greiner BIO-ONE	**Product Safety Data Sheet** **VACUETTE® Tube FX** **Sodium Fluoride / Potassium Oxalate**	Version 1.1 Valid from 20-Jan-2025

In accordance with Regulation (EC) No. 1907/2006; ISO 11014:2009

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

1.1. Product identifier

VACUETTE® Tube FX Sodium Fluoride / Potassium Oxalate

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

Identified use of the product: For in-vitro diagnostic.

1.3. Details of the supplier of the safety data sheet

AUSTRIA
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USA
Greiner Bio-One North America Inc.
4238 Capital Drive Monroe
28110 North Carolina
USA
Tel: +1 704 261 7800
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BRASIL
Greiner Bio-One Brasil
Produtos Médicos Hospitalares Ltda
Rua Affonso Pansan no. 1967
13473-620 Vila Bertini
Americana, São Paulo
Brasil
Tel: +55 19 3468 9600
E-mail: office@br.gbo.com

1.4. Emergency telephone number

UK Poison Information Center: NHS Direct +44 111 (for medical advice)
USA Poison Control: American Association of Poison Control Centers +1 800 222 1222

2. Section: Hazards identification

2.1. Classification of the substance or mixture

The mixture in the article is classified according to the CLP Regulation and to the Globally Harmonized System (GHS).

GHS06

Acute Tox. 3 (oral) H301 Toxic if swallowed.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

2.2. Label elements

Hazard pictogram:

Signal word: Danger

Hazard statements:
H301 Toxic if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary statements:
P280: Wear protective gloves/protective clothing/eye protection.
P301+P310: If swallowed: Immediately call a POISON CENTER/doctor
P302+P352: If on skin: Wash with plenty of water.
P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Additional hazard information (EU):
EUH032: Develops very toxic gases when in contact with acid.

2.3. Other hazards

The product does not contain any components considered to be either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in quantities of 0.1 % or more.

The product does not contain components considered to be endocrine disruptors according to Article 57 (f) of REACH or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 in quantities of 0.1 % or more.

3. Section: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Description: VACUETTE® blood collection tubes made of PET (polyethylene terephthalate) with substances listed below and non-hazardous additives.

Chemical name:

- Sodium fluoride
- Potassium oxalate monohydrate

CAS-No.:

- Sodium fluoride 7681-49-4
- Potassium oxalate monohydrate 6487-48-5

Hazardous ingredients:

CAS-No. 7681-49-4 Sodium fluoride
EC-No. 231-667-8 Acute Tox. 3 (oral), H301; Skin Irrit. 2 H315; Eye Irrit. 2, H319
EUH032 Develops very toxic gases when in contact with acids.

CAS-No. 6487-48-5 Potassium oxalate monohydate
EC-No. 209-506-8 Acute Tox. 4 (oral), H302; Acute Tox. 4 (dermal), H312

Quantity of substances/components in the mixture:

- Sodium fluoride 50 - 70 % (% mass)
- Potassium oxalate monohydate 30 - 50 % (% mass)

Due to trade secrets, not all components and their proportions are listed.

Additional information: For the wording of the listed hazard phrases refer to section 16.

4. Section: First aid measures

4.1. Description of first aid measures

General note:
Pay attention to self-protection. Observe the Instructions for Use to ensure safe use.

After inhalation: Supply fresh air. Seek medical advice if symptoms occur.
After skin contact: Immediately rinse with polyethylene glycol 400. Rinse with water. May cause skin irritation. Consult doctor in case of complaints.
After eye contact: Rinse opened eye for several minutes under running water. Remove contact lenses if present and easy to do. May cause eye irritation. Consult doctor in case of complaints.
After swallowing: Rinse mouth several times with water immediately. Do not induce vomiting. Do not administer chemical antidotes. Seek medical advice/medical service immediately. Contact poison center.

4.2. Most important symptoms and effects, both acute and delayed

After inhalation: Dry throat/sore throat. Coughing. Respiratory tract irritation. Nasal mucous membrane irritation.
After skin contact: Red skin. Tingling/skin irritation.
After eye contact: Eye tissue irritation.
After swallowing: Nausea. Salivation.

4.3. Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5. Section: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.

5.2. Special hazards arising from the substance or mixture

On heating/burning release of toxic and corrosive gases/vapors (hydrofluoric acid).

5.3. Advice for firefighters

Protective equipment: Wear self-contained respiratory protective device.

6. Section: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protective equipment.

6.2. Environmental precautions

Store in suitable containers for disposal.

6.3. Methods and material for containment and cleaning up

Pick up mechanically. Dispose of the collected material according to section 13. Clean with water with the addition of cleaning agents if necessary.

6.4. Reference to other sections

See section 8 for information on personal protection equipment.
See section 13 for disposal information.

7. Section: Handling and storage

7.1. Precautions for safe handling

No special measures required.

Information about fire and explosion protection: No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles: See Instruction for Use for correct storage.

Information about storage in one common storage facility: Store away from incompatible materials such as strong acids.

Further information about storage conditions: None.

7.3. Specific end use(s)

No further relevant information available.

8. Section: Exposure controls/personal protection

8.1. Control parameters

Components with limit values that require monitoring at the workplace:
Sodium fluoride:
EU IOELV TWA 2,5 mg/m³
USA ACGIH TWA: 2,5 mg/m³

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

8.2. Exposure controls

Appropriate engineering controls: No further data, see section 7.
Individual protection measures, such as personal protective equipment:
General protective and hygienic measures: The usual precautionary measures in the laboratory and when handling chemicals must be observed.
Respiratory protection: Not required.
Hand protection: Use suitable gloves.
Material of gloves:

- Nitrile rubber
- Butyl rubber

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.
Penetration time of glove material: The exact break through time must be found out by the manufacturer of the protective gloves and must be observed.
Eye/face protection: Safety goggles recommended.

9. Section: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Spray-dried suspension.
Color	White to yellow.
Odor	Odorless.
Odor threshold	Not determined.
Melting point/freezing point	Not determined.
Boiling point or initial boiling point and boiling range	Not determined.
Flammability	Not determined.
Lower and upper explosion limit	Not determined.
Flash point	Not applicable.
Decomposition temperature	Not determined.
pH value at 20 °C	Not determined.
Viscosity	Not determined.
Kinematic viscosity	Not determined.
Dynamic	Not determined.
Solubility in water	Soluble.
Partition coefficient *n*-octanol/water (log value)	Not determined.
Vapor pressure	Not determined.
Relative density	Not determined.
Density	Not determined.
Vapor density	Not determined.
Solids content	Not determined.

9.2. Other information

No further relevant information available.

10. Section: Stability and reactivity

10.1. Reactivity

No further relevant information available.

10.2. Chemical stability

Thermal decomposition/conditions to be avoided:
No decomposition if used according to specifications.

10.3. Possibility of hazardous reactions

No dangerous reactions known.

10.4. Conditions to avoid

No further relevant information available.

10.5. Incompatible materials

Sodium fluoride: Strong acids and oxidizing agents, glass.

10.6. Hazardous decomposition products

Sodium fluoride reacts with (some) acids: Release of toxic and corrosive gases/vapors (hydrogen fluoride).

11. Section: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity: Oral: Contained mixture is harmful if swallowed.
Sodium fluoride: LD50 oral rat > 52 mg/kg (rat, oral)..
Skin corrosion/irritation: Contained mixture may cause skin irritation.
Serious eye damage/irritation: Contained mixture may cause severe eye irritation.
Respiratory or skin sensitization: Based on available data, the classification criteria are not met.
Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Based on available data, the classification criteria are not met.
Specific Target Organ Toxicity-single exposure: Based on available data, the classification criteria are not met.
Specific Target Organ Toxicity-repeated exposure: Based on available data, the classification criteria are not met.
Aspiration hazard: Based on available data, the classification criteria are not met.

11.2. Information on other hazards

Endocrine disrupting properties:
Based on available data, the classification criteria are not met.

12. Section: Ecological information

12.1. Toxicity

Aquatic toxicity: No further relevant information available.

12.2. Persistence and degradability

No further relevant information available.

12.3. Bioaccumulative potential

No further relevant information available.

12.4. Mobility in soil

No further relevant information available.

12.5. Results of PBT and vPvB assessment

PBT: Not applicable.
vPvB: Not applicable.

12.6. Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

12.7. Other adverse effects

Additional ecological information:
General notes: Not hazardous for water. Harmful to aquatic organisms, with long lasting effects.

13. Section: Disposal considerations

13.1. Waste treatment methods

Recommendation:
Comply with applicable national or regional regulations.
After proper use:
Disposal in accordance with the regulations of the authorities and health facilities.

14. Section: Transport information

14.1. UN number or ID number

ADR, ADN, IMDG, IATA: Not applicable.

14.2. UN proper shipping name

ADR, ADN, IMDG, IATA: Not applicable.

14.3. Transport hazard class(es)

ADR, ADN, IMDG, IATA: Not applicable.

14.4. Packing group

ADR, ADN, IMDG, IATA: Not applicable.

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

UN „Model Regulation“: Not applicable.

15. Section: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the article

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances
Named dangerous substances - Annex I: None of the ingredients is listed.
Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II: None of the ingredients is listed.
Regulation (EU) 2019/1148 on the marketing and use of explosives precursors
Annex I – Restricted explosives precursors: None of the ingredients is listed.
Annex II – Reportable explosives precursors: None of the ingredients is listed.
Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors: None of the ingredients is listed.

15.2. Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

16. Section: Other information

H301 Toxic if swallowed.
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
EUH032 Develops very toxic gases when in contact with acids.

According to the **European Union Regulations (EC) No 1907/2006** Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) an **article** is defined as an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

The product (see section 1) is considered as such an article and therefore the manufacturer is not obliged to provide a safety data sheet. Further, it is not intended to release hazardous substances under normal or reasonably foreseeable conditions of use. Information on safe use is provided in the Instruction for Use (IFU) for these products. It is the responsibility of the user to use the article for the purpose for which it is intended and to exercise caution during use.