SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: KOVA-Trol® III Normal (60mL and 15mL)

Product Component: 87327, 87328, 87331, 87528, 87327E, 87328E, 87331E, 87528E, 87327M, 87331M

1.2. Intended Use of the Product

Use of the Substance/Mixture: For in vitro diagnostic use only.

1.3. Name, Address, and Telephone of Manufacturer/Supplier

Kova International, Inc.
7272 Chapman Avenue, Suite B
Garden Grove, CA 92841
Tel: 1-714-902-1700
Fax: 1-714-908-7945
Business hours: (8:00 a.m. - 5:00 p.m., PST, Monday - Friday)

1.4. Emergency Telephone Number

Emergency Number: Contact your local Poison Center.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Repr. 2  H361

Full text of hazard classes and H-statements: see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :

Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H361 - Suspected of damaging fertility or the unborn child.

Precautionary Statements (GHS-US) :
P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves, protective clothing, and eye protection.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions. May cause an allergic reaction in sensitive individuals.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product Identifier</th>
<th>%</th>
<th>GHS-US classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine, Human</td>
<td>(CAS No) Not applicable</td>
<td>50</td>
<td>Not classified</td>
</tr>
<tr>
<td>Water</td>
<td>(CAS No) 7732-18-5</td>
<td>49.44</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium phosphate dibasic</td>
<td>(CAS No) 7558-79-4</td>
<td>0.25</td>
<td>Not classified</td>
</tr>
<tr>
<td>Gonadotropin, chorionic</td>
<td>(CAS No) 9002-61-3</td>
<td>0.12</td>
<td>Repr. 2, H361</td>
</tr>
<tr>
<td>Phosphoric acid, potassium salt (1:1)</td>
<td>(CAS No) 7778-77-0</td>
<td>0.1</td>
<td>Not classified</td>
</tr>
</tbody>
</table>
**KOVA-Trol® III Normal (60mL and 15mL)**

**Safety Data Sheet**

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide*</td>
<td>1310-73-2</td>
<td>H290</td>
<td>1A, H314</td>
<td>1, H318</td>
<td>3, H402</td>
<td>2, H401</td>
</tr>
<tr>
<td>Hydrochloric acid*</td>
<td>7647-01-0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>1A, H317</td>
<td>1B, H314</td>
<td>3, H335</td>
<td>2, H334</td>
<td></td>
</tr>
<tr>
<td>4H-Imidazol-4-one, 2-amino-1,5-dihydro-1-methyl-</td>
<td>60-27-5</td>
<td>Not classified</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D-erythro-Hex-2-enonic acid, .gamma.-lactone</td>
<td>89-65-6</td>
<td>2, H315</td>
<td>2A, H319</td>
<td>3, H335</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

* These components are added to adjust pH as necessary.

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### Full text of H-phrases: see section 16

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**SECTION 4: FIRST AID MEASURES**

#### 4.1 Description of First-aid Measures

**First-aid Measures General**: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

**First-aid Measures After Inhalation**: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**First-aid Measures After Skin Contact**: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact**: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

**First-aid Measures After Ingestion**: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

#### 4.2 Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries After Inhalation**: Prolonged exposure may cause irritation. May cause exacerbation of asthma if mist is inhaled.

**Symptoms/Injuries After Skin Contact**: Prolonged exposure may cause skin irritation. May cause an allergic reaction in sensitive individuals.

**Symptoms/Injuries After Eye Contact**: May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion**: Ingestion may cause adverse effects.

**Chronic Symptoms**: Suspected of damaging fertility or the unborn child.

#### 4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

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**SECTION 5: FIRE-FIGHTING MEASURES**

#### 5.1 Extinguishing Media

**Suitable Extinguishing Media**: Water spray, dry chemical, foam, carbon dioxide.

**Unsuitable Extinguishing Media**: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

#### 5.2 Special Hazards Arising From the Substance or Mixture

**Fire Hazard**: Not considered flammable but may burn at high temperatures.

**Explosion Hazard**: Product is not explosive.

**Reactivity**: Hazardous reactions will not occur under normal conditions.

#### 5.3 Advice for Firefighters

**Precautionary Measures Fire**: Exercise caution when fighting any chemical fire.

**Firefighting Instructions**: Use water spray or fog for cooling exposed containers. Remove containers from fire area if this can be done without risk. Do not breathe fumes from fires or vapors from decomposition.

**Protection During Firefighting**: Do not enter fire area without proper protective equipment, including respiratory protection.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

6.1. **Personal Precautions, Protective Equipment and Emergency Procedures**

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray.

6.1.1. **For Non-Emergency Personnel**

Protective Equipment: Use appropriate personal protection equipment (PPE).


6.1.2. **For Emergency Personnel**

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. **Environmental Precautions**

Prevent entry to sewers and public waters.

6.3. **Methods and Materials for Containment and Cleaning Up**

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Ventilate area. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. **Reference to Other Sections**

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

**SECTION 7: HANDLING AND STORAGE**

7.1. **Precautions for Safe Handling**

Precautions for Safe Handling: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not get in eyes, on skin, or on clothing. Do NOT breathe (dust, vapor, mist, gas).

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash contaminated clothing before reuse.

7.2. **Conditions for Safe Storage, Including Any Incompatibilities**

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep only in original container. Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up.

Incompatible Products: Strong acids, strong bases, strong oxidizers. Water reactive materials.

Storage Temperature: 2 - 8 °C (35.6 to 46.4°F)

7.3. **Specific End Use(s)**

For in vitro diagnostic use only.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

8.1. **Control Parameters**

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

<table>
<thead>
<tr>
<th>Substance</th>
<th>USA ACGIH (1310-73-2)</th>
<th>USA NIOSH</th>
<th>USA IDLH</th>
<th>USA OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>ACGIH Ceiling (mg/m³)</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NIOSH REL (ceiling) (mg/m³)</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>US IDLH (mg/m³)</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>OSHA PEL (TWA) (mg/m³)</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrochloric acid (7647-01-0)</td>
<td>ACGIH Ceiling (ppm)</td>
<td>2 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ACGIH chemical category</td>
<td>Not Classifiable as a Human Carcinogen</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NIOSH REL (ceiling) (mg/m³)</td>
<td>7 mg/m³</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>US IDLH (ppm)</td>
<td>50 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>OSHA PEL (Ceiling) (mg/m³)</td>
<td>7 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>OSHA PEL (Ceiling) (ppm)</td>
<td>5 ppm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8.2. Exposure Controls

Appropriate Engineering Controls: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Local exhaust and general ventilation must be adequate to meet exposure standards. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. Ensure all national/local regulations are observed.


Materials for Protective Clothing: Chemically resistant materials and fabrics.
Hand Protection: Wear protective gloves.
Eye Protection: Chemical safety goggles.
Skin and Body Protection: Wear suitable protective clothing. In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact is possible.
Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
Environmental Exposure Controls: Avoid release to the environment.
Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State: Liquid
Appearance: No data available
Odor: No data available
Odor Threshold: No data available
pH: No data available
Evaporation Rate: No data available
Melting Point: No data available
Freezing Point: No data available
Boiling Point: No data available
Flash Point: No data available
Auto-ignition Temperature: No data available
Decomposition Temperature: No data available
Flammability (solid, gas): No data available
Vapor Pressure: No data available
Relative Vapor Density at 20°C: No data available
Relative Density: No data available
Solubility: No data available
Partition Coefficient: N-Octanol/Water: No data available
Viscosity: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.
10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).
10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials.
KOVA-Trol® III Normal (60mL and 15mL)

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10.5. **Incompatible Materials:** Strong acids, strong bases, strong oxidizers. Water reactive materials.

10.6. **Hazardous Decomposition Products:** Under normal conditions of storage and use, hazardous decomposition products should not be produced.

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1. Information on Toxicological Effects

**Acute Toxicity:** Not classified

| Substance                                                      | Route          | Toxicity     |
|                                                               |                |             |
| **Gentamicin (1403-66-3)**                                    | Oral Rat       | 6600 mg/kg  |
| **Sodium phosphate dibasic (7558-79-4)**                      | Oral Rat       | > 2000 mg/kg|
|                                                               | Dermal Rat     | > 2000 mg/kg|
| **D-erythro-Hex-2-enonic acid, \( \gamma \)-lactone (89-65-6)** | Oral Rat       | 18 g/kg     |
|                                                               | Dermal Rabbit  | 18,000.00 mg/kg body weight |

**Skin Corrosion/Irritation:** Not classified

**Serious Eye Damage/Irritation:** Not classified

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

**Hydrochloric acid (7647-01-0)**

| Route          | Toxicity     |
|                |              |
| LD50 Dermal Rabbit | > 5010 mg/kg |

**Ingestion:**

- **Chronic Symptoms:** Suspected of damaging fertility or the unborn child.

**Skin Contact:**

- **Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation. May cause an allergic reaction in sensitive individuals.

**Eye Contact:**

- **Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Inhalation:**

- **Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation. May cause exacerbation of asthma if mist is inhaled.

#### 11.2. Specific Target Organ Toxicity

**Single Exposure:** Not classified

**Repeated Exposure:** Not classified

**Aspiration Hazard:** Not classified

**Hydrochloric acid (7647-01-0)**

| Route          | Toxicity     |
|                |              |
| IARC group     | 3            |

**Reproductive Toxicity:** Suspected of damaging fertility or the unborn child.

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation. May cause exacerbation of asthma if mist is inhaled.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation. May cause an allergic reaction in sensitive individuals.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** Suspected of damaging fertility or the unborn child.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1. Toxicity

**Ecology - General:** Not classified.

| Substance                        | Value                              |
|                                 |                                   |
| **Sodium hydroxide (1310-73-2)** |                                   |
| LC50 Fish 1                      | 45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |
| EC50 Daphnia 1                   | 40 mg/l                            |
| **Hydrochloric acid (7647-01-0)**|                                   |
| LC50 Fish 1                      | 7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h) |

#### 12.2. Persistence and Degradability

**KOVA-Trol® III Normal (60mL and 15mL)**

- **Persistence and Degradability:** Not established.

#### 12.3. Bioaccumulative Potential

**KOVA-Trol® III Normal (60mL and 15mL)**

- **Bioaccumulative Potential:** Not established.

#### 12.4. Mobility in Soil

- **No additional information available**

#### 12.5. Other Adverse Effects

**Other Information:** Avoid release to the environment.

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**SDS 04A.4**

EN (English US) 5/7
**SECTION 13: DISPOSAL CONSIDERATIONS**

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment.

**SECTION 14: TRANSPORT INFORMATION**

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

**SECTION 15: REGULATORY INFORMATION**

15.1. US Federal Regulations

Kova-Trol III Normal (60mL and 15mL)

SARA Section 311/312 Hazard Classes Delayed (chronic) health hazard

Sodium phosphate dibasic (7558-79-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ 5000 lb

Phosphoric acid, potassium salt (1:1) (7778-77-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

D-erythro-Hex-2-enonic acid, ,gamma.-lactone (89-65-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

4H-Imidazol-4-one, 2-amino-1,5-dihydro-1-methyl- (60-27-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ 1000 lb

Hydrochloric acid (7647-01-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Subject to reporting requirements of United States SARA Section 302

Listed on the United States SARA Section 302 Threshold Planning Quantity (TPQ) 500 lb (gas only)

EPA TSCA Regulatory Flag T - T - indicates a substance that is the subject of a Section 4 test rule under TSCA

CERCLA RQ 5000 lb

SARA Section 302 Threshold Planning Quantity (TPQ) 500 lb (gas only)

SARA Section 313 - Emission Reporting 1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

15.2. US State Regulations

Sodium phosphate dibasic (7558-79-4)

U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
U.S. - Pennsylvania - RTK (Right to Know) List

Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
U.S. - Pennsylvania - RTK (Right to Know) List

Hydrochloric acid (7647-01-0)

U.S. - Massachusetts - Right To Know List
SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date: 09/16/2016
Other Information: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

<table>
<thead>
<tr>
<th>GHS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Acute 2</td>
<td>Hazardous to the aquatic environment - Acute Hazard Category 2</td>
</tr>
<tr>
<td>Aquatic Acute 3</td>
<td>Hazardous to the aquatic environment - Acute Hazard Category 3</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation Category 1</td>
</tr>
<tr>
<td>Eye Irrit. 2A</td>
<td>Serious eye damage/eye irritation Category 2A</td>
</tr>
<tr>
<td>Met. Corr. 1</td>
<td>Corrosive to metals Category 1</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>Reproductive toxicity Category 1B</td>
</tr>
<tr>
<td>Repr. 2</td>
<td>Reproductive toxicity Category 2</td>
</tr>
<tr>
<td>Resp. Sens. 1A</td>
<td>Respiratory sensitisation Category 1A</td>
</tr>
<tr>
<td>Skin Corr. 1A</td>
<td>Skin corrosion/irritation Category 1A</td>
</tr>
<tr>
<td>Skin Corr. 1B</td>
<td>Skin corrosion/irritation Category 1B</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>Skin corrosion/irritation Category 2</td>
</tr>
<tr>
<td>Skin Sens. 1A</td>
<td>Skin sensitization Category 1A</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity (single exposure) Category 3</td>
</tr>
<tr>
<td>H290</td>
<td>May be corrosive to metals</td>
</tr>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H334</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled</td>
</tr>
<tr>
<td>H335</td>
<td>May cause respiratory irritation</td>
</tr>
<tr>
<td>H360</td>
<td>May damage fertility or the unborn child</td>
</tr>
<tr>
<td>H361</td>
<td>Suspected of damaging fertility or the unborn child</td>
</tr>
<tr>
<td>H401</td>
<td>Toxic to aquatic life</td>
</tr>
<tr>
<td>H402</td>
<td>Harmful to aquatic life</td>
</tr>
</tbody>
</table>

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)