# SECTION 1: IDENTIFICATION

## 1.1. Product Identifier

**Product Form:** Mixture  
**Product Name:** TRALEMENT™ (trace elements injection 4*, USP)  
*zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg*  
**Product Code:** 0517-9305-25; 0517-9305-01

## 1.2. Intended Use of the Product

**Use of the Substance/Mixture:** Tralement is a fixed-dose combination of four trace elements indicated in adults and pediatric patients weighing at least 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

## 1.3. Name, Address, and Telephone of the Responsible Party

**Company**  
American Regent, Inc.  
5 Ramsey Road  
Shirley, NY 11967  
1-800-645-1706  
www.americanregent.com

## 1.4. Emergency Telephone Number

**Emergency Number:** CHEMTREC 1-800-424-9300

# SECTION 2: HAZARDS IDENTIFICATION

## 2.1. Classification of the Substance or Mixture

| Skin Corr. | H314  
| Eye Dam. | H318  
| Aquatic Acute | H402  
| Aquatic Chronic | H412 |

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

## 2.2. Label Elements

**GHS-US Labeling**

<table>
<thead>
<tr>
<th>Hazard Pictograms (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="GHS05" /></td>
</tr>
</tbody>
</table>

**Signal Word (GHS-US):** Danger

**Hazard Statements (GHS-US):**  
H314 - Causes severe skin burns and eye damage.  
H318 - Causes serious eye damage.  
H402 - Harmful to aquatic life.  
H412 - Harmful to aquatic life with long lasting effects.

**Precautionary Statements (GHS-US):**  
P260 - Do not breathe vapors, mist, or spray.  
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.  
P273 - Avoid release to the environment.  
P280 - Wear protective gloves, protective clothing, and eye protection.  
P301+P330+P331 - If swallowed: rinse mouth. Do NOT induce vomiting.  
P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
P304+P340 - If inhaled: Keep person to fresh air and keep at rest in a position comfortable for breathing.  
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P310 - Immediately call a poison center or doctor.  
P321 - Specific treatment (see section 4 on this SDS).  
P363 - Wash contaminated clothing before reuse.  
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.

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>Synonyms</th>
<th>Product Identifier</th>
<th>%</th>
<th>GHS US classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water (injection purposes)</td>
<td>AQUA</td>
<td>(CAS-No.) 7732-18-5</td>
<td>98.535</td>
<td>Not classified</td>
</tr>
<tr>
<td>Zinc sulfate heptahydrate</td>
<td>Sulfuric acid, zinc salt (1:1), heptahydrate / Zinc sulfate heptahydrate (1:1:7) / Zinc sulphate heptahydrate / Zinc sulphate, heptahydrate / Zinc sulphate</td>
<td>(CAS-No.) 7446-20-0</td>
<td>1.32</td>
<td>Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410</td>
</tr>
<tr>
<td>Sulfuric acid, copper(2+) salt (1:1), pentahydrate</td>
<td>Copper(II) sulfate, pentahydrate (1:1:5) / Sulfuric acid, copper(2+) salt, pentahydrate / Copper sulphate, pentahydrate / Copper sulphate, pentahydrate / Copper sulphate pentahydrate / Copper(II) sulphate, pentahydrate / Copper(II) sulphate pentahydrate / Copper(II) sulphate pentahydrate / Copper(II) sulphate pentahydrate / Cupric sulphate pentahydrate / Copper(II) sulphate pentahydrate / Copper(II) sulphate pentahydrate / Cupric sulphate / Copper sulphate / Cupric sulphate / Copper sulphate</td>
<td>(CAS-No.) 7758-99-8</td>
<td>0.118</td>
<td>Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410</td>
</tr>
<tr>
<td>Manganese sulfate monohydrate</td>
<td>Manganese, monosulphate, monohydrate / Sulfuric acid, manganese(2+) salt (1:1), monohydrate / Manganese(II) sulphate monohydrate / Manganese sulphate monohydrate / Manganese(II) sulphate, monohydrate / Manganous sulphate monohydrate / Sulfuric acid, manganese(2+) salt, hydrate (1:1:1)</td>
<td>(CAS-No.) 10034-96-5</td>
<td>0.017</td>
<td>STOT RE 2, H373 Aquatic Chronic 2, H411</td>
</tr>
<tr>
<td>Sulfuric acid</td>
<td>Sulphuric acid / SULFURIC ACID / Hydrogen sulfite / Sulphuric acid ...% / Sulphuric acid ... %</td>
<td>(CAS-No.) 7664-93-9</td>
<td>&lt; 0.01</td>
<td>Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 3, H402</td>
</tr>
<tr>
<td>Selenious acid</td>
<td>Selenious acid (H2SeO3) / Selenous acid</td>
<td>(CAS-No.) 7783-00-8</td>
<td>0.01</td>
<td>Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Inhalation), H331 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410</td>
</tr>
</tbody>
</table>

Full text of H-phrases: see section 16

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).
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First-aid Measures After Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Immediately call a poison center or doctor/physician.
First-aid Measures After Skin Contact: Immediately remove contaminated clothing. Immediately flush skin with plenty of water for at least 30 minutes. Get immediate medical advice/attention.
First-aid Measures After Eye Contact: Immediately rinse with water for at least 30 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.
First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed
Symptoms/Injuries: Causes severe skin burns and eye damage.
Symptoms/Injuries After Inhalation: May be corrosive to the respiratory tract.
Symptoms/Injuries After Skin Contact: Causes severe irritation which will progress to chemical burns.
Symptoms/Injuries After Eye Contact: Causes permanent damage to the cornea, iris, or conjunctiva.
Symptoms/Injuries After Ingestion: May cause burns or irritation of the linings of the mouth, throat, and gastrointestinal tract.
Chronic Symptoms: None expected under normal conditions of use.

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.

SECTION 5: FIRE-FIGHTING MEASURES
5.1. Extinguishing Media
Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.
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: May react exothermically with water releasing heat. Adding an acid to a base or base to an acid may cause a violent reaction.

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.
Protection During Fighting: Do not enter fire area without proper protective equipment, including respiratory protection.
Other Information: Do not allow run-off from fire fighting to enter drains or water courses.

SECTION 6: ACCIDENTAL RELEASE MEASURES
6.1. Personal Precautions, Protective Equipment and Emergency Procedures
General Measures: Do not breathe vapor, mist or spray. Do not get in eyes, on skin, or on clothing.

6.1.1. For Non-Emergency Personnel
Protective Equipment: Use appropriate personal protective 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. Avoid release to the environment.

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. As an immediate precautionary measure, isolate spill or leak area in all directions.
Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill. Cautiously neutralize spilled liquid.

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
Additional Hazards When Processed: May release corrosive vapors.
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Precautions for Safe Handling: Do not breathe mist, spray, vapors. 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. Handle empty containers with care because they may still present a hazard.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store in original container or corrosive resistant and/or lined container. Store locked up/in a secure area.


Storage Temperature: Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].

7.3. Specific End Use(s)

Tralement is a fixed-dose combination of four trace elements indicated in adults and pediatric patients weighing at least 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

SECTION 8: EXPOSURE CONTROLS/PERSOAL 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>Sulfuric acid (7664-93-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA ACGIH ACGIH TWA (mg/m³)</td>
</tr>
<tr>
<td>USA ACGIH ACGIH chemical category</td>
</tr>
<tr>
<td>USA NIOSH NIOSH REL (TWA) (mg/m³)</td>
</tr>
<tr>
<td>USA IDLH US IDLH (mg/m³)</td>
</tr>
<tr>
<td>USA OSHA OSHA PEL (TWA) (mg/m³)</td>
</tr>
</tbody>
</table>

8.2. Exposure Controls

Appropriate Engineering Controls: Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.


Materials for Protective Clothing: Chemically resistant materials and fabrics. Corrosion-proof clothing.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles and face shield.

Skin and Body Protection: Wear suitable protective clothing.

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.

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

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear, colorless to slightly blue solution essentially free from visible particulates</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>1.5 - 3.5</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: May react exothermically with water releasing heat. Adding an acid to a base or base to an acid may cause a violent reaction.

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.


SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Not classified
Acute Toxicity (Dermal): Not classified
Acute Toxicity (Inhalation): Not classified

Sulfuric acid (7664-93-9)
LD50 Oral Rat 2140 mg/kg

Selenious acid (7783-00-8)
ATE (Oral) 100.00 mg/kg body weight
ATE (Gases) 700.00 ppmV/4h
ATE (Vapors) 3.00 mg/l/4h
ATE (Dust/Mist) 0.50 mg/l/4h

Sulfuric acid, copper(2+) salt (1:1), pentahydrate (7758-99-8)
LD50 Oral Rat 960 mg/kg
LD50 Dermal Rabbit > 8 g/kg

Zinc sulfate heptahydrate (7446-20-0)
LD50 Oral Rat 1260 mg/kg

Skin Corrosion/Irritation: Causes severe skin burns and eye damage.

pH: 1.5 - 3.5

Serious Eye Damage/Irritation: Causes serious eye damage.

pH: 1.5 - 3.5

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Sulfuric acid (7664-93-9)

IARC group 1

OSHA Hazard Communication Carcinogen List In OSHA Hazard Communication Carcinogen list.

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified
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Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: May be corrosive to the respiratory tract.
Symptoms/Injuries After Skin Contact: Causes severe irritation which will progress to chemical burns.
Symptoms/Injuries After Eye Contact: Causes permanent damage to the cornea, iris, or conjunctiva.
Symptoms/Injuries After Ingestion: May cause burns or irritation of the linings of the mouth, throat, and gastrointestinal tract.
Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Harmful to aquatic life with long lasting effects.

<table>
<thead>
<tr>
<th>Compounds</th>
<th>LC50 Fish 1</th>
<th>LC50 Fish 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfuric acid (7664-93-9)</td>
<td>500 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])</td>
<td>42 mg/l (Exposure time: 96 h - Species: Gambusia affinis [static])</td>
</tr>
<tr>
<td>Sulfuric acid, copper(2+) salt (1:1), pentahydrate (7758-99-8)</td>
<td>0.66 (0.66 - 1.15) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [semi-static])</td>
<td>0.147 (0.147 - 0.227) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])</td>
</tr>
<tr>
<td>Zinc sulfate heptahydrate (7446-20-0)</td>
<td>0.09 (0.09 - 0.19) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])</td>
<td></td>
</tr>
</tbody>
</table>

12.2. Persistence and Degradability

TRALEMENT™ (trace elements injection 4*, USP)
Persistence and Degradability: May cause long-term adverse effects in the environment.

12.3. Bioaccumulative Potential

TRALEMENT™ (trace elements injection 4*, USP)
Bioaccumulative Potential: Not established.

<table>
<thead>
<tr>
<th>Compounds</th>
<th>BCF Fish 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfuric acid (7664-93-9)</td>
<td>(no bioaccumulation)</td>
</tr>
</tbody>
</table>

12.4. Mobility in Soil: No additional information available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

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. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

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

<table>
<thead>
<tr>
<th>Compounds</th>
<th>Hazard Classes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tralement</td>
<td>Health hazard - Serious eye damage or eye irritation</td>
</tr>
<tr>
<td>SARA Section 311/312</td>
<td>Health hazard - Skin corrosion or Irritation</td>
</tr>
<tr>
<td>Water (injection purposes) (7732-18-5)</td>
<td>Listed on the United States TSCA (Toxic Substances Control Act) inventory</td>
</tr>
<tr>
<td>Sulfuric acid (7664-93-9)</td>
<td></td>
</tr>
</tbody>
</table>

The data provided is a snapshot and may not reflect the most current information.
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Listed on the United States TSCA (Toxic Substances Control Act) inventory
Listed on the United States SARA Section 302
Subject to reporting requirements of United States SARA Section 313

CERCLA RQ 1000 lb
SARA Section 302 Threshold Planning Quantity (TPQ) 1000 lb
SARA Section 313 - Emission Reporting 1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

Selenious acid (7783-00-8)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Listed on the United States SARA Section 302

CERCLA RQ 10 lb
SARA Section 302 Threshold Planning Quantity (TPQ) 1000 - 10000 lb

15.2. US State Regulations

Sulfuric acid (7664-93-9)
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

Selenious acid (7783-00-8)
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

California Proposition 65
WARNING: This product can expose you to Sulfuric acid, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

<table>
<thead>
<tr>
<th>Chemical Name (CAS No.)</th>
<th>Carcinogenicity</th>
<th>Developmental Toxicity</th>
<th>Female Reproductive Toxicity</th>
<th>Male Reproductive Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfuric acid (7664-93-9)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision: 10/26/2020
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:

- Acute Tox. 3 (Inhalation) Acute toxicity (inhalation) Category 3
- Acute Tox. 3 (Oral) Acute toxicity (oral) Category 3
- Acute Tox. 4 (Oral) Acute toxicity (oral) Category 4
- Aquatic Acute 1 Hazardous to the aquatic environment - Acute Hazard Category 1
- Aquatic Acute 3 Hazardous to the aquatic environment - Acute Hazard Category 3
- Aquatic Chronic 1 Hazardous to the aquatic environment - Chronic Hazard Category 1
- Aquatic Chronic 2 Hazardous to the aquatic environment - Chronic Hazard Category 2
- Aquatic Chronic 3 Hazardous to the aquatic environment - Chronic Hazard Category 3
- Eye Dam. 1 Serious eye damage/eye irritation Category 1
- Met. Corr. 1 Corrosive to metals Category 1
- Skin Corr. 1 Skin corrosion/irritation Category 1
- Skin Corr. 1A Skin corrosion/irritation Category 1A
- STOT RE 2 Specific target organ toxicity (repeated exposure) Category 2
- STOT SE 3 Specific target organ toxicity (single exposure) Category 3
- H290 May be corrosive to metals
- H301 Toxic if swallowed
- H302 Harmful if swallowed
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H331</td>
<td>Toxic if inhaled</td>
</tr>
<tr>
<td>H335</td>
<td>May cause respiratory irritation</td>
</tr>
<tr>
<td>H373</td>
<td>May cause damage to organs through prolonged or repeated exposure</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life</td>
</tr>
<tr>
<td>H402</td>
<td>Harmful to aquatic life</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects</td>
</tr>
<tr>
<td>H411</td>
<td>Toxic to aquatic life with long lasting effects</td>
</tr>
<tr>
<td>H412</td>
<td>Harmful to aquatic life with long lasting effects</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.