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

1.1 PRODUCT IDENTIFIERS

Product name: URISET PRESERVATIVE TUBE

<table>
<thead>
<tr>
<th>Product number</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>URISET PRESERVATIVE TUBE</td>
<td>94024</td>
</tr>
<tr>
<td>URISET PRESERVATIVE TUBE WITH HOLDER</td>
<td>94026</td>
</tr>
<tr>
<td>URISET PRESERVATIVE TUBE I.S</td>
<td>94024/IS</td>
</tr>
<tr>
<td>URISET PRESERVATIVE TUBE WITH HOLDER I.S</td>
<td>94026/IS</td>
</tr>
</tbody>
</table>

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
Production plant: Via delle Rose, 10 – Loc. Tognazza
Via delle Rose, 10 – Loc. Tognazza
20144 Milan, Italy
Via delle Rose, 10 – Loc. Tognazza
53035 Monteriggioni (SI), Italy
Tel: +39 02 4859121
Tel: +39 0577 319560/61
Fax: +39 02 48008530
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


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: 233-139-2

Restrict to professional users

Supplemental hazards: None

2.3 OTHER HAZARDS

None

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

Not Applicable

3.2 MIXTURES

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Boric acid</td>
<td></td>
<td>60-70% R60 R61</td>
<td>Repr. 1B – H360FD</td>
</tr>
<tr>
<td>Cas No:</td>
<td>10043-35-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC No:</td>
<td>233-139-2</td>
<td></td>
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<tr>
<td>Index No:</td>
<td>005-007-00-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reach No:</td>
<td>01-2119486683-25-0000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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,
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 (CO₂, 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/PERSOAL PROTECTION

8.1 CONTROL PARAMETERS

<table>
<thead>
<tr>
<th>Applicable exposure limits:</th>
<th>Description</th>
<th>Kind</th>
<th>TWA/8h</th>
<th>STEL/15min</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>mg/m³</td>
<td>ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ppm</td>
<td>mg/m³</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
<th>Kind</th>
<th>TWA/8h</th>
<th>STEL/15min</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Inorganic borates
Inhalable fraction
TLV-ACGIH 2008
2 6

Other information:
Boric Acid
Derived no-effect levels (IUCLID)
Systemic effects for long-term exposure - Dermal: 392 mg/kg bw/day
Systemic effects for long-term exposure - Inhalation: 8.3 mg/m³
DNEL (population)
Systemic effects for long-term exposure - Dermal: 196 mg/kg bw/day
Systemic effects for long-term exposure - Inhalation: 4.15 mg/m³
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 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.
9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

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

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
Acute toxicity: LD50 (oral, rat) >2600 mg/kg bw  
LC50 (inhalation, rat, 4h) >2,03 mg/l  
LD50(dermal, rabbit)>2000 mg/kg bw

Skin irritation/corrosion: Results of tests performed on rabbits: non-corrosive, can cause slight skin irritation, reversible within 72h.

Eye lesions/severe eye irritation: Results of tests performed on rabbits: slightly irritant with completely reversible effects.

Respiratory/skin sensitization: Results of sensitization tests (OECD TG 406): negative

Mutagenicity for germ cells: Results of genotoxicity in vitro tests (Ames test) : negative

Carcinogenicity: Results of carcinogenity tests (OECD 451) : negative

Reproductive toxicity: Experimental results showed negative effects for the fertility and for the fetus

Toxicity for target organs (single and repeated exposures) : None

Hazards in case of inhalation: Not applicable

Additional information: 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 PERSISTANCE 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.
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).

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
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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