

TK1 210 ELISA 4K-TK1-01 Version 5

Publication date: 2015-04-24

Section 1 Identification of the substance/mixture and of the company/undertaking.

1.1 Product identifiers.

Product Name: TK 210 ELISA kit Item number: 1001-15 and 1002-15

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

Identified uses: For measuring of TK1

1.3 Details of the supplier of the safety data sheet

Eagle Biosciences, Inc.

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Section 2 Hazards Identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008

Coated microtiter plate (TK PLATE): Considered non-hazardous. Sample dilution buffer (SAM DIL): Considered non-hazardous. Biotinylated Mab anti-TK1 (BIOT TK): Considered non-hazardous. Reagent buffer (REAG BUF): Considered non-hazardous. Streptavidin-HRP conjugate (STREP HRP): Considered non-hazardous. Calibrators (CAL A -E): Considered non-hazardous. Control (CTRL I and CTRL II): Considered non-hazardous. Wash buffer tablet (WASH): Considered non-hazardous. TMB Substrate solution (SUB): Considered non-hazardous. Stop solution (STOP): Considered non-hazardous.

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2.2 Labeling elements

Labeling according Regulation (EC) 1272/2008

Not applicable.

Supplemental Hazard information:

Not applicable.

2.3 Other hazards.

This product contains material of human source and animal origin. Therefore this product should be considered potentially infectious.

Section 3 Composition/Information of Ingredients.

3.1. Substance

Not applicable.

3.2. Mixture

Not applicable.

Hazardous ingredients

Considered non-hazardous.

Section 4 First Aid Measures

4.1 Description of first aid measurers

Skin Contact:

In case of skin contact, wash thoroughly with soap and plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical attention.

Eye Contact:

If product enters eyes, wash gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

Never give anything by mouth to an unconscious person. If ingested, wash mouth out with water and seek medical attention.

Inhalation:

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

General advice:

Consult a physician. Show this safety data sheet to the doctor in attendance.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labeling (see section 2.2) and/or in section 4.1.

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4.3 Indication of any immediate medical attention and special treatment needed For any immediate medical attention see section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media:

Use extinguishing media suitable for surrounding fire. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture Non identified.

5.3 Advice for firefighters

Self-contained breathing apparatus is recommended.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist, dust, or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations. As a precautionary measure, because some products contain materials from human or animal origin, treat spilled material with a 1:10 bleach water solution.

6.4 Reference to other sections

For disposal see section 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Avoid contact with eyes or skin. Avoid formation of vapors, dust, mist or gas. Do not eat, drink or smoke during handling this product. Wash hands after handling. Use only in a well-ventilated area. This product contains material of human source and animal origin. Therefore this product should be considered potentially infectious. Universal precautions should be followed when using this product. For further precautions see section 2.2.

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7.2 Conditions for safe storage, including any incompatibilities

The products should be stored in the original vials in a dry and well-ventilated place. Keep containers tightly closed. Containers which are opened must be carefully resealed and kept upright to prevent leakage. For storage temperatures see product label.

7.3 Specific end use(s)

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

Section 8 Exposure controls and personal protection

8.1 Control parameters

Not applicable.

8.2 Exposure controls

Engineering Controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands after handling this product.

Personal protecting equipment

Respiratory Protection:

Under normal conditions of use, as mentioned in section 1.2, the use of this product should not require respiratory protection.

Eye Protection:

Safety glasses or chemical goggles. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EU Regulation 2016/425 and the standard EN 166 (EU) derived from it.

Skin Protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Regulation 2016/425 and the standard EN 374 derived from it.

Full contact and splash contact:

Material: Nitrile rubber.

Minimum layer thickness: 0,11 mm.

8.3 Environmental exposure controls

See section 6.

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Section 9 Physical and Chemical Properties

Appearance:

Sample dilution buffer (SAM DIL): Lyophilized pellet. Lyophilized pellet. Biotinylated Mab anti-TK1 (BIOT TK):

Reagent buffer (REAG BUF): Clear liquid.

Streptavidin-HRP conjugate (STREP HRP): Clear liquid. Calibrators (CAL A -E): Lyophilized pellets.

Controls (CTRL I and CTRL II): Lyophilized pellets. Wash buffer tablets (WASH): solid tablets.

TMB substrate solution (SUB): Clear to faint blue liquid.

Stop solution (STOP): Clear liquid.

Odor: No data available. No data available.

Odor Threshold:

:Ha

Oxidizing properties:

Sample dilution buffer (SAM DIL): 8.2

Biotinylated anti-TK1 reagent (BIOT TK): No data available.

7.4 Reagent buffer (REAG BUF): 7.4 Streptavidin-HRP conjugate (STREP HRP):

Calibrators (CAL A -E): No data available. Controls (CTRL I and CTRL II): No data available.

Wash buffer tablets (WASH): 7.4

TMB Substrate solution (SUB): No data available. No data available. Stop solution (STOP):

Melting point/Freezing Point: No data available. **Boiling Point/Boiling range:** No data available. **Flash Point:** No data available. **Evaporation rate:** No data available.

Flammability (Solid, Gas): Not applicable. Upper/lower flammability or explosion limits: No data available. **Vapor Pressure:** No data available.

Vapor Density: No data available. Relative density: No data available. No data available. Solubility Partition coefficient of Water/Oil: No data available. **Auto-ignition Temp.:** No data available.

Decomposition Temp.: No data available. No data available. **Viscosity: Explosive properties:** No data available.

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No data available.

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Section 10 Stability and reactivity

10.1 Reactivity

No data available.

10.2 Stability

Stable under normal temperatures and pressures.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

No data available.

10.6. Hazardous decomposition products

No decomposition products posing significant hazards would be expected from this product. For hazardous decomposition products in case of fire or extreme heat see section 5.2.

Section 11 Toxicological Information

11.1. Information on toxicological effects

Acute Toxicity :No data available.Skin corrosion and irritation:No data available.Serious eye damage/irritation:No data available.Respiratory or skin sensitization:No data available.Germ cell mutagenicity:No data available.

Carcinogenicity:

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

Reproductive toxicity:

Specific target organ toxicity - single exposure:

No data available.

Primary routes of exposure:

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Additional Information:

This product contains materials of human source and animal origin and should be considered

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potentially infectious.

Section 12 Ecological Information

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.

12.3. Bio accumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6 Other Adverse Effects

No information available.

12.7 Additional information

No information available.

Section 13 Disposable Considerations

13.1. Waste treatment methods.

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

Section 14 Transport regulations

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	UN number	Transport hazard class	PG	UN Proper shipping name	Environmental hazard
IATA	N/A	N/A	N/A	N/A	N/A
ADR/RID	N/A	N/A	N/A	N/A	N/A
IMDG	N/A	N/A	N/A	N/A	N/A

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Section 15 Regulatory Information

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Not applicable.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out for this mixture by the supplier.

Section 16 Other Information

Indications of changes.

Composition change, calibrator F is removed. EU Directive 89/686/EEC replaced by EU Regulation 2016/425, effective from 21st April 2016.

Further information.

The above mentioned information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to the appropriate safety precautions. It does not represent any guarantee of the properties of this product. Eagle Biosciences, Inc. shall not be held liable for any damage resulting from handling or contact with the product. The burden of safe use of these materials rests solely with the user.

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