


YO Home Sperm Test- SAFETY DATA SHEET

YO Home Sperm Test is a kit intended for at home semen analysis, In Vitro use only.

The kit contains the following material which are subject to SDS requirements: Eosin Y Disodium salt and Chymotrypsin. The YO device itself and other accessories included in the kit are exempt from SDS requirements.

| Section 1: Identification | |
|---|--|
| Product identifier | YO Home Sperm Test Kit |
| Product number | YO-FA-01633-00, YO-FA-01634-00, YO-FA-01635-00, YO-FA-01315-00, YO-FA-01374-00 |
| Manufacturer/supplier | Medical Electronic Systems 5757 West Century Blvd. Suite #805, Los Angeles, CA 90045 Tel: 310 670-9066 Fax: 310 670-9069 Web: www.mes-global.com |
| Recommended use | The following components which are included in the YO Home Sperm Test Kit are subjected to SDS requirements: <ul style="list-style-type: none"> Eosin Y Disodium salt (G-CA-01735-00) is used as a reagent (dye) which allows visualization of the slide filling. For in-vitro use only. Chymotrypsin (G-CA-00304-00) is used to accelerate the liquefaction of viscous semen samples in order to prepare them for automated or manual semen analysis. For in-vitro use only. |
| Section 2: Hazard Identification | |
| Classification of the substance or mixture | <ul style="list-style-type: none"> Eosin Y Disodium salt: Classification according to Regulation (EC) No 1272/2008 This salt is not classified as dangerous and is not a hazardous substance or mixture. Chymotrypsin: Classification according to Regulation (EC) No 1272/2008 Eye irritation: (Category 2), H319 Specific target organ toxicity - single exposure: (Category 3), H335 Skin irritation: (Category 2), H315 Respiratory sensitization: (Category 1), H334 For the full text of the H-Statements mentioned in this Section, see Section 12. |
| Label elements | <ul style="list-style-type: none"> Eosin Y Disodium salt: The product does not need to be labeled in accordance with EC directives or respective national laws. Chymotrypsin: Labeling according Regulation (EC) No 1272/2008  Pictogram Signal word: Danger Hazard statement(s) H315 Causes skin irritation. H319 Causes serious eye irritation. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 May cause respiratory irritation. Precautionary statement(s) P261 Avoid breathing dust. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician. Supplemental Hazard Statements: none |

| | |
|---------------|------|
| Other hazards | None |
|---------------|------|

Section 3: Composition/Information of Ingredients

| Mixtures | <ul style="list-style-type: none"> Eosin Y Disodium salt: (Sigma-Aldrich, catalog # 119830-25g, CAS # 17372-87-1) - 0.5% Chymotrypsin: | | | | | | |
|---|---|----------------|----------------|-----------------------------------|-----------------------------------|--|--------|
| | <p>Hazardous ingredients according to Regulation (EC) No 1272/2008</p> | | | | | | |
| | <table border="1"> <thead> <tr> <th>Component</th> <th>Classification</th> <th>Concentration</th> </tr> </thead> <tbody> <tr> <td>Chymotrypsin CAS-No. 9004-07-3</td> <td>Skin Irrit. 2; Eye Irrit. 2; Resp. Sens. 1; STOT SE 3; H315, H319, H334, H335</td> <td><=100%</td> </tr> </tbody> </table> | Component | Classification | Concentration | Chymotrypsin CAS-No. 9004-07-3 | Skin Irrit. 2; Eye Irrit. 2; Resp. Sens. 1; STOT SE 3; H315, H319, H334, H335 | <=100% |
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Section 4: First-Aid Measures

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance.
Inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
Eyes: Flush eyes immediately with copious amounts of water. Seek medical attention if symptoms occur.
Skin: Wash with soap and water after each contact. Seek medical attention if symptoms occur.
Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Most important symptoms and effects, both acute and delayed: Described in the labeling (see Section 2) and/or in section 11.

Section 5: Fire-Fighting Measures

- Eosin Y Disodium salt:
Extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special hazards arising from the substance or mixture: Carbon oxides, hydrogen bromide gas.
Advice for firefighters: Wear self contained breathing apparatus for fire-fighting if necessary.
- Chymotrypsin:
Extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special hazards arising from the substance or mixture: No data available.
Advice for firefighters: Wear self contained breathing apparatus for fire-fighting if necessary.

Section 6: Accidental Release Measures

- Eosin Y Disodium salt:
Personal precautions, protective equipment and emergency procedures: Avoid breathing vapors, mist or gas. For personal protection see section 8.
Environmental precautions: Do not let product enter drains.
Methods and materials for containment and cleaning up: Sweep up and shovel. Keep in suitable, closed containers for disposal.
- Chymotrypsin:
Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid breathing dust. Ensure adequate ventilation. For personal protection see section 8.
Environmental precautions: Use and dispose of without creating dust. Do not let product enter drains. Avoid discharging material into the environment.
Methods and materials for containment and cleaning up: Use and dispose of without creating dust. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

- Eosin Y Disodium salt:

Precautions for safe handling: Appropriate exhaust ventilation. Normal measures for preventive fire protection. For precautions see section 2.

Conditions for safe storage, including any incompatibilities: Store at room temperature. Keep containers tightly closed in a dry and well-ventilated place. Stable and show no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20°C to +37°C.

- Chymotrypsin:

Precautions for safe handling: Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.

Conditions for safe storage, including any incompatibilities: Store at room temperature. Keep containers tightly closed in a dry and well-ventilated place. Stable and show no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20°C to +37°C.

Section 8: Exposure Controls/ Personal Protection

- Eosin Y Disodium salt:

Exposure controls: General industrial hygiene practice.

Personal protective equipment:

Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards (NIOSH (US) or EN 166(EU)).

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 Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection: Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection: Respiratory protection is not required.

Control of environmental exposure: Do not let product enter drains.

- Chymotrypsin:

Exposure controls: Appropriate engineering controls. Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment:

Eye/face protection: Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

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 Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection: Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection: For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure: Do not let product enter drains. Discharge into the environment must be avoided.

Section 9: Physical and Chemical Properties

- Eosin Y Disodium salt:

Information on basic physical and chemical properties

- Appearance Form: liquid
- Odor/Odor Threshold: no data available
- pH: no data available
- Melting point/freezing point: no data available
- Initial boiling point and boiling range: no data available
- Flash point: no data available
- Evaporation rate: no data available
- Flammability (solid, gas): no data available
- Upper/lower flammability or explosive limits: no data available
- Vapor pressure/density: no data available
- Relative density: no data available
- Water solubility: no data available
- Partition coefficient: n-octanol/water: no data available
- Auto-ignition temperature: no data available
- Decomposition temperature: no data available
- Viscosity: no data available
- Explosive properties: no data available
- Oxidizing properties: no data available

- Chymotrypsin:

Information on basic physical and chemical properties

- Appearance Form: powder, lyophilized
- Odor/Odor Threshold: no data available
- pH: no data available
- Melting point/freezing point: no data available
- Initial boiling point and boiling range: no data available
- Flash point: no data available
- Evaporation rate: no data available
- Flammability (solid, gas): no data available
- Upper/lower flammability or explosive limits: no data available
- Vapor pressure/density: no data available
- Relative density: no data available
- Water solubility: no data available
- Partition coefficient: n-octanol/water: no data available
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- Viscosity: no data available
- Explosive properties: no data available
- Oxidizing properties: no data available

Section 10: Stability and Reactivity

Reactivity: no data available
Chemical stability: stable under recommended storage conditions.
Possibility of hazardous reactions: no data available
Conditions to avoid: no data available
Incompatible materials: strong oxidizing agents
Hazardous decomposition products: no data available
Other decomposition products: no data available
In the event of fire: see Section 5

Section 11: Toxicological Information

- Eosin Y Disodium salt:

Information on toxicological effects

Acute toxicity: no data available

Skin corrosion/irritation: no data available

Serious eye damage/eye irritation: no data available

Respiratory or skin sensitization: no data available

Germ cell mutagenicity: no data available

Carcinogenicity IARC: No component of this product present at levels $\geq 0.1\%$ is identified as probable, possible or a confirmed human carcinogen by IARC.

Reproductive toxicity: no data available

Specific target organ toxicity - single exposure: no data available

Specific target organ toxicity - repeated exposure: no data available

Aspiration hazard: no data available

Additional Information: RTECS: LM5800000

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

- Chymotrypsin:

Information on toxicological effects

Acute toxicity: LD50

Oral - rat: > 4.000 mg/kg

Inhalation: no data available

Skin corrosion/irritation: no data available

Serious eye damage/eye irritation: no data available

Respiratory or skin sensitization: no data available

Germ cell mutagenicity: no data available

Carcinogenicity 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.

Reproductive toxicity: no data available

Specific target organ toxicity - single exposure: may cause respiratory irritation.

Specific target organ toxicity - repeated exposure: no data available

Aspiration hazard: no data available

Additional Information: RTECS: GC3050000

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

Section 12: Ecological information

Toxicity: no data available

Persistence and degradability: no data available

Bioaccumulative potential: no data available

Mobility in soil: no data available

Results of PBT and vPvB assessment: PBT/vPvB assessment not available as chemical safety assessment not required/ not conducted

Other adverse effects: no data available

Section 13: Disposal considerations

- Eosin Y Disodium salt:

According to applicable regulations for aqueous, physiological salt solutions, i.e., open container and flush contents with tap water via a drain into the sewage system according to local community, state or federal regulations.

- Chymotrypsin:

Waste treatment methods Product Offer surplus and non-recyclable solutions to a licensed disposal company.

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging Dispose of as unused product.

Section 14: Transport information

UN number:

- ADR/RID: -
- IMDG: -
- IATA: -

UN proper shipping name

- ADR/RID: Not dangerous goods
- IMDG: Not dangerous goods
- IATA: Not dangerous goods

Transport hazard class(es)

- ADR/RID: -
- IMDG: -
- IATA: -

Packaging group

- ADR/RID: -
- IMDG: -
- IATA: -

Environmental hazards

- ADR/RID: no
- IMDG Marine pollutant: no
- IATA: no

Special precautions for user: no data available

Section 15: Regulatory information

This product complies with regulations:

CE: IVD 98\79\EC

FDA: K161493

Health Canada: # 98797

Section 16: Additional Comments

NA

All information presented above is correct to the best of our knowledge and Medical Electronic Systems does not claim that the information is all-inclusive but recommends that it should be used as a guide. Medical Electronic Systems shall not be held liable for any damage resulting from handling or from contact with the product.