

Progesterone LIA Kit (CAN-P-6050)

1. Data on Components

Regarding components in the kit, the following products are defined as hazardous chemicals according to the Directive 67/548/EEC.

Accordingly, Material Safety Data Sheets for the following chemicals are enclosed:

2-Methyl-2H-isothiazol-3-one: At a final concentration from 0.001-0.05% is used as a preservative in the following components of the kit: *Calibrators and Control, HRP Conjugate Concentrate, Assay Buffer, LIA Substrate Reagent C and Wash Buffer Concentrate.*

LIA Substrate Reagent A: Contains two proprietary ingredients, both measured 3%-5% by weight.

LIA Substrate Reagent B: Contains hydrogen peroxide ($\leq 0.03\%$).

2. General Information

The information contained in this document is believed to be correct, however, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Section 1 - Identification of Substance

Product Identification:

Progesterone LIA Kit (CAN-P-6050)

Calibrators and Control

HRP Conjugate Concentrate

Assay Buffer

LIA Substrate Reagent C


Wash Buffer Concentrate

Further Information Obtainable From: Quality Management Representative (QMR).

Section 2 - Data on Components

Chemical Characterization: Preparation

Description: Mixture of substances listed below with nonhazardous additions.

Hazardous Ingredients	%	CAS Number	EC Number
2-Methyl-2H-isothiazol-3-one	0.001-0.05%	2682-20-4	220-239-6
			C; R34-R43

Section 3 - Hazard Identification

Hazard Description: C Corrosive

Information concerning to particular hazards to man and environment: Irritating to eyes and skin. May cause sensitization by skin contact.

Classification System: The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

Section 4 - First Aid Measures

General Information: No special measures required.

After Inhalation: Supply fresh air; consult doctor in case of complaints.

After Skin Contact: Wash off with soap and plenty of water.

After Eye Contact: Rinse opened eye for several minutes under running water.

After Ingestion: If symptoms persist consult doctor.

Section 5 - Fire Fighting Measures

Suitable Extinguishing Agents: CO₂ powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Protective Equipment: No special measures required.

Section 6 - Accidental Release Measures

Person-Related Safety Precautions: Not required.

Measures for Environmental Protection: Dilute with plenty of water. Do not allow to enter sewers / surface or ground water.

Measures for Cleaning/Collecting: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Additional Information: No dangerous substances are released.

Section 7 - Handling and Storage

Handling:

Information for Safe Handling: Avoid contact with skin and eyes.

Information for Fire and Explosion Protection: No special measures required.

Storage:

Requirements to be met by Storerooms and Receptacles: No special requirements.

Information About Storage in One Common Storage Facility: Not required.

Further Information About Storage Conditions: None.

Storage Class:

Class According to Regulation on Flammable Liquids: Void.

Section 8 - Exposure Controls and Personal Protection Gear

Additional Information About Design of Technical Facilities: No further data; see item 7.

Ingredients with Limit Values that Require Monitoring at the Workplace: The products does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional Information: The lists valid during the making were used as the basis.

Personal Protective Equipment:

General Protective and Hygienic Measures: The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory Protection: Not required.

Protection of Hands: Protective gloves.

Eye Protection: Goggles recommended during refilling.

Section 9 - Physical and Chemical Properties

Form: Liquid

Colour: Colourless

Odour: Odourless

Change in Condition

Melting Point/Melting Range: Undetermined

Boiling Point/Boiling Range: Undetermined

Flash Point: Not applicable

Self-Igniting: Product is not self-igniting.

Danger of Explosion: Product does not present an explosion hazard

Density: Undetermined

Solubility in/Miscibility With: Water: Fully miscible

pH value at 20°C: Undetermined

Section 10 – Stability and Reactivity

Thermal Decomposition: No decomposition if used according to specifications.

Dangerous Reaction: No dangerous reactions known.

Dangerous Decomposition Products: No dangerous decomposition products known.

Section 11 - Toxicological Information

Acute Toxicity

Primary Irritant Effect:

On the Skin: No irritant effect.

On the Eye: No irritant effect.

Sensitization: No sensitizing effects known.

Additional Toxicological Information: The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

Section 12 - Ecological Information

General Notes: Generally not hazardous for water.

Section 13 - Disposal Considerations

Product:

Recommendation: Smaller quantities can be disposed of with household water.

Uncleaned Packaging:

Recommended Cleansing Agents: Water, if necessary together with cleansing agents.

Section 14 - Transport Information

Special Shipping Information: Does not constitute a hazard.

Section 15 - Regulations

Labelling According to European Labelling Guidelines: Observe the general safety regulations when handling chemicals. The product is not subject to identification regulations under EC Directives.

Section 16 - Other Information

Text of R phrases listed in section 2:

R 34 - Causes burns.

R 43 – May cause sensitization by skin contact.

This information is prepared based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Section 1- Identification of Substance

Product Identification:

Progesterone LIA Kit (CAN-P-6050)

LIA Substrate Reagent A

Further Information Obtainable From: Quality Management Representative (QMR).

Section 2 - Data on Components

Chemical Characterization: Preparation

Description: Mixture of proprietary ingredients.

Hazardous Ingredients: Void.

Section 3 - Hazard Identification

Hazard Description: This product contains two proprietary ingredients, both measured 3%-5% by weight, that contain materials which may cause birth defects based on animal data.

Information concerning to particular hazards to man and environment: Teratogenic effects are not available for humans. This product contains materials which may cause damage to the following organs: kidneys, central nervous system, liver, reproductive system, skin and eyes.

Classification System: The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

Section 4 - First Aid Measures

General Information: Remove contaminated clothing and shoes, and wash before reuse.

After Inhalation: Remove the exposed person to fresh air and support breathing, if necessary. If not breathing, administer CPR. Obtain medical attention.

After Skin Contact: Remove contaminated clothing and wash effected skin with soap and water. Seek medical attention if irritation is noted.

After Eye Contact: Immediately flush eyes thoroughly with fresh water or eyewash saline for at least 15 minutes.

After Ingestion: DO NOT induce vomiting. If conscious, give plenty of water and seek medical attention immediately.

Section 5 - Fire Fighting Measures

Suitable Extinguishing Agents: CO₂ powder, water spray, dry chemical powder or appropriate foam can all be used.

Protective Equipment: Use self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

Person-Related Safety Precautions: Wear suitable protective equipment to prevent inhalation and skin or eye contact.

Measures for Environmental Protection: No special measures required.

Measures for Cleaning/Collecting: Absorb with inert material and place spilled material in appropriate waste container. If necessary, neutralize residue with a dilute solution of acetic acid.

Additional Information: Observe all national, state, and local environmental regulations.

Section 7 - Handling and Storage

Handling:

Information for Safe Handling: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Keep container tightly closed. Avoid contact with eyes, skin and clothing. Avoid ingestion and inhalation.

Information for Fire and Explosion Protection: No special measures required.

Storage:

Requirements to be met by Storerooms and Receptacles: Store refrigerated ($-4-8^{\circ}\text{C}$) in a dry, well-ventilated area away from incompatible substances (see section 10). Protect from exposure to sunlight.

Information About Storage in One Common Storage Facility: Not required.

Further Information About Storage Conditions: None.

Storage Class:

Class According to Regulation on Flammable Liquids: Void.

Section 8 - Exposure Controls and Personal Protection Gear

Additional Information About Design of Technical Facilities: No further data; see item 7.

Ingredients with Limit Values that Require Monitoring at the Workplace: The products does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional Information: The lists valid during the making were used as the basis.

Personal Protective Equipment:

General Protective and Hygienic Measures: The usual precautionary measures are to be adhered to when handling chemicals. Avoid contact with eyes and skin.

Respiratory Protection: Not required.

Protection of Hands: Protective gloves.

Eye Protection: Goggles recommended during refilling.

Section 9 - Physical and Chemical Properties

Form: Liquid solution

Colour: Clear, Colourless

Odour: Odourless

Change in Condition

Melting Point/Melting Range: No data available

Boiling Point/Boiling Range: No data available

Flash Point: No data available

Self-Igniting: Product is not self-igniting.

Danger of Explosion: Product does not present an explosion hazard.

Density: 1 ($\text{H}_2\text{O}=1.0$)

Solubility in/Miscibility With: Water: Fully miscible.

pH value at 20°C: Undetermined

Section 10 – Stability and Reactivity

Thermal Decomposition: N/A

Incompatibilities: Avoid contact with oxidizing agents, combustible materials, organic materials, acids, alkalis and metals.

Protect from exposure to sunlight.

Dangerous Decomposition Products: N/A

Section 11 - Toxicological Information

Acute Toxicity

Primary Irritant Effect:

On the Skin: Irritant to mucous membranes.

On the Eye: Irritant.

Sensitization: No sensitizing effects known.

Additional Toxicological Information: The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

Toxicity to Animals: Acute Oral (LD50): 1650 mg/kg (cat)

Acute Dermal (LD50): 9530 mg/kg (rabbit)

Chronic Effects on Humans: Carcinogenic Effects: Classified None by NIOSH.

Developmental Toxicity: Contains materials which may cause damage to the following organ:

reproductive system (based on animal data).

Other Toxic Effects on Humans: Slightly hazardous in case of eye contact (irritant).

Section 12 - Ecological Information

General Notes: Slightly hazardous for water. Do not allow product to reach ground water, water course or sewage system. Must not reach sewage water or drainage ditch undiluted.

Section 13 - Disposal Considerations

Product:

Recommendation: Smaller quantities can be disposed of with household water.

Uncleaned Packaging:

Recommended Cleansing Agents: Water, if necessary together with cleansing agents.

Section 14 - Transport Information

Special Shipping Information: Does not constitute a hazard.

Section 15 - Regulations

Labelling According to European Labelling Guidelines: Observe the general safety regulations when handling chemicals. The product is not subject to identification regulations under EC Directives.

Safety Phrases:

S 60 – This material and its container must be disposed of as hazardous waste.

Section 16 - Other Information

This information is prepared based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Prepared By: QA Department (QMR)

Contact: Mr. Ian Higgins

Section 1- Identification of Substance

Product Identification:

Progesterone LIA Kit (CAN-P-6050)

LIA Substrate Reagent B

Further Information Obtainable From: Quality Management Representative (QMR).

Section 2 - Data on Components

Chemical Characterization: Preparation

Description: Mixture of proprietary ingredients.

Hazardous Ingredients: Void.

Section 3 - Hazard Identification

Hazard Description: This product does not contain any hazardous materials.

Information concerning to particular hazards to man and environment: Materials and mixtures may present unknown hazards and should be used by workers technically qualified to handle potentially hazardous chemicals.

Classification System: The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

Section 4 - First Aid Measures

General Information: Remove contaminated clothing and shoes, and wash before reuse.

After Inhalation: Remove the exposed person to fresh air and support breathing, if necessary. If not breathing, administer CPR. Obtain medical attention.

After Skin Contact: Remove contaminated clothing and wash effected skin with soap and water. Seek medical attention if irritation is noted.

After Eye Contact: Immediately flush eyes thoroughly with fresh water or eyewash saline for at least 15 minutes.

After Ingestion: Induce vomiting and seek medical attention immediately.

Section 5 - Fire Fighting Measures

Suitable Extinguishing Agents: CO₂ powder, water spray, dry chemical powder or appropriate foam can all be used.

Protective Equipment: Use self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

Person-Related Safety Precautions: Wear suitable protective equipment to prevent inhalation and skin or eye contact.

Measures for Environmental Protection: No special measures required.

Measures for Cleaning/Collecting: Cover with absorbent. Dispose of with copious amounts of water.

Additional Information: Observe all national, state, and local environmental regulations.

Section 7 - Handling and Storage

Handling:

Information for Safe Handling: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Keep container tightly closed. Avoid contact with eyes, skin and clothing. Avoid ingestion and inhalation.

Information for Fire and Explosion Protection: No special measures required.

Storage:

Requirements to be met by Storerooms and Receptacles: Store refrigerated (-4-8°C) in a dry, well-ventilated area away from incompatible substances (see section 10). Protect from exposure to sunlight.

Information About Storage in One Common Storage Facility: Not required.

Further Information About Storage Conditions: None.

Storage Class:

Class According to Regulation on Flammable Liquids: Void.

Section 8 - Exposure Controls and Personal Protection Gear

Additional Information About Design of Technical Facilities: No further data; see item 7.

Ingredients with Limit Values that Require Monitoring at the Workplace: The products does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional Information: The lists valid during the making were used as the basis.

Personal Protective Equipment:

General Protective and Hygienic Measures: The usual precautionary measures are to be adhered to when handling chemicals. Avoid contact with eyes and skin.

Respiratory Protection: Not required.

Protection of Hands: Protective gloves.

Eye Protection: Goggles recommended during refilling.

Section 9 - Physical and Chemical Properties

Form: Liquid solution

Colour: Clear, Colourless

Odour: Odourless

Change in Condition

Melting Point/Melting Range: No data available

Boiling Point/Boiling Range: No data available

Flash Point: No data available

Self-Igniting: Product is not self-igniting.

Danger of Explosion: Product does not present an explosion hazard.

Density: 1 (H₂O=1.0)

Solubility in/Miscibility With: Water: Fully miscible.

pH value at 20°C: Undetermined

Section 10 – Stability and Reactivity

Thermal Decomposition: N/A

Incompatibilities: Avoid contact with oxidizing agents, acids, alkalis and metals.

Protect from exposure to sunlight.

Dangerous Decomposition Products: N/A

Section 11 - Toxicological Information

Acute Toxicity

Primary Irritant Effect:

On the Skin: Irritant to mucous membranes.

On the Eye: Irritant.

Sensitization: No sensitizing effects known.

Additional Toxicological Information: The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

Section 12 - Ecological Information

General Notes: Slightly hazardous for water. Do not allow product to reach ground water, water course or sewage system. Must not reach sewage water or drainage ditch undiluted.

Section 13 - Disposal Considerations

Product:

Recommendation: Smaller quantities can be disposed of with household water.

Uncleaned Packaging:

Recommended Cleansing Agents: Water, if necessary together with cleansing agents.

Section 14 - Transport Information

Special Shipping Information: Does not constitute a hazard.

Section 15 - Regulations

Labelling According to European Labelling Guidelines: Observe the general safety regulations when handling chemicals. The product is not subject to identification regulations under EC Directives.

Safety Phrases: -

Section 16 - Other Information

This information is prepared based on our present knowledge. However, this shall not constitute a guarantee for any specific product

features and shall not establish a legally valid contractual relationship.

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