Date : 30/03/2020
Version : 1

SAFETY DATA SHEET

NxTAG® Gastrointestinal Pathogen Panel

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

1.1 Product identifier

Product name : NxTAG® Gastrointestinal Pathogen Panel

Product code : R053C0459, X053C0461, I053C0458

Product description : Not available.

Component name :
Component 1 NxTAG® Gastrointestinal Pathogen Panel Plate
Component 2 MS2

Product type :
Component 1 Solid.
Component 2 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 : N/A

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

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]

Not classified.

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

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

SECTION 2: Hazards identification

2.2 Label elements

GHS label elements for the kit

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

GHS label elements by component

Signal word	:	**Component 1**	No signal word.
		Component 2	No signal word.
Hazard statements	:	**Component 1**	No known significant effects or critical hazards.
		Component 2	No known significant effects or critical hazards.
Precautionary statements			
Prevention	:	**Component 1**	Not applicable.
		Component 2	Not applicable.
Response	:	**Component 1**	Not applicable.
		Component 2	Not applicable.
Storage	:	**Component 1**	Not applicable.
		Component 2	Not applicable.
Disposal	:	**Component 1**	Not applicable.
		Component 2	Not applicable.

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 fastenings : Not applicable.

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

There are no 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.

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact : Not applicable.

Inhalation : Not applicable.

Skin contact : Not applicable.

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

Eye contact	:	**Component 1**	No known significant effects or critical hazards.
		Component 2	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.
Skin contact	:	**Component 1**	No known significant effects or critical hazards.
		Component 2	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.

Over-exposure signs/symptoms

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

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

SECTION 5: Firefighting measures

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.

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: Store at 2˚C to 8˚C.
Component 2: Store at -25˚C to 8˚C.

7.3 Specific end use(s)

Recommendations : Not available.

SECTION 7: Handling and storage

Industrial sector specific solutions : Not available.

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

No exposure limit value known.

Recommended monitoring procedures : 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

No DNELs/DMELs available.

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**	Solid. [Opaque lyophilized beads.]
		Component 2	Liquid. [Clear.]
Colour	:	**Component 1**	One white bead and one pink bead.
		Component 2	Colourless.
Odour	:	**Component 1**	Odourless.
		Component 2	Odourless.
Odour threshold	:	Not available.	
pH	:	**Component 1**	Not available.
		Component 2	Not available.
Melting point/freezing point	:	Not available.	
Initial boiling point and boiling range	:	**Component 1**	Not available.
		Component 2	Not available.
Flash point	:	**Component 1**	Not available.
		Component 2	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.
		Component 2	Not available.
Vapour density	:	**Component 1**	Not available.
		Component 2	Not available.
Relative density	:	**Component 1**	Not available.
		Component 2	Not available.
Solubility(ies)	:	**Component 1**	Not available.
		Component 2	Not available.
Partition coefficient: n-octanol/ water	:	Not available.	
Auto-ignition temperature	:	Not available.	
Decomposition temperature	:	Not available.	
Viscosity	:	**Component 1**	Not available.
		Component 2	Not available.
Explosive properties	:	Not available.	
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.

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

SECTION 10: Stability and reactivity

10.4 Conditions to avoid : **Component 1** No specific data.
Component 2 No specific data.

10.5 Incompatible materials : **Component 1** Reactive or incompatible with the following materials: oxidising materials.
Component 2 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.

Irritation/Corrosion

There is no data available.

Sensitisation

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

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

Potential acute health effects

Eye contact : **Component 1** No known significant effects or critical hazards.
Component 2 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.

Skin contact : **Component 1** No known significant effects or critical hazards.
Component 2 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.

SECTION 11: Toxicological information

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

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 effects : No known significant effects or critical hazards.

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

Long term exposure

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

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

Potential chronic health effects

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Other information : Not available.

SECTION 12: Ecological information

12.1 Toxicity

There is no data available.

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 (K_{OC}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

SECTION 12: Ecological information

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 : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

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. 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.

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.

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 on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

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.

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
Not classified.	

Full text of abbreviated H statements

Not applicable.

Full text of classifications [CLP/GHS]

Not applicable.

History

Date of issue (dd/mm/yyyy) : 30/03/2020

Date of previous issue : Not applicable.

Version : 1

SECTION 16: Other information

Prepared by : KMK Regulatory Services Inc.

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.