

Material Safety Data Sheet

Testosterone Saliva ELISA

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, Testosterone-Biotin Conjugate Concentrate, Streptavidin-HRP Conjugate Concentrate, Biotin Conjugate Buffer, HRP Conjugate Buffer and Wash Buffer Concentrate.*

Sulfuric Acid: At a final concentration of 5% (v/v) is used in the *Stopping Solution.*

TMB Substrate

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. Diagnostic Automation, Inc. shall not be liable for any damages resulting from handling or from contact with the above products.

Section 1- Identification of Substance

Catalog No: 7095-38
 Synonyms: N/A
 Intended Use: Laboratory Use

*Calibrators and Control
 Testosterone-Biotin Conjugate Concentrate
 Streptavidin-HRP Conjugate Concentrate
 Biotin Conjugate Buffer
 HRP Conjugate Buffer
 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

Labeling According to European Labeling 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

Catalog No: 9095-38
 Synonyms: N/A
 Intended Use: Laboratory Use


Stopping Solution

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
Sulfuric Acid	5%	7664-93-9	N/A
			C; R35

Section 3 - Hazard Identification

Hazard Description: C Corrosive

Information concerning to particular hazards to man and environment: Causes burns.

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: Immediately remove any clothing contaminated by the product.

After Inhalation: In case of unconsciousness place patient stably in side position for transportation.

After Skin Contact: Immediately wash with water and soap and rinse thoroughly.

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

After Ingestion: Do not induce vomiting. Drink plenty of water and provide fresh air. Call for a doctor immediately.

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: Wear protective equipment. Keep unprotected persons away.

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

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

Use neutralizing agent. Dispose contaminated material as waste according to section 13. Ensure adequate ventilation.



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: No special requirements.

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

Further Information About Storage Conditions: Keep receptacle tightly sealed.

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 and resistant gloves.

Eye Protection: Tightly sealed goggles.

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: <1

Section 10 – Stability and Reactivity

Thermal Decomposition/Conditions to be Avoided: No decomposition if used according to specifications.

Dangerous Reaction: No dangerous reactions known.

Incompatibilities (Concentrated Sulfuric Acid): Avoid contact with alkaline solutions, metals, metal powders, chlorates, nitrates, strong oxidizing or reducing materials, combustible organic materials and excess heat.

Dangerous Decomposition Products (Concentrated Sulfuric Acid): Toxic fumes of oxides of sulfur when heated to decomposition. Will react with water or steam to produce toxic and corrosive fumes. Reacts with carbonates to generate carbon dioxide gas, and with cyanides and sulfides to form poisonous hydrogen cyanide and hydrogen sulfide, respectively.

Section 11 - Toxicological Information

Acute Toxicity

Primary Irritant Effect:

On the Skin: Caustic effect on skin and mucous membranes.

On the Eye: Strong caustic effect.

Sensitization: No sensitizing effects known.

Additional Toxicological Information: The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version: Corrosive.



Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

Section 12 - Ecological Information

General Notes: 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 or unneutralized. Danger to drinking water even if small quantities leak into the ground.

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 has been classified and marked according to EC Directives.

Code Letter and Hazard Designation of Product: C Corrosive

Risk Phrases:

R 34 – Causes burns.

Safety Phrases:

S 26 – In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 36/37/39 – Wear suitable protective clothing, gloves and eye/face protection.

S 45 – In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

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.

Section 1- Identification of Substance

Catalog No: 9095-38
 Synonyms: N/A
 Intended Use: Laboratory Use

TMB Substrate

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: Void.

Section 3 - Hazard Identification

Hazard Description: N/A
Information concerning to particular hazards to man and environment: N/A
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: Immediately remove any clothing contaminated by the product.
After Inhalation: Remove the exposed person to fresh air and support breathing, if necessary. 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. Remove contact lenses, if any, and seek medical attention.
After Ingestion: Wash out mouth immediately provided that person is conscious. Obtain medical attention.

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: 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: Clean up small spills with a sponge or mop and water. Larger volumes can be absorbed with sand or vermiculite.
Additional Information: N/A



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

Colour: Colourless

Odour: Odourless

Change in Condition

Melting Point/Melting Range: N/A

Boiling Point/Boiling Range: 81°C

Flash Point: 187°F (Closed cup)

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: During heating, carbon monoxide and nitrogen oxides may be produced.

Incompatibilities: Avoid contact with strong oxidizing agents. Protect from exposure to sunlight.

Dangerous Decomposition Products: Toxic fumes of oxides of carbon monoxide and nitrogen oxide.

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

Labeling According to European Labeling 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.

Quality Control

Diagnostic Automation/Cortez Diagnostics INC.

DAI code # 7095-38

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