

AmoyDx® EML4-ALK Fusion Gene Detection Kit**SECTION 1 – IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY**

Product Code: 8.01.22001W012A, 8.01.22001W012B, 8.01.22001W012D, 8.01.22001X024H

Product name: AmoyDx® EML4-ALK Fusion Gene Detection Kit

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SECTION 2 - COMPOSITION, INFORMATION ON INGREDIENTS

Chemical Name: HEPES CAS-No. 7365-45-9

Chemical Name: Ammonium Sulfate CAS-No. 7783-20-2

Chemical Name: Potassium Chloride CAS-No. 7447-40-7

Chemical Name: Water CAS-No. 7732-18-5

Chemical Name: DNA Polymerase CAS-No. 9012-90-2

Chemical Name: MgCl₂ CAS-No. 7786-30-3

Chemical Name: Primer CAS-No. No Listed

Chemical Name: Probe CAS-No. No Listed

Chemical Name: Plasmid CAS-No. No Listed

Hazard Symbols: None Listed.

Risk Phrases: None Listed.

SECTION 3 - HAZARDS IDENTIFICATION**EMERGENCY OVERVIEW**

Appearance: Liquid form

Harmful if swallowed

Potential Health Effects

Eye: May cause eye irritation.

Skin: May cause skin irritation.

Ingestion: May cause irritation of the digestive tract. The toxicological properties of this substance have not been fully investigated.

Inhalation: May cause respiratory tract irritation. The toxicological properties of this substance have not been fully investigated.

Chronic: No information found.

SECTION 4 - FIRST AID MEASURES

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Skin: Wash off immediately with plenty of water

Ingestion: Never give anything by mouth to an unconscious person.

Inhalation: Move to fresh air. If not breathing give artificial respiration.

Notes to Physician: Treat symptomatically

SECTION 5 - FIRE FIGHTING MEASURES

General Information:

Extinguishing Media:

In case of fire, use water, dry chemical, chemical foam, or alcohol-resistant foam. Use agent most appropriate to extinguish fire.

Special protective equipment for fire-fighters

Wear self contained breathing apparatus for fire-fighting if necessary.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment.

Methods for cleaning up: Scrape off liquid, wash with plenty of water.

SECTION 7 - HANDLING and STORAGE

Handling: No special handling advice required

Storage: Store in a tightly closed container. Store in -20°C, away from incompatible substances.

SECTION 8 - EXPOSURE CONTROLS, PERSONAL PROTECTION

Occupational exposure controls

Engineering Controls: Ensure adequate ventilation, especially in confined areas

Personal Protective Equipment

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by eye and face.

Protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin: Wear appropriate protective gloves to prevent skin exposure.

Clothing: Wear appropriate protective clothing to prevent skin exposure.

Respirators: A respiratory protection program that meets 29 CFR 1910.134 and ANSI Z88.2 requirements or European Standard EN 149 must be followed whenever workplace conditions warrant respirator use.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

General Information:

Form: Liquid

Vapor Pressure: Not available.

Viscosity: Not available.

Boiling Point: Not available.

Freezing/Melting Point:

Autoignition Temperature: Not available.

Flash Point: > 80°C.

Explosion Limits, lower: Not available.

Explosion Limits, upper: Not available.

Decomposition Temperature:

Solubility in water:

Specific Gravity/Density:

Molecular Formula: Not available

Molecular Weight: Not available

SECTION 10 - STABILITY AND REACTIVITY

Stability: Stable in -20°C in closed containers under normal storage and handling conditions.
Conditions to Avoid:

Hazardous Decomposition Products: No information available

Hazardous Polymerization: No information available

SECTION 11 - TOXICOLOGICAL INFORMATION

Acute toxicity: no data available

Irritation and corrosion: no data available

Sensitisation: no data available

Chronic exposure:

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Skin: May be harmful if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

Ingestion: May be harmful if swallowed.

Additional Information RTECS: TL6809000

SECTION 12 - ECOLOGICAL INFORMATION

Elimination information (persistence and degradability): no data available

Ecotoxicity effects: no data available

Further information on ecology: no data available

SECTION 13 - DISPOSAL CONSIDERATIONS

Dispose of in a manner consistent with federal, state, and local regulations.

SECTION 14 - TRANSPORT INFORMATION

UN number: Not regulated as a dangerous good.

UN proper shipping name: Not regulated as a dangerous good.

Transport hazard class(es): Not regulated as a dangerous good as per IATA DGR 61st Edition.

Packing group: Not regulated as a dangerous good.

Environmental hazards: Not regulated as a dangerous good.

Special precautions for user: Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA DGR 61st Edition.

SECTION 15 - REGULATORY INFORMATION

European/International Regulations

European Labeling in Accordance with EC Directives

Hazard Symbols: Not available.

Risk Phrases: Not available.

Safety Phrases: Not available.

SECTION 16 - ADDITIONAL INFORMATION

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no way shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.