

Revision Date: 24-Aug-2021

Section 1 - Product and Company Identification

Manufacturer Information

Quansys BiosciencesPhone:(435) 752-0531Web: www.quansysbio.com365 North 600 WestFax:(435) 750-6869Email: info@quansysbio.com

Logan, UT 84321 Emergency: 1-800-535-5053

Product Information

Product Name: Enzyme-Linked Immunosorbent Assay (ELISA) Kits

Suggested Use: The kits are for Research Use Only and not for use in diagnostic procedures.

Components: Arrayed microplate, Multiplexed Calibrators, High/Mid/Low Controls, Specimen Controls, Detection Mix,

Wash Buffer Concentrate 20x, Streptavidin-HRP, Substrate A, and Substrate B

Section 2 - Hazards Identification

Classification of Substance or Mixture

Substance	OSHA Hazards	Target Organs	Description	
Specimen Diluent	Irritant	Skin	Skin Sensitizer (Category 1)	
Detection Mix	Irritant	Skin	Skin Sensitizer (Category 1)	

GHS Label Elements, Including Precautionary Statements

Component	Pictogram	Hazard Statements Precautionary Statements			
Specimen Diluent		H317 May cause an allergic skin reaction.	P264 Wash hands thoroughly after handling.		
Detection Mix			P303+P361+P353:		
			IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water.		
	Warning		P333+P313:		
			If skin irritation or rash occurs: Get medical attention.		
Supplemental Hazard Statements		1. Follow Universal Precautions when working with this kit. Refer to additional Universal Precaution information in Section 7, Handling and Storage.			
		2. Avoid release to the environment.			
		3. Sodium azide (<0.1%) used a Diluent.	as a preservative in the Specimen		
		4. Prevent the components lis	ted above from entering drains.		



Revision Date: 24-Aug-2021

Section 3 - Composition / Information on Ingredients

Composition/Information on Ingredients

Component	Chemical Name	CAS#	EC-No.	Conc. (%)
1. Specimen Diluent	Mixture: 5-Chloro-2-methyl-2, 3-			
2. Detection Mix	dihydroisothiazol-3-one; 2-Methyl-2,3-	55965-84-9	911-418-6	< 0.001
	dihydroisothiazol-3-one			

Section 4 - First Aid Measures

Description of First Aid Measures

Move out of exposure area. Consult a medical professional.

Inhalation: Move the person to fresh air and support breathing as required.

Skin contact: Wash affected area with soap and water. Seek medical advice if irritation develops.

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present

and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

Ingestion: Rinse mouth with water and drink 1 to 2 glasses of water. Never give anything by

mouth to an unconscious person. Seek medical advice if irritation develops.

Note to Physicians: Treat symptomatically.

Most Important Symptoms and Effects (both acute and delayed)

Not applicable.

Indication of Any Immediate Medical Attention and Special Treatment Needed

None

Section 5 – Fire Fighting Measures

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

Extinguishing Media

For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.

General Fire Hazards

The components within this kit will not significantly contribute to the intensity of a fire.

Hazardous Combustion Products

No data available

Fire Fighting Equipment

Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures



Revision Date: 24-Aug-2021

Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the solutions, controls or reagents within this kit. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.

Methods and Materials for Clean-Up

Wipe up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release.

Environmental Precautions

Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.

Reference to Other Sections

See section 8 for more information.

Section 7 - Handling and Storage

Specific Use

Refer to product specific Package Insert. Not for use by the general public.

Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the components within this kit <u>ON YOU</u> or <u>IN YOU</u>. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Universal Precautions should be followed when handling and working with this kit.

Universal Precautions

No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma used in components of this kit will not transmit infectious agents. All blood or other human/animal derived products should be treated as potentially infectious; use universal precautions. Users should ensure the use of proper personal protective equipment (PPE), covering of any cuts or abrasions on the skin (hands), and follow standard protocols for the decontamination of work surfaces when testing has been completed. Always wash hands thoroughly after handling the components within this kit.

Conditions for Safe Storage

To maintain efficacy, store according to the kit specific Package Insert instructions.

Incompatibilities

Incompatible with strong acids and bases. Incompatible with oxidizing agents.

Section 8 – Exposure Controls and Personal Protection

Exposure Limits

No data available for the specific components within this kit.

Exposure Controls:

Engineering Measures Use with adequate ventilation.

Personal Protective Equipment

Respiratory Protection: None needed under normal conditions of use.

Handle with appropriately rated chemical resistant gloves. Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid

inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.



Safety Data Sheet Revision Date: 24-Aug-2021

Eye Protection: Wear safety glasses with side shields or goggles to prevent eye contact.

Skin and Body Protection: Use body protection appropriate for the task. A laboratory coat is

recommended.

Hygiene Measures: Wash hands before and after use. Handle in accordance with good industrial

hygiene and safety practice.

Environmental Exposure Controls

No special environmental controls are required.

Section 9 – Physical and Chemical Properties

Characteristic	Specimen Diluent	Detection Mix
Appearance	Clear, colorless to light straw-colored liquid	Clear, colorless liquid
Odor	Odorless	Odorless
рН	7.3	7.3
Specific Gravity	No data available	No data available
Boiling Point	No data available	No data available
Melting point/Freezing point	No data available	No data available
Flash Point	No data available	No data available
Evaporation Rate	No data available	No data available
Vapor pressure	No data available	No data available
Vapor density	No data available No data availal	
Solubility in water	Soluble	Soluble

Section 10 – Stability and Reactivity

	Characteristic	Specimen Diluent	Detection Mix
--	----------------	------------------	---------------



Safety Data Sheet
Revision Date: 24-Aug-2021

		NEVISION DUIC. 24 Aug 2021		
Reactivity	Not reactive under normal conditions	Not reactive under normal conditions		
Chemical Stability	Stable under recommended storage conditions	Stable under recommended storage conditions		
Possibility of Hazardous Reaction	No data available	No data available		
Conditions to Avoid	No data available	No data available		
Incompatible Materials	No data available	No data available		
Hazardous Decomposition Products	No data available	No data available		

Section 11 - Toxicological Information

Information on Toxicological Effects

Specimen Diluent and Detection Mix

Component Analysis – LD50 / LC50 / Irritation (No data available for specific kit components)

Chemical Name	CAS#	RTECS #	Information		
Mixture: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one	55965-84-9	Not available	Oral LD ₅₀ Inhalation LC ₅₀ Dermal LD ₅₀	Rat No data available No data available	53 mg/kg

Acute Toxicity

No data available
Skin Corrosion/ Irritation

No data available
Serious Eye Damage / Irritation:

Respiratory or Skin Sensitization

Generative Cell Mutagenicity

No data available

Carcinogenicity No component of this kit is present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by the ACGIH,

NTP or OSHA.

Reproductive Toxicity

No data available

Teratogenicity

No data available

Specified Target Organ Toxicity

Single Exposure (GHS): No data available
Repeated Exposure (GHS): No data available

Section 11 – Toxicological Information (cont'd)

Potential Health Effects

Inhalation May cause respiratory tract irritation.

Ingestion May be harmful if swallowed.

Skin May cause skin irritation upon contact.

Eyes May cause serious eye irritation.

Aspiration Respiratory Organs Hazard



Revision Date: 24-Aug-2021

None anticipated under product use conditions.

Synergistic Effects

No data available

Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components contained within this kit.

Additional Information

Sensitization: Contains a small volume of a dilute, sensitizing preservative, Proclin 150. Though the potential for an

allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle

accordingly.

Section 12 - Ecological Information

Ecotoxicity No data available

Persistence / Degradability No data available

Bioaccumulation No data available

Mobility in Soil No data available

PBT and vPvB Assessment No data available

Other Adverse Effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid release to the environment and municipal or industrial drains.

Section 13 – Disposal Considerations

Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge any of the solutions, reagents or controls into drains, water courses or onto the ground.

Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country, federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

Section 14 – Transportation Information

U.S. Department of Transportation (DOT): Not regulated

International Air Transportation (IATA): Not regulated

International Maritime Dangerous Goods (IMDG): Not regulated

Section 15 - Regulatory Information

U.S. Federal Regulations

OSHA Hazards Specimen Diluent, Detection Mix: Sensitizer



Revision Date: 24-Aug-2021

SARA 302	The following chemicals are subject to reporting levels established by SARA Title III, Section 302:
	No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313	The following chemicals are subject to reporting levels established by SARA Title III, Section 313:
	No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 313.
SARA 311/312	The following chemicals are subject to reporting levels established by SARA Title III, Section 311/312:
	Mixture: 5-Chloro-2-methyl-2, 3- dibydecisethicael 2 and 2 Methyl 2

Mixture: 5-Chloro-2-methyl-2, 3-	CAS#: 55965-84-9	Acute Health Hazard
dihydroisothiazol-3-one; 2-Methyl-2,		
3-dihydroisothiazol-3-one		

State Regulations

The following chemical(s) appear on one or more of the following state hazardous substances lists:

Chemical Name	CAS#	CA	MA	MN	NJ	PA	RI
Mixture: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one	55965-84-9	No	No	No	Yes	Yes	No

California Prop 65: This kit does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Additional Regulatory Information

Safety, Health and Environmental regulations specific for the mixture:

European Union - Regulation (EC) No. 1907/2006

Chemical Safety Assessment:

Not completed for components contained within this kit.

NFPA Kit Classification:

Health Hazard (blue): 1
Fire Hazard (red): 0
Reactivity Hazard (yellow): 0
Special Hazard (white): None





Revision Date: 24-Aug-2021

Section 16 - Other Information

PREPARED BY: Quansys Biosciences

365 North 600 West Logan, UT 84321

ISSUE DATE: 24-Sep-2021

REVISION DATE: 24-Sep-2021

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability, fitness for a particular purpose or of any other type, expressed or implied, with respect to products described or data or information provided, and we assume no liability resulting from the use of such products, data or information. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Quidel be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages of any kind, howsoever arising, even if Quidel has been advised of the possibility of such damages.