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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 Urine CCM

### **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**

Greiner Bio-One GmbH  
Bad Haller Straße 32  
4550 Kremsmünster  
Austria  
Tel: +43 7583 6791 0  
E-mail: office@at.gbo.com

#### **USA**

Greiner Bio-One North America Inc.  
4238 Capital Drive Monroe  
28110 North Carolina  
USA  
Tel: +1 704 261 7800  
E-mail: office@us.gbo.com

#### **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

#### **THAILAND**

Greiner Bio-One Thailand Ltd.  
700 / 172 Moo. 1 Amata Nakorn Industrial Estate  
Tambon Bankao Amphur Phanthong  
20160 Chonburi  
Thailand  
Tel: +66 38 4656 33  
E-mail: office@th.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**

#### **Classification according to Regulation (EC) No. 1272/2008**

The mixture in the article is classified according to the CLP Regulation.

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GHS08

Repr. 1B H360FD May damage fertility. May damage the unborn child.

## **2.2. Label elements**

**Labeling according to Regulation (EC) No 1272/2008:**

**Hazard pictogram:**



**Signal word:** Danger

**Hazard statements:**

**H360FD** May damage fertility. May damage the unborn child.

**Precautionary statements:**

**P202** Do not handle until all safety precautions have been read and understood.

**P280** Wear protective gloves/protective clothing/eye protection/face protection.

**P308+P313** If exposed or concerned: Get medical advice/attention.

## **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® tubes made of PET (polyethylene terephthalate) with CCM granules.

**Chemical name:**

- Mannitol
- Disodium tetraborate decahydrate
- Boric acid
- Sodium formate

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**CAS-No.:**

- Mannitol 69-65-8
- Disodium tetraborate decahydrate 1303-96-4
- Boric acid 10043-35-3
- Sodium formate 141-53-7

**Hazardous ingredients:**

CAS-No. 1303-96-4     Disodium tetraborate decahydrate  
EG-No. 215-540-4     Repr. 1B, H360FD

CAS-No. 10043-35-3     Boric acid  
EG-No. 233-139-2     Repr. 1B, H360FD

**Quantity of substances/components in the mixture:**

- Disodium tetraborate decahydrate < 35 % (mass %)
- Boric acid < 30 % (mass %)

**Substances of very high concern (SVHC):**

CAS-No. 1303-96-4     Disodium tetraborate decahydrate  
CAS-No. 10043-35-3     Boric acid

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.

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## 4. Section: First aid measures

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### 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. Consult doctor in case of complaints.

**After skin contact:** Generally, the product does not irritate the skin.

**After eye contact:** Rinse opened eye for several minutes under running water. Consult doctor in case of complaints.


**After swallowing:** Immediately rinse mouth thoroughly with water for several times. Consult doctor in case of complaints.

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

No further relevant information available.

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

No further relevant information available.

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## 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

No further relevant information available.

### 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:** Not required.

**Further information about storage conditions:** None.

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### **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:**

Disodium tetraborate decahydrate

REL Long-term value 5 mg/m<sup>3</sup>

TLV Short-term value 6 mg/m<sup>3</sup>

Long-term value 2 mg/m<sup>3</sup>  
as inhalable fraction, A4

Boric acid

TLV Short-term value 6 mg/m<sup>3</sup>

Long-term value 2 mg/m<sup>3</sup>  
as inhalable fraction, A4

**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.

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## 9. Section: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	Powder.
Color	White.
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 <i>n</i> -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.

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## 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

No further relevant information available.

### 10.6. Hazardous decomposition products

No dangerous decomposition products known.


## 11. Section: Toxicological information

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

**Acute toxicity:** Based on available data, the classification criteria are not met  
**Skin corrosion/irritation:** Based on available data, the classification criteria are not met.  
**Serious eye damage/irritation:** Based on available data, the classification criteria are not met.  
**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:** May damage fertility. May damage the unborn child.  
**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.

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## **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**


The product does not contain any substances with endocrine-disrupting properties.

### **12.7. Other adverse effects**

**Additional ecological information:**

**General notes:** Not hazardous for water.



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## **13. Section: Disposal considerations**

### **13.1. Waste treatment methods**

**Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system. 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.

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## 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.

**Other regulations, restrictions, and bans:**

**Substances of Very High Concern (SVHC) according to REACH, Article 57**

CAS-No. 1303-96-4

Disodium tetraborate decahydrate

CAS-No. 10043-35-3

Boric acid

### 15.2. Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## 16. Section: Other information

**H360FD** May damage fertility. May damage the unborn child.

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.