Material Safety Data Sheet

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

Product name: Creatinine
Product number: 47002
Global material number: 20739650322
Business area: Point of Care.
Product line: Mira.
Instrument type: Not applicable.

Supplier:
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
Site Phone Number: 1-800-428-5074

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component 1: Buffer Reagent

| Components          | CAS Number | Weight % | OSHA PEL: | OSHA STEL: | ACGIH TLV: | ACGIH STEL:
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>1-5</td>
<td>2 mg/m³</td>
<td>NA</td>
<td>NA</td>
<td>2 mg/m³ Ceiling</td>
</tr>
<tr>
<td>Sodium borate</td>
<td>1333-73-9</td>
<td>1-5</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

Component 2: Picric Acid Reagent

| Components          | CAS Number | Weight % | OSHA PEL: | OSHA STEL: | ACGIH TLV: | ACGIH STEL:
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Sodium borate</td>
<td>1333-73-9</td>
<td>1-5</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Picric Acid</td>
<td>88-89-1</td>
<td>1-5</td>
<td>0.1 mg/m³ prevent or reduce skin absorption</td>
<td>NA</td>
<td>0.1 mg/m³</td>
<td>NA</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

Emergency Overview

NFPA Ratings: Health= 3. Flammability= 0 Reactivity= 0 Special= CO, I.
Special Definitions: A=Allergen CA=Carcinogen CO=Corrosive F=Flammable H=Harmful I=Irritant Ox=Oxidizer PB=Potential Biohazard R=Reproductive S=Sensitizer T=Toxic T+=Highly Toxic W=Water Reactive

Principle routes of exposure:
Ingestion, inhalation, skin and/or eye contact.
Inhalation: May cause irritation of respiratory tract.
Ingestion: Ingestion causes burns of the upper digestive and respiratory tracts.
Skin contact: Moderately irritating to the skin.
Eye contact: Risk of serious damage to eyes.

Sensitization:
None.

Medical conditions aggravated by exposure:
None known

Additional information:
None

Target organ effects:
The following chemical(s) have target organ effects:
Components | NIOSH - Pocket Guide - Target Organs:
--- | ---
Sodium hydroxide | eyes, skin, respiratory system

Components | NIOSH - Pocket Guide - Target Organs:
--- | ---
Picric Acid | kidneys, liver, blood, skin, eyes

4. FIRST AID MEASURES

Inhalation: Consult a physician. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion: Call a physician immediately. Do not induce vomiting without medical advice. Drink 1 or 2 glasses of water.

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Notes to physician: None determined

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use dry chemical, CO2, water spray or "alcohol" foam.

Unusual hazards: None known.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Evacuate personnel to safe areas. Remove all sources of ignition. Avoid dust formation. Ensure adequate ventilation.

Environmental precautions: Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Do not flush into surface water or sanitary sewer system. Do not let product enter drains.

Methods for cleaning up: Never return spills in original containers for re-use. Soak up with oil absorbent material. Neutralize corrosive material prior to cleaning. Sweep up or vacuum (if powder) or soak up with inert absorbent material (if liquid), then place into a suitable clean, dry, closed container, and label for disposal.

7. HANDLING AND STORAGE

Handling: Protect from contamination. Wear personal protective equipment.

Storage: Keep containers dry and tightly closed to avoid moisture absorption and contamination.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering measures: Ensure adequate ventilation.

Personal Protective Equipment

Respiratory protection: Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation, 29CFR1910.134. Always use a NIOSH approved respirator when necessary.

Hand protection: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Skin and body protection: Wear appropriate body protection to prevent skin contact.

Eye protection: Wear appropriate eye protection to prevent eye contact.

Hygiene measures: When using, do not eat, drink or smoke. Keep away from food and drink. Keep away from tobacco products. Wash hands before breaks and immediately after handling the product. Handle in accordance with good industrial hygiene and safety practice for diagnostics.

Product number: 47002

Product name: Creatinine
### Components

<table>
<thead>
<tr>
<th>Components</th>
<th>NIOSH IDLH:</th>
<th>OSHA - 29 CFR 1910 Specifically Regulated Chemicals:</th>
<th>AIHA - WEEL - TWA:</th>
<th>AIHA-WEEL-Ceilings or Short Term TWA:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>10 mg/m³ IDLH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Picric Acid</td>
<td>75 mg/m³ IDLH</td>
<td></td>
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</tbody>
</table>

### AIHA - Odor Threshold Values: Switzerland-Occupational Exposure Limits-
8 Hour: Switzerland-Occupational Exposure Limits-15 Minute:

<table>
<thead>
<tr>
<th>Components</th>
<th>AIHA - Odor Threshold Values:</th>
<th>Switzerland-Occupational Exposure Limits-8 Hour:</th>
<th>Switzerland-Occupational Exposure Limits-15 Minute:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>2 mg/m³</td>
<td>= 2 mg/m³ STEL inhalable</td>
<td></td>
</tr>
<tr>
<td>Picric Acid</td>
<td>0.1 mg/m³</td>
<td>= 0.1 mg/m³ STEL inhalable</td>
<td></td>
</tr>
</tbody>
</table>

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Boiling point/range:** No information available
- **Melting point/range:** Not determined
- **pH:** Buffer Reagent=>13. Picric Acid Reagent=8.
- **Physical state:** Liquid.
- **Flash point:** No information available.
- **LEL (%):** Not determined
- **UEL (%):** Not determined

### 10. STABILITY AND REACTIVITY

- **Stability:** Stable under recommended storage conditions.
- **Polymerization:** None under normal processing.
- **Hazardous decomposition products:** Thermal decomposition can lead to release of irritating gases and vapours. Sulphur oxides.
- **Materials to avoid:** Incompatible with strong acids and bases. Oxidising agents (strong). Heavy metals.

### 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Components</th>
<th>EPA-IRIS Oral Reference Dose (RID) Information:</th>
<th>EPA-IRIS Inhalation Reference Concentration (RIC) Information:</th>
<th>NIOSH - Selected LD50s and LC50s:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Picric Acid</td>
<td></td>
<td></td>
<td>= 200 mg/kg Oral LD50 Rat</td>
</tr>
</tbody>
</table>

- **Inhalation:** No data available
- **Skin:** No data available
- **Oral:** No data available
- **Mutagenic effects:** No data is available on the product itself
- **Reproductive toxicity:** No data is available on the product itself
- **Carcinogenic effects:**

### 12. ECOLOGICAL INFORMATION

- **Bioaccumulation:** Not determined
- **Aquatic toxicity:** Not applicable
- **Ecotoxicity effects:**

### 13. DISPOSAL CONSIDERATIONS

**Waste from residues / unused products:** Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous.
H. TRANSPORT INFORMATION

Is product hazardous to ship?  Yes

DOT

<table>
<thead>
<tr>
<th>Proper shipping name: Sodium hydroxide solution</th>
<th>Hazard class: 8</th>
<th>Subsidiary risk: Not applicable</th>
<th>Packing group: III</th>
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</thead>
<tbody>
<tr>
<td>UN Number: UN 1824</td>
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ICAO/IATA

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I. REGULATORY INFORMATION

U.S. Regulations:

U.S. TSCA/SARA/CERCLA Regulatory Information:  The following chemicals are listed under the following TSCA/SARA/CERCLA lists

<table>
<thead>
<tr>
<th>Components</th>
<th>CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)</th>
<th>CERCLA/SARA 304 RQ (40 CFR Table 302.4)</th>
<th>SARA 313 Emission reporting</th>
<th>TSCA Inventory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>= 1000 lb final RQ</td>
<td>= 454 kg final RQ</td>
<td></td>
<td>XU</td>
</tr>
<tr>
<td>Sodium borate</td>
<td></td>
<td></td>
<td></td>
<td>Present</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)</th>
<th>CERCLA/SARA 304 RQ (40 CFR Table 302.4)</th>
<th>SARA 313 Emission reporting</th>
<th>TSCA Inventory</th>
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<tbody>
<tr>
<td>Sodium borate</td>
<td></td>
<td></td>
<td></td>
<td>Present</td>
</tr>
<tr>
<td>Picric Acid</td>
<td></td>
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<td>Listed</td>
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U.S. Clean Air Act (CAA):  The following chemicals are listed under the following CAA lists

U.S. Clean Water Act (CWA):  The following chemicals are listed under the following CWA lists

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<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>Present</td>
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California Safe Drinking Water and Toxic Enforcement Act (Prop 65):  The following chemicals are listed under the California Prop 65 list

Canadian Regulations:

Canada DSL Inventory List -  This product complies with DSL
Canada NDSL Inventory List -  This product does not comply with NDSL

<table>
<thead>
<tr>
<th>Components</th>
<th>Canada - WHMIS: Classifications of Substances:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>E</td>
</tr>
</tbody>
</table>

<table>
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</tr>
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<tbody>
<tr>
<td>Picric Acid</td>
<td>C; E; F</td>
</tr>
</tbody>
</table>

OTHER INFORMATION

Reason for revision:  Not applicable
References:  None.
Additional advice:  None
Prepared by:  Roche Diagnostics Corporation, Safety and Environmental Department, MSDS Contact: 317-521-7425

Product number:  47002  Page 4 of 5
Product name:  Creatinine
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End of Safety Data Sheet