until well after fire is out. Isolate the hazard area and deny entry to unnecessary and unprotected personnel. Keep out of drains, sewers, ditches and waterways. Inhalation is a health risk. Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Wear self-contained breathing apparatus and protective clothing. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8).

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

### **6.1 Personal precautions, protective equipment and emergency procedures**

#### **For non-emergency personnel**

No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering.

#### **For emergency responders**

For large spillages, evacuate the area of all non-essential personnel. Ventilate contaminated area thoroughly. Avoid contact with spilled or released material. Immediately remove all contaminated clothing. Stay upwind and away from spill/release.

Wear appropriate protective equipment, such as gloves, goggles and protective clothing, as conditions warrant (see Section 8).

See Sections 2 and 7 for additional information on hazards and precautionary measures.

See Section 13 for disposal guidance.

### **6.2 Environmental precautions**

Avoid disposal of spilt material and runoff and contact with soil, waterways, drains and sewers. May be harmful to the environment if released in large quantities. Collect spillage.

### **6.3 Methods and materials for containment and cleaning up**

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

### **6.4 Reference to other sections**

See Section 1 for emergency contact information.

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

## **SECTION 7: HANDLING AND STORAGE**

### **7.1 Precautions for safe handling**

Use only with adequate ventilation. Wear appropriate personal protective equipment and use exposure controls as indicated in Section 8. Avoid contact with skin and eyes. Avoid breathing product dust or vapours. 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.

### **7.2 Conditions for safe storage, including any incompatibilities**

Store in accordance with local regulations.

Storage temperature:

Components 1-11 Store at -25°C to -15°C.

Component 12: Store at 2°C to 6°C.

**7.3 Specific end use(s):**

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

**SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION****8.1 Control parameters****Occupational exposure limit values:**

<b>Ingredient name</b>	<b>CAS Number</b>	<b>Occupational exposure limits</b>	<b>Source</b>
<b>Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3- tetramethylbutyl)phenyl]- ω-hydroxy-</b>	9002-93-1	Short-term value: None known Long-term value: None known	UK EH40/2005 Workplace exposure limits (updated 2020)
<b>Potassium hydroxide</b>	1310-58-3	Short-term value: 2 mg/m <sup>3</sup> Long-term value: None known	UK EH40/2005 Workplace exposure limits (updated 2020)
<b>2-Mercaptoethanol</b>	60-24-2	Short-term value: None known Long-term value: None known	UK EH40/2005 Workplace exposure limits (updated 2020)

**Monitoring procedures:** Use methods described in European Standards.**Derived No Effect Level (DNEL):****Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-**

None known

**Potassium hydroxide**

Workers	Inhalation	Long-term local effects	1 mg/m <sup>3</sup>
General population	Inhalation	Long-term local effects	1 mg/m <sup>3</sup>

**2-Mercaptoethanol**

Workers	Inhalation	Long-term systemic effects	0.17 mg/m <sup>3</sup>
Workers	Inhalation	Short-term systemic effects	0.17 mg/m <sup>3</sup>
Workers	Dermal	Long-term systemic effects	0.05 mg/kg bw/day
Workers	Dermal	Short-term systemic effects	0.05 mg/kg bw/day
General population	Oral	Long-term systemic effects	0.025 mg/kg bw/day
General population	Oral	Short-term systemic effects	0.025 mg/kg bw/day

**Predicted No Effect Concentration (PNEC):****Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy- (Plug 4)**

None known

**Potassium hydroxide**

No data available: testing technically not feasible

**2-Mercaptoethanol**

Component	Value
Fresh water	0.006 mg/L
Marine water	0.001 mg/L
Sewage treatment plant	60 mg/L
Fresh water sediment	0.024 mg/kg sediment dw
Marine sediment	0.002 mg/kg sediment dw
Soil	0.908 mg/kg soil dw

**8.2 Exposure controls****Appropriate Engineering Measures**

No special ventilation requirements. Apply technical measures to comply with the occupational exposure limits. Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Ensure adequate ventilation to keep airborne concentrations low. Do not empty waste into water drains.

**Individual protection measures, such as personal protective equipment:**

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

Skin protection:

Hand protection: Not required under normal conditions of use.

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

Respiratory protection: Not required under normal conditions of use.

Thermal hazards: None known.

**Environmental exposure controls:** Prevent further leakage or spillage if safe to do so. Prevent product from entering drains or water systems.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES****9.1 Information on basic physical and chemical properties**

Physical State:	Liquid (all components)
Colour:	Colourless (components 1 - 11) Light pink (component 12)
Odour and odour threshold:	Odourless (all components)
Melting point/Freezing point:	Not available
Boiling point or initial boiling point and boiling range:	Not available
Flammability:	Not available
Lower and upper explosion limit::	
Lower (%):	Not available
Upper (%):	Not available
Flash point:	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
pH:	Component 8. 6 to 8

Kinematic viscosity:	Not available
Solubility:	Not available
Partition coefficient n-octanol/water (log value):	Not available
Vapour pressure:	Not available
Density and/or relative density:	Not available
Relative vapour density:	Not available
Decomposition temperature:	Not available
Particle characteristics:	Not applicable

**9.2 Other information:**

Information with Regard to Physical Hazard Classes:	None known
Other Safety Characteristics:	None known

**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**

All components are stable under normal conditions.

**10.3 Possibility of hazardous reactions**

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

**10.4 Conditions to avoid**

None known

**10.5 Incompatible materials**

Reactive or incompatible with the following materials: oxidizing 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: None expected

Product/ingredient name	Test	Species	Dose
<b>Poly(oxy-1,2-ethanediyl), <math>\alpha</math>-[4-(1,1,3,3-tetramethylbutyl)phenyl]-<math>\omega</math>-hydroxy-</b>	LD50 Oral	Rat	None known
	LD50 Dermal	Rabbit	None known
	LC50 Inhalation	Rat	None known
<b>Potassium hydroxide</b>	LD50 Oral	Rat	333 mg/kg
	LD50 Dermal	Rabbit	None known
	LC50 Inhalation	Rat	None known
<b>2-Mercaptoethanol</b>	LD50 Oral	Rat	336 mg/kg
	LD50 Dermal	Rabbit	112 – 224 mg/kg
	LC50 Inhalation	Rat	2 mg/L 4h

<b>Skin corrosion/irritation:</b>	Causes skin irritation (component 8)
<b>Serious eye damage/eye irritation:</b>	Causes serious eye irritation (component 8)
<b>Respiratory or skin sensitization:</b>	Not expected to cause respiratory sensitization. Not expected to cause skin sensitization or allergic reaction.
<b>Germ cell mutagenicity:</b>	This product is not expected to cause genetic defects.
<b>Carcinogenicity:</b>	This product is not expected to cause cancer.
<b>Reproductive toxicity:</b>	Not expected to cause damage to fertility or the unborn child.
<b>STOT – Single exposure:</b>	This product is not expected to cause specific target organ toxicity after a single exposure
<b>STOT – Repeat exposure:</b>	This product is not expected to cause specific target organ toxicity after prolonged or repeated exposure.
<b>Aspiration hazard:</b>	Not expected to cause an aspiration hazard.
<b>11.2 Information on other hazards:</b>	
<b>Endocrine disrupting properties:</b>	Poly(oxy-1,2-ethanediyl), $\alpha$ -[(1,1,3,3-tetramethylbutyl)phenyl]- $\omega$ -hydroxy- is classified as having endocrine disrupting properties and is on the Candidate List of substances of very high concern.
<b>Information on other hazards:</b>	None known.

**SECTION 12: ECOLOGICAL INFORMATION****12.1 Toxicity:**

<b>Substance name</b>	<b>Toxicity to fish / other aquatic invertebrates</b>
<b>Poly(oxy-1,2-ethanediyl), <math>\alpha</math>-[4-(1,1,3,3-tetramethylbutyl)phenyl]-<math>\omega</math>-hydroxy-</b>	Fish - LC50 Pimephales promelas 4 - 8.9 mg/L 96 h Invertebrates - EC50 Daphnia magna 18 - 26 mg/L 48 h
<b>Potassium hydroxide</b>	None knowm
<b>2-Mercaptoethanol</b>	Fish – LC50 Leuciscus idus 37 mg/L 96h Invertebrates - EC50 Daphnia magna 0.4 mg/L 48h Algae – EC50 Desmodesmus subspicatus 19 mg/L 72h

**12.2 Persistence and Degradability:**

No data available for this product

**12.3 Bioaccumulative potential:**

No data available for this product

**12.4 Mobility in soil:**

No data available for this product

**12.5 Results of PBT and vPvB assessment:**

This kit contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Endocrine disrupting properties**Poly(oxy-1,2-ethanediyl),  $\alpha$ -[(1,1,3,3-tetramethylbutyl)phenyl]- $\omega$ -hydroxy- is classified as having endocrine disrupting properties and is on the Candidate List of substances of very high concern.

**12.7 Other adverse effects:**

None known.

**SECTION 13: DISPOSAL CONSIDERATIONS****13.1 Waste treatment methods:****Methods of disposal**

The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

**Hazardous Waste**

The classification of the product may NOT meet the criteria for a hazardous waste.

**Contaminated 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 where 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 disposal of spilt material and runoff and contact with soil, waterways, drains and sewers.

**SECTION 14: TRANSPORT INFORMATION****International transport regulations****14.1 UN number:**ADR/RID/ADN: Not applicableIMDG: Not applicableIATA: Not applicable**14.2 Proper shipping name:**ADR/RID/ADN: Not regulated as hazardous for transportIMDG: Not regulated as hazardous for transportIATA: Not regulated as hazardous for transport**14.3 Transport hazard class(es)**ADR/RID/ADN: n/aIMDG: n/aIATA: n/a**14.4 Packing group**ADR/RID/ADN: n/aIMDG: n/aIATA: n/a**14.5 Environmental hazard**

Marine Pollutant: Not expected

**Additional information:**ADR/RID/ADN: Limited Quantity – not applicableIATA: Limited Quantity – not applicableIMDG: Limited Quantity – not applicable

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#### **14.6 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.

#### **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**

This safety datasheet complies with the requirements of:

EU Commission Regulation (EU) 2020/878 (REACH)

EU Regulation (EC) No 1272/2008 (CLP)

EINECS: All components in this product are listed on the European Inventory of Existing Chemical Substance

#### **Annex XIV - List of substances subject to authorisation**

Intrinsic property	Ingredient Name	Status	Reference number	Date of revision
Substance of equivalent concern for environment	Poly(oxy-1,2-ethanediyl), $\alpha$ -[(1,1,3,3-tetramethylbutyl)phenyl]- $\omega$ -hydroxy-	Listed	42	Sunset date 2021-01-04 – IVD exempted as SR&D activity

#### **15.2 Chemical safety assessment**

For this product a chemical safety assessment was not carried out on this product.

### **Section 16: OTHER INFORMATION**

#### **Full text of H and P-Statements referred to under sections 2 and 3.**

Acute Tox	Acute Toxicity
Skin Corr	Skin corrosion
Skin Irrit	Skin Irritation
Skin Sens	Skin sensitization
Eye Dam	Eye damage
Eye Irrit	Eye irritation
Repr	Reproductive toxicity
STOT RE	Specific target organ toxicity repeated exposure
Aquatic acute	Aquatic short term chronic exposure
Aquatic chronic	Aquatic long term chronic exposure
H315	Causes skin irritation
H319	Causes serious eye irritation
P264	Wash thoroughly after handling
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321	Specific treatment (see sections 4 to 8 on this SDS and any further information on the label).
P332+P313	If skin irritation occurs: Get medical advice/attention
P337+P313	If eye irritation persists: Get medical advice/attention

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

**Training advice:** Before using/handling the product one must read carefully present SDS.

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

Classification	Justification
<b>Component 8: Platinum<sup>®</sup> <i>Tfi</i> Reaction Buffer, 5x</b> Skin irritation 2 H315 Eye irritation 2 H319	Calculation method

**Abbreviations and acronyms:**

ADR:	Accord européen sur le transport des marchandises dangereuses par Route (European)
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
CLP:	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DNEL:	Derived No Effect Level
EC50:	Half maximal effective concentration
EINECS:	European Inventory of Existing Commercial Chemical Substances
EU:	European Union
GHS:	Globally Harmonized System of Classification and Labeling of Chemicals
IATA:	International Air Transport Association
IBC:	International Bulk Code
IMDG:	International Maritime Code for Dangerous Goods
IOELV:	Indicative Occupational Exposure Limit Value
LC50:	Lethal concentration, 50 percent
LD50:	Lethal dose, 50 percent
MARPOL:	International Convention for the Prevention of Pollution from Ships
OEL:	Occupational Exposure Level
PBT:	Persistent, Bioaccumulative and Toxic
PNEC:	Predicted No Effect Level
REACH:	Registration, Evaluation, Authorisation and Restriction of Chemicals
SCBA:	Self Contained Breathing Apparatus
SCL:	Specific Concentration Limits
UN:	United Nations
VPvB:	Very Persistent and very Bioaccumulative
WEL:	Workplace Exposure Limit

**Additional information:****Concentration breakdown for BOX 1:**

Component 1: xTAG <sup>®</sup> CFTR PCR Primer Mix v2	240 µL	0.24 mL	0.6%
Component 2: xTAG <sup>®</sup> CFTR Bead Mix A v2	2.16 mL	2.16 mL	5.7%
Component 3: xTAG <sup>®</sup> CFTR Bead Mix B v2	2.16 mL	2.16 mL	5.7%
Component 4: xTAG <sup>®</sup> CFTR ASPE Primer Mix A v2	192 µL	0.192 mL	0.5%
Component 5: xTAG <sup>®</sup> CFTR ASPE Primer Mix B v2	192 µL	0.192 mL	0.5%
Component 6: xTAG <sup>®</sup> Reporter Buffer	12 mL x 2 vials	24 mL	63.5%
Component 7: Platinum <sup>®</sup> <i>Tfi</i> Exo(-) DNA Polymerase	115 µL x 3 vials	345 µL 0.345 mL	0.9%
Component 8: Platinum <sup>®</sup> <i>Tfi</i> Reaction Buffer, 5x	1.3 mL x 4 vials	5.2 mL	13.7%
Component 9: Platinum <sup>®</sup> <i>Tfi</i> 50mM MgCl <sub>2</sub>	1 mL x 3 vials	3 mL	7.9%
Component 10: xTAG <sup>®</sup> Shrimp Alkaline Phosphatase	120 µL x 2 vials	240 µL 0.24 mL	0.6%

Component 11: xTAG <sup>®</sup> Exonuclease I	48uL x 2 vials	96 µL	0.096 mL	0.25%
Total volume of BOX 1: 37.825 mL				

**Concentration breakdown for BOX 2:**



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Component 12: xTAG<sup>®</sup> Streptavidin, R-Phycoerythrin Conjugate – 120 µL x 2 vials 100%

**Document history**

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