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### SAFETY DATA SHEET

acc. to ISO 11014, 29 CFR 1910.1200

# VACUETTE® FE Glucose Test Sodium Fluoride / K3EDTA

greiner bio-one

A AN SOP 04.03.02-065 Rev.01 Valid from: Sept 12, 2016

# SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name: VACUETTE<sup>®</sup> FE Glucose Test Sodium Fluoride / K3EDTA

Manufacturer/Supplier:

**AUSTRIA** 

Greiner Bio-One GmbH Bad Haller Strasse 32 4550 Kremsmünster

Austria

Tel: (+43) 7583 6791-0 Fax: (+43) 7583 114 Email: office@at.gbo.com

Emergency phone number: (+43) 7583 6791-0

**USA** 

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4238 Capital Drive Monroe, NC 28110

USA

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**BRASIL** 

Greiner Bio-One Brasil Produtos Médicos Hospitalares Ltda. Av. Affonso Pansan no. 1.967 13473-620 Vila Bertini Americana, São Paulo - Brasil

Tel: +55 (19) 3468-9600 Fax: +55 (19) 3468-9601 Email: info@br.gbo.com

Emergency phone number: (+55) 19 3468-9600

· Recommended use / restrictions of use :

To collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory. To be used only by trained healthcare professionals according to instructions of use.

# **SECTION 2: HAZARDS IDENTIFICATION**

• Classification according to NFPA 704 (Possible Rating 0-4):

K3EDTA:

Health Rating: 1 Flammability Rating: 1 Reactivity Rating: 0

Sodium Fluoride: Health Rating: 3 Flammability Rating: 0 Reactivity Rating: 0





Classification according to Regulation (EC) No. 1272/2008 [EU-GHS/CLP]:

K3EDTA:

Skin irritation: Category 2
Eye irritation: Category 2A
Acute toxicity: Category 4 (Oral)

Specific target organ toxicity: Category 3 (Respiratory tract irritation)

Sodium Fluoride:

Acute Toxicity: Category 3 (Oral)

Eye Irritation: Category 2 Skin irritation: Category 2



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# Classification according to EU Directives 67/548/EEC or 1999/45/EC:

K3EDTA: Irritating to eyes, respiratory system and skin

Sodium Fluoride: Toxic if swallowed, contact with acids liberates very toxic gas, irritating to eyes and

skin

**Signal Word:** 

K3EDTA: Warning Sodium Fluoride: Danger



## **Hazard Statements:**

K3EDTA:

H315 Causes Skin irritation

**H319** Causes serious eye irritation

**H335** May cause respiratory irritation

Sodium Fluoride:

H301 Toxic if swallowed

**H315** Causes Skin irritation

H319 Causes serious eye irritation

# **Precautionary Statements:**

K3EDTA:

Avoid breathing dust/fume/gas/mist/vapors/spray

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Sodium Fluoride:

P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

#### **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical name: Ethylendiaminetetraacetic Acid Tripotassium Dihydrate K3EDTA

Sodium Fluoride

CAS No. Ethylendiaminetetraacetic Acid Tripotassium Dihydrate K3EDTA 65501-24-8

Sodium Fluoride 7691-49-4

**Quantity of substances:** < 1%

Because of trade secrets, not all components and their percentages are listed.

#### **SECTION 4: FIRST AID MEASURES**

Hazard description: Contact causes eye and skin irritation and may cause burns. May cause severe irritation of the respiratory tract with possible burns. Aspiration may lead to pulmonary edema. Prolonged exposure to dusts or vapors may result in perforation of the nasal septum. Ingestion is harmful and may be fatal. Symptoms may include salivation, nausea, vomiting, abdominal pain, fever and labored breathing. May cause respiratory paralysis and cardiac arrest. May cause systemic effects on heart, liver and kidneys.

Repeated exposure can also lead to fluoride poisoning (fluorosis) characterized by weight loss, weakness, anemia, brittle bones, and stiff joints. Skeletal effects may include increased bone density, calcium deposits in ligaments, and mottled tooth enamel. May cause developmental and fetal effects, which may be delayed. Animal studies have reported development of tumors. Avoid contact with skin and eyes. Do not inhale or swallow.

Primary route of entry: Dermal, eyes, inhalation, and ingestion.



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# Health effects:

# Acute exposure effect:

Skin: Causes severe irritation. May cause rash and cold, clammy skin with bluish or pale color (milder cases). May cause burns, especially if skin is wet or moist.

Eyes: Causes severe irritation and may cause burns. May cause chemical conjunctivitis and eye damage.

Inhalation: May cause severe irritation of the respiratory tract and may cause burns.

Ingestion: Harmful if swallowed and may be fatal. Symptoms may include salivation, nausea, vomiting, abdominal pain, fever and labored breathing. May cause respiratory paralysis and cardiac arrest.

# **Repeated Exposure Effects:**

Repeated ingestion may cause systemic effects on heart, liver and kidneys. Repeated ingestion may also result in depleted calcium levels in the body leading to hypocalcemia and death. Chronic inhalation and ingestion can also lead to fluoride poisoning (fluorosis) characterized by weight loss, weakness, anemia, brittle bones, and stiff joints. Skeletal effects may include increased bone density, calcium deposits in ligaments, and mottled tooth enamel. May cause developmental and fetal effects, which may be delayed. Animal studies have reported development of tumors.

# Medical conditions which might be aggravated:

Pre-existing diabetes insipidus or renal impairment.

• Skin: Wash with soap and copious amounts of water. Remove contaminated clothing. Wash

clothing and thoroughly clean shoes before reuse. Get medical attention.

Eyes: Flush eyes with copious amounts of water for at least 15 minutes. Get medical

attention.

• **Inhalation:** Remove to fresh air. If breathing is difficult, give oxygen.

• Ingestion: Victim should drink copious amounts of water to dilute. Get medical attention.

# **SECTION 5: FIRE-FIGHTING MEASURES**

- Personal precautions: Avoid overexposure. Wear suitable protective clothing.
- Methods for cleaning up: Carefully sweep up and remove.
- Methods of containment: Dispose as of hazardous waste. Keep in suitable, closed containers for disposal
- **Emergency procedures:** Wear respiratory protection. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

# **SECTION 6: ACCIDENTAL RELEASE MEASURES**

- Personal precautions: Avoid overexposure. Wear suitable protective clothing.
- Methods for cleaning up: Carefully sweep up and remove.
- Methods of containment: Dispose as of hazardous waste. Keep in suitable, closed containers for disposal
- **Emergency procedures:** Wear respiratory protection. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

# **SECTION 7: HANDLING AND STORAGE**

### Handling:

**Advice for safe handling:** Keep container tightly closed. Suitable for any general chemical storage area.

**Information about protection against explosions and fires:** Avoid contact with incompatible material, minimize dust generation and accumulation. Material must be handled with adequate ventilation.

### Storage:

**Requirements to be met by storerooms and receptacles**: Keep container closed when not in use. Store in a cool, dry, well-ventilated area. Store away from incompatible substances.



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**Information about storage in one common storage facility:** Keep container closed when not in use. Do not store in glass. Store in a cool, dry, well-ventilated area. Store protected from moisture. Store away from incompatible substances, such as strong acids and alkalies.

# SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits:

OSHA PEL: Sodium Fluoride: TWA 2.5 mg/m<sup>3</sup> ACGIH TLV: Sodium Fluoride: 2.5 mg/m<sup>3</sup>TWA

Other recommended limits: N/A

- Additional information about design of technical systems: Use general or local exhaust ventilation to reduce exposure.
- Personal protective equipment:

**General protective and hygienic measures:** Wash thoroughly after handling. Remove contaminated and wash before reuse. Avoid contact with eyes, skin and clothing. Avoid ingestion and inhalation. Use with adequate ventilation. Provide eye bath and safety shower.

**Breathing equipment:** None required, where adequate ventilation conditions exist. For conditions where dust is apparent and engineering controls are not feasible, a NIOSH/MSHA approved respirator is recommended. If concentration exceeds capacity of respirator, a self-contained breathing apparatus is recommended.

**Hand protection:** Wear appropriate protective gloves to prevent skin exposure.

Eye protection: Use chemical safety goggles

**Body protection:** Wear appropriate protective clothing to prevent skin exposure.

- Special requirements for PPE: N/A
- Hygiene measures: N/A
- **Appropriate engineering controls:** Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

# SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

General information

Form: Crystalline powder

Color: White Odor: Odorless Odor Threshold: N/A

PH-value: Ethylendiaminetetraacetic Acid Tripotassium Dihydrate K3EDTA: N/A

Sodium Fluoride: 10,2 (4%, 20 °C)

Change in condition

Melting point/Melting range: Ethylendiaminetetraacetic Acid Tripotassium Dihydrate K3EDTA: N/A

Sodium Fluoride: 993 °C

Boiling point/Boiling range: not determined

Flash point: N/A

• Flammability (solid, gaseous): N/A

Danger of explosion: Product does not present an explosion hazard

Vapor pressure: Not determined

Density: Ethylendiaminetetraacetic Acid Tripotassium Dihydrate EDTA K<sub>3</sub>: N/A

Sodium Fluoride: 2,8 g/cm<sup>3</sup>

Solubility in/Miscibility w/H<sub>2</sub>O: Soluble

Organic solvents: N/ASolids content: N/A

Partition coefficient: n-octanol/water: N/A

Auto-ignition temperature: N/A
 Decomposition temperature: N/A

Viscosity: N/A

• Oxidizing properties: N/A



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# **SECTION 10: STABILITY AND REACTIVITY**

- Reactivity: No data available
- Chemical Stability: No data available
- Possibility of hazardous reactions: No data available
- Conditions to avoid: Avoid generation and accumulation of dusts.
- Incompatible materials: Moisture, acids, alkalies, oxidizing agents, and glass.
- **Hazardous decomposition products:** Hydrogen fluoride, sodium oxide. May form under fire conditions: nitrogen oxides (NOx), carbon oxides, potassium oxides

# **SECTION 11: TOXICOLOGICAL INFORMATION**

Acute toxicity (LD 50 oral rat > 200 mg/kg)

Eye: Severely irritating to the eyes.

Skin: Severely irritating to the skin.

Inhalation: Harmful if inhaled and may be fatal.

Ingestion: Toxic if swallowed. May be fatal.

Primary irritant effect:

On the skin: Severely irritating to the skin.
On the eye: Severely irritating to the eyes.

Sensitization: Not established

Additional toxicological information:

**Chronic:** Repeated ingestion may cause systemic effects on heart, liver and kidneys. Repeated ingestion may also result in depleted calcium levels in the body leading to hypocalcemia and death. Chronic inhalation and ingestion can also lead to fluoride poisoning (fluorosis) characterized by weight loss, weakness, anemia, brittle bones, and stiff joints. Skeletal effects may include increased bone density, calcium deposits in ligaments, and mottled tooth enamel. May cause developmental and fetal effects, which may be delayed. Animal studies have reported development of tumors.

# **SECTION 12: ECOLOGICAL INFORMATION**

- **Ecotoxilogical effects:** Unspecified. No data is available on the adverse effects of this material on the environment.
- Other information: The ecological effects have not been thoroughly investigated, but currently none
  have been identified.
- **General notes:** Dangerous to aquatic life in high concentrations. Soil can bind fluorides tightly if pH is greater than 6.5. Fluorides can be damaging to plants when present in acid soils.

# **SECTION 13: DISPOSAL CONSIDERATION**

### • Product: Recommendation

Disposal should be done in accordance with all federal, state and local environmental regulations. Disposal must be made according to the regulations found in 40 CFR 261. This product is not a hazardous waste according to local regulations.

# • Packaging: Recommendation

Disposal should be done in accordance with all federal, state and local environmental regulations. Disposal must be made according to the regulations found in 40 CFR 261. This product is not a hazardous waste according to local regulations.

# Recommended cleansing agent

Water, if necessary with cleansing agents



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# **SECTION 14: TRANSPORT INFORMATION**

• DOT regulations: Not regulated

Land transport ADR/RID: Not regulated
 Maritime transport IMDG: Not regulated

• Air transport ICAO-TI and IATA-DGR: Not regulated

# **SECTION 15: REGULATORY INFORMATION**

- OSHA, 29 CFR 1910.1200(g) and Appendix D. United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), third revised edition, United Nations, 2009
- EC directives: 91/155/EEC, 93/112/EC, 88/379/EEC
- Water hazard class: N/A
- **Note:** Please note that there may be additional legal provisions to be observed. We recommend that you keep yourself informed about all applicable international, national and local regulations.

# **SECTION 16: OTHER INFORMATION**

To the best of our knowledge, the information contained herein is accurate. However, neither Greiner Bio-One nor any of its subcontractors or suppliers assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.