



# MATERIAL SAFETY DATA SHEET

## URISSET PRESERVATIVE TUBE WITH HOLDER

(According to Regulation (EC) No. 1097/2006 and 453/2010)

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### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 PRODUCT IDENTIFIERS

**Product name:** URISSET PRESERVATIVE TUBE

**Product number:**

Product	Code
URISSET PRESERVATIVE TUBE	94024
URISSET PRESERVATIVE TUBE WITH HOLDER	94026
URISSET PRESERVATIVE TUBE I.S	94024/IS
URISSET PRESERVATIVE TUBE WITH HOLDER I.S.	94026/IS

**Brand:** DIESSE

#### 1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCES OR MIXTURE AND USES ADVISED AGAINST

**Identified use:**

Professional use as laboratory reagent.  
Vacuum-filled tube designed for the collection of urine samples. It contains a special powder preservative, which prevents bacterial growth for a time of 24 hours at room temperature.  
To use with Robobact and Uribact.

#### 1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

**Company:** DIESSE Diagnostica Senese SpA

Registered office:  
Via A. Solari 19  
20144 Milan, Italy  
Tel: +39 02 4859121  
Fax: +39 02 48008530

Production plant:  
Via delle Rose, 10 – Loc. Tognazza  
53035 Monteriggioni (SI), Italy  
Tel: +39 0577 319560/61  
Fax: +39 0577 318763

#### 1.4 EMERGENCY TELEPHONE NUMBER

**Emergency number:**

Centro Antiveleni, Ospedale Niguarda Ca' Granda - Milano  
Tel: +39 02 66101029

Centro Antiveleni, Azienda Ospedaliera "S.G.Battista" – Molinette di Torino - Torino  
Tel: +39 011 6637637

Centro Antiveleni – U.O. Tossicologia Medica, Azienda Ospedaliera Careggi – Firenze  
Tel: +39 055 4277238

Centro Antiveleni, Policlinico A. Gemelli – Università Cattolica del Sacro Cuore - Roma  
Tel: +39 06 3054343

Centro Antiveleni, Azienda Ospedaliera A. Cardarelli – Napoli  
Tel: +39 081 7472870

web: [http://www.salute.gov.it/servizio/documenti/centri\\_antiveleni.pdf](http://www.salute.gov.it/servizio/documenti/centri_antiveleni.pdf)

### 2. HAZARDS IDENTIFICATION

#### 2.1 CLASSIFICATION OF THE SUBSTANCES OR MIXTURE

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

Reproductive toxicity - Category 1B

**Hazard statement(s):**

H360FD May damage fertility. May damage unborn child

**Classification according to European Directive 67/548/EEC and 1999/45/EC**

Repr. Cat 2– Categoria 2

**R-phrases:**

R60 – May impair fertility

R61 – May cause harm to the unborn child

**2.2 LABEL ELEMENTS****Pictograms:** GHS08**Signal word:** Danger**Hazard statement(s):** H360FD May damage fertility. May damage unborn child**Precautionary statement(s):***Prevention precautions*

P201 – Obtain special instruction before use

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

P281 – Use personal protective equipment as required

*Response precautions*

P308+P313 – IF exposed or concerned: Get medical advice/attention

*Storage precautions*

P405 – Store locked up

*Disposal*

P501 – Dispose of contents/container to ...

**Contains:** Boric Acid  
EC No:233-139-2Restrict to professional users**Supplemental hazards:** None**2.3 OTHER HAZARDS**

None

**3. COMPOSITION/INFORMATION ON INGREDIENTS****3.1 SUBSTANCES** Not Applicable**3.2 MIXTURES**

	Directive 67/548/EEC	Classification	
		Regulation EC 1272/2008	
Boric acid			
Cas No: 10043-35-5	60-70%	T	R60
EC No: 233-139-2			R61
Index No: 005-007-00-2			
Reach No: 01-2119486683-25-XXXX			

The entire test of Hazard Statements and R-phrases is reported at Section 16 of the sheet

**4. FIRST AID MEASURES****4.1 DESCRIPTION OF FIRST AID MEASURES****General advice:** Move the person from the exposure to open air. Consult a physician and show this safety data sheets to the doctor in attendance**Skin contact:** Wear off the contaminated clothes and wash with copious amounts of water.**Eye contact:** If present, remove immediately contact lenses. Wash with plenty of water at least 15 minutes, keeping eyelids opened. If irritation persists consult a physician.  
Move the person from the exposure to open air.**Ingestion:** If swallowed, rinse mouth immediately and drink a copious amounts of water. Call a physician immediately.**4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS**

The ingestion of boric acid can cause diarrhea, nausea, vomiting, fatigue, ataxia, decreasing of body temperature, agitation,



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spasms.  
Inhalation may cause irritation of the respiratory tract.

#### 4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available

### 5. FIREFIGHTING MEASURES

#### 5.1 EXTINGUISH MEDIA

**Suitable extinguishing media:** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

**Not Suitable extinguishing media:** None

#### 5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

The mixture is not flammable, however, in case of fire, irritating fumes and/or toxic gases (CO<sub>2</sub>, CO, boranes) can be released.

#### 5.3 ADVICE FOR FIREFIGHTERS

Wear full firefighting apparatus. Avoid that fire extinguishing water contaminates surface water and/or groundwater.

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Send people not involved in the intervention operations away. Avoid the generation and the inhalation of dust and avoid the contact with the mixture. Ensure an adequate ventilation of the affected area.  
Do not handle damaged containers or the leaked product before wearing appropriate protective outfit.

#### 6.2 ENVIRONMENTAL PRECAUTIONS

Avoid the contamination of surface water, soil and the dispersion in the air.

#### 6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Collect the spilled material with mechanical means avoiding raising of dust and store it in suitable containers for disposal. Use water only to remove residuals, to avoid the danger of spill of product into the sewers.

#### 6.4 REFERENCE TO OTHER SECTIONS

For further information see section 8 and 13

### 7. HANDLING AND STORAGE

#### 7.1 PRECAUTION FOR SAFE HANDLING

Work in well ventilated areas and in the presence of ventilation systems or personal protective equipment. Do not breathe dust.

#### 7.2 CONDITION FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep the containers tightly closed and in a cool, well-ventilated area, away from heat sources and protected from humidity.

#### 7.3 SPECIFIC END USE

None.

### 8. EXPOSURE CONTROL/PERSONAL PROTECTION

#### 8.1 CONTROL PARAMETERS

##### Applicable exposure limits:

Description	Kind	TWA/8h		STEL/15min	
		mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>	ppm



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Inorganic borates	TLV-ACGIH	2	6
Inhalable fraction	2008		

### Other information:

#### Boric Acid

Derived no-effect levels (IUCAL)

DNEL (workers)

Systemic effects for long-term exposure - Dermal: 392 mg/kg bw/day

Systemic effects for long-term exposure - Inhalation: 8.3 mg/m<sup>3</sup>

DNEL (population)

Systemic effects for long-term exposure - Dermal: 196 mg/kg bw/day

Systemic effects for long-term exposure - Inhalation: 4.15 mg/m<sup>3</sup>

Systemic effects from exposure to long/short term - Oral: 0.98 mg/kg bw/day

PNEC

Fresh water/sea water: 1.35 mg/l

Intermittent release water: 9.1 mg/l

Water treatment systems: 1.75 mg/l

Sediments of water/sea water: 1.8 mg/kg dry weight sediment

Land: 5.4 mg/kg soil dry weight

### 8.2 EXPOSURE CONTROLS

Work and handle according to the usual precautionary measures for handling chemicals. Do not eat, drink or smoke while handling the product; wash hands thoroughly with soap and water before meals and after the work shift. Immediately remove all contaminated clothing.

#### Appropriate engineering controls:

Ensure an adequate ventilation of the working area. Use aspiration system located on the emission points in the event of exceeding of the acceptable limit.

#### Personal Protective Equipment

The suggestions on the use of specific PPE are indicative. Their choice should be made according to the use of the product and the instructions given by the supplier of the device.

##### Hand protections:

Chemical-resistant gloves, comply with EN 374. Suitable material: nitrile rubber

##### Eye protections:

Sealed protective goggles comply with EN 166

##### Body protections:

Work outfits

##### Respiratory protections:

According to the risk evaluation and analysis may be necessary the use of a dust mask with FFP3 filters.

#### Environmental Exposure Controls:

Do not discard residuals in the environment.



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### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	Solid, white
<b>Odour:</b>	Odorless
<b>Odour threshold:</b>	No data available
<b>pH:</b>	Not pertinent
<b>Melting point/freezing point</b>	No data available
<b>Initial boiling point and boiling range</b>	No data available
<b>Flash point</b>	Not pertinent
<b>Evaporation rate</b>	Not pertinent
<b>Flammability</b>	Not pertinent
<b>Upper/lower flammability or explosive limit</b>	Not pertinent
<b>Vapour pressure</b>	No data available
<b>Vapour density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	Soluble in water
<b>Partition coefficient: n-octano/water</b>	No data available
<b>Autoignition temperature</b>	Not pertinent
<b>Decomposition temperature</b>	185°C (Boric Acid)
<b>Viscosity</b>	No data available
<b>Explosive properties:</b>	Not explosive
<b>Oxidizing properties</b>	Not oxidant

#### 9.2 OTHER SAFETY INFORMATION

None

### 10. STABILITY AND REACTIVITY

#### 10.1 REACTIVITY

See point 10.3.

#### 10.2 CHEMICAL STABILITY

The product is stable under the recommended transport, handling and storage conditions

#### 10.3 POSSIBILITY OF HAZARDOUS REACTIONS

**Boric acid:** may react with strong reducing agents such as alkali metals or metallic anhydrides with the formation of gas hydrogen which may increase the danger of explosion.

#### 10.4 CONDITIONS TO AVOID

Avoid the formation and the disposal of dust

#### 10.5 INCOMPATIBLE MATERIALS

Alkali metals and metallic anhydrides

#### 10.6 HAZARDOUS DECOMPOSITION PRODUCTS

When heated or in case of fire, vapors potentially dangerous to health (boric oxide, COx) may be produced.

### 11. TOXICOLOGICAL INFORMATION

#### 11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Toxic to reproduction. In case of exposure may damage fertility and the fetus.  
The product may be absorbed into the body by inhalation and if swallowed.

Boric Acid



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<b>Acute toxicity:</b>	LD50 (oral, rat) >2600 mg/kg bw LC50 (inhalation, rat, 4h) >2,03 mg/l LD50(dermal, rabbit)>2000 mg/kg bw
<b>Skin irritation/corrosion:</b>	Results of tests performed on rabbits: non-corrosive, can cause slight skin irritation, reversible within 72h.
<b>Eye lesions/severe eye irritation:</b>	Results of tests performed on rabbits: slightly irritant with completely reversible effects.
<b>Respiratory/skin sensitization:</b>	Results of sensitization tests (OECD TG 406): negative
<b>Mutagenicity for germ cells:</b>	Results of genotoxicity in vitro tests (Ames test) : negative
<b>Carcinogenicity:</b>	Results of carcinogenicity tests (OECD 451) : negative
<b>Reproductive toxicity:</b>	Experimental results showed negative effects for the fertility and for the fetus
<b>Toxicity for target organs (single and repeated exposures) :</b>	None
<b>Hazards in case of inhalation:</b>	Not applicable
<b>Additional information:</b>	None

## 12. ECOLOGICAL INFORMATION

### 12.1 TOXICITY

Use according to the good working practices, avoiding the disposal in the environment. In case the product reach waterways or sewers or contaminate soil or vegetation, inform the competent authorities.

Ecotoxicological properties of the components.

#### **Boric Acid**

Toxicity for fishes: CL50 (Limanda Limanda,96h): 74mg/l

Toxicity for invertebrates:LC50 (Daphnia Magna, 48h): 133 mg/l

### 12.2 PERSISTENCE AND DEGRADABILITY

No data available.

### 12.3 BIOACCUMULATIVE POTENTIAL

The bioaccumulation of the product in the environment is not expected

### 12.4 MOBILITY IN SOIL

No data available

### 12.5 RESULTS OF PBT AND VPVB ASSESSMENT

No data available


### 12.6 OTHER ADVERSE EFFECTS

The product doesn't contain AOX substances

## 13. DISPOSAL CONSIDERATIONS

### 13.1 WASTE TREATMENT METHODS

The product and its containers should be considered special waste.  
Their transport and disposal should be performed by authorized specialized companies according to the law.

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#### 14. TRANSPORT INFORMATION

No hazardous good according to the transport regulations

#### 15. REGULATORY INFORMATION

##### 15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Hazard labeling under directives 1272/2008 (EC) and its subsequent amendments.

Legislative Decree 81/2008:

The use of this chemical entails the obligation of "Risk Assessment" by the employer in accordance with the provisions of the Decree April 9, 2008 n. 81 and subsequent amendments. Workers exposed to this chemical agent must not undergo health checks whether the results of the risk assessment show that, depending on the type and quantity of chemical agent and the method and frequency of exposure to this agent, there is only one "Low risk to the safety and irrelevant to the health" of the workers and the measures provided for in the same Decree are sufficient to reduce the risk

European Standards:1907/2006/EC:

The product contains boric acid inserted in the Candidate List (SVHC - Substances of Very High Concern).

The product is subject to restrictions in Annex XVII of Regulation 1907/2006:

Item 30 - Substances listed in Annex I to Directive 67/548/EEC and classified as "toxic to reproduction of category 1 or category 2" and labeled with risk phrase R60: "May impair fertility" and/or R 61: "May cause harm to the unborn child" ..... Shall not be placed on the market or use: - as substances, - as constituents of other substances, or - in mixtures, for sale to the public when the individual concentration in the substance or mixture is equal to or exceeding: - relevant specific concentration limit set out in Annex VI, part 3 of Regulation (EC) n. 1272/2008, or - the relevant concentration specified in Directive 1999/45/EC.

Without prejudice to the application of other Community provisions on the classification, packaging and labeling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly marked as follows: "Restricted to professional users".

Directive 96/82/EC (Seveso Directive):

Not applicable

##### 15.2 CHEMICAL SAFETY ASSESSMENT

Not performed for the product

#### 16. OTHER INFORMATION

This product has to be used for diagnostic use only by personnel who is qualified and trained on the hazards shown in this safety sheet.

##### Test of the hazard statements present at point 3

H360FD May damage fertility. May damage unborn child

##### Test of the Risk phrases present at point 3

R60 – May impair fertility

R61 – May cause harm to the unborn child

##### REFERENCES:

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and technical adjustments
3. Regulation (EC) 1907/2006 of the European Parliament (REACH) as amended
4. Regulation (EC) 1272/2008 of the European Parliament (CLP) as amended
5. Commission Regulation (EU) 453/2010
6. ECHA European Chemicals Agency [www.echa.europa.eu](http://www.echa.europa.eu)
7. The Merck Index.
8. Handling Chemical Safety
9. NIOSH - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxicologique



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