

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: QuickVue Strep A Liquid Controls (Catalog #: 00354)

Intended Use: The QuickVue Strep A Controls are intended to be used as quality control samples representative of positive and negative test results and to verify proper performance of the procedure and reagents of the QuickVue Step A test systems. This test is intended for professional and laboratory use only.


Components: Kit is composed of a Positive Control (containing heat-inactivated group A *Streptococcus*) and Negative Control (containing heat-inactivated group C *Streptococcus*).

Section 2 – Hazards Identification

Emergency Overview

Component	OSHA Hazards	Target Organs	GHS Classification
Positive and Negative Controls (Microcide III, 0.3%)	Irritant, Sensitizer	Skin, eyes	Eye Irritation (Category 2A) Skin Irritation (Category 2) Skin Sensitizer (Category 1)

GHS Label Elements & Precautionary Statements

Component	Pictogram	Hazard Statements	Precautionary Statements
Positive and Negative Controls (Microcide III, 0.3%)	 Warning	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.	P261 Avoid breathing mist or spray. P280 Wear protective gloves and eye protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Supplemental Hazard Statements		Avoid release to the environment.	

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume	Chemical Classification
Positive and Negative Controls	Microcide III	55965-84-9	N/A	0.3	2.5 mL (per control)	Acute Tox. 3, Skin Corr. 1B, Skin Sens. 1, Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1; H301, H331, H311, H314, H317, H400, H410

**For the full text of the H-Statements and R-Phrases mention in this Section, see Section 16.

Section 4 – First Aid Measures

General Advice

Move out of exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance.

<i>If inhaled:</i>	Move the person to fresh air and support breathing as required.
<i>In case of skin contact:</i>	Wash affected area with soap and water. Seek medical advice if irritation develops.
<i>In case of eye contact:</i>	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.
<i>If swallowed:</i>	Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

Note to Physicians: Treat symptomatically.

Section 5 – Fire Fighting Measures

General Advice

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

<i>Extinguishing Media:</i>	For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.
<i>General Fire Hazards:</i>	The components within this kit will not significantly contribute to the intensity of a fire.
<i>Hazardous Combustion Products:</i>	No data available.
<i>Fire Fighting Equipment:</i>	Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release.

<i>Personal Precautions:</i>	Use personal protective equipment, including protective gloves and safety glasses when cleaning up 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.
<i>Materials / Methods for Clean-Up:</i>	Soak up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.
<i>Recovery and Neutralization:</i>	Collect spilled material and clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.
<i>Environmental Precautions:</i>	Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.

Section 7 – Handling and Storage

Specific Use: Control set for use with QuickVue Dipstick Strep A, QuickVue+ Strep A or QuickVue In-Line Strep A kits.

Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while handling these controls. 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. Keep out of reach of the general public.

Conditions for Safe Storage: To maintain efficacy, store according to the kit specific Package Insert instructions.

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

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.

Hand Protection: Handle with appropriately rated chemical resistant gloves (nitrile or equivalent). Gloves should be 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.

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 and at the end of the workday.

Environmental Exposure Controls

No special environmental controls are required.

Section 9 – Physical and Chemical Properties

Characteristic	Positive and Negative Controls
Boiling Point (°C)	No data available
Melting Point (°C)	No data available
Specific Gravity (H ₂ O = 1)	No data available
Vapor Pressure (mm Hg)	No data available
Vapor Density (Air = 1)	No data available
Evaporation Rate (Ether = 1)	No data available
pH	Neutral
Solubility in Water	Soluble
Appearance and Odor	Clear with no odor

Section 10 – Stability and Reactivity

Characteristic	Positive and Negative Controls
Component Stability	Stable
Hazard Reaction Potential	No data available
Conditions to Avoid	No data available
Materials to Avoid	No data available
Hazardous Decomposition Products	No data available

Section 11 – Toxicological Information

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

Chemical Name	CAS #	RTECS #	Information
Microcide III	55965-84-9	--	Oral LD ₅₀ Rat >5000 mg/kg
			Inhalation LC ₅₀ Rat (4-hr) 0.33 mg/L (dust/mist)
			Dermal LD ₅₀ Rabbit >5000 mg/kg

Potential Health Effects:

<i>Skin Corrosion/Irritation:</i>	May cause transient irritation.	<i>Inhalation:</i>	May be harmful if inhaled, Causes respiratory tract irritation.
<i>Serious Eye Damage / Irritation:</i>	No data available	<i>Skin:</i>	May be harmful if absorbed through skin. Causes skin irritation.
<i>Respiratory or Skin Sensitization:</i>	May cause sensitization by skin contact.	<i>Eyes:</i>	Causes eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available	<i>Ingestion:</i>	May cause irritation if swallowed.

Carcinogenicity

ACGIH, IARC, NTP, OSHA: No component of this material present at levels greater than or equal to 0.1% is identified as a carcinogen, anticipated carcinogen or potential carcinogen.

Reproductive Toxicity No data available

Teratogenicity No data available

Specified Target Organ General Toxicity (GHS)
Single Exposure (GHS): No data available

Repeated Exposure (GHS): No data available

Aspiration Respiratory Organs Hazard 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 controls contained within this kit.

Synergistic Effects No data available

Additional Information No data available

Section 12 – Ecological Information

Ecotoxicity No data available **Mobility in Soil** No data available

Persistence / Degradability No data available **PBT and vPvB Assessment** No data available

Bioaccumulation No data available

Other Adverse Effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

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 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 (e.g., Canada, EU, Japan, etc.), 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): This kit is not regulated for transport.

International Air Transportation (IATA): This kit is not regulated for transport.

International Maritime Dangerous Goods (IMDG): This kit is not regulated for transport.

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards Positive and Negative Control: Irritant, Sensitizer

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 No SARA hazards.

State Regulations

The following chemicals appear on one or more of the following state hazardous substances lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Microcide III	55965-84-9	No	No	No	No	No	No

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

Canadian - WHMIS IDL

Chemical Name	CAS #	Minimum Concentration
Microcide III	55965-84-9	No data available

Section 15 – Regulatory Information (cont'd)

Additional Regulatory Information

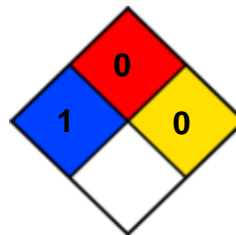
Safety, Health and Environmental regulations/legislation specific for the mixture: No data available

Chemical Safety Assessment: Not completed for the components contained within this kit.

HMIS Classification:



NFPA Classification:



Section 16 – Other Information

Microcide III Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)

Text of H-code(s) mentioned in Section 3:

H301	Toxic if swallowed.	Acute Tox.	Acute toxicity
H311	Toxic in contact with skin.		
H331	Toxic if inhaled.		
H314	Causes severe skin burns and eye damage.	Eye Dam.	Eye damage
H317	May cause an allergic skin reaction	Skin Sens.	Skin sensitizer
H400	Very toxic to aquatic life.	Aquatic Acute	Acute aquatic toxicity
H410	Very toxic to aquatic life with long lasting effects	Aquatic Chronic	Chronic aquatic toxicity

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REVISIONS: General formatting update and addition of kit component detail to Sections 2 and 3.

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.