

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. 1 H314

Eye Dam. 1 H318

Aquatic Acute 3 H402

Aquatic Chronic 3 H412

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) :

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: Remove 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.

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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

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

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

Hazardous Combustion Products: Sulfur oxides. Manganese oxides. Copper oxides. Carbon oxides (CO, CO₂).

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).

Emergency Procedures: Evacuate unnecessary personnel.

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.

Incompatible Materials: Strong acids, strong bases, strong oxidizers. Metals. Strong reducing agents. Alkalis.

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/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).

Sulfuric acid (7664-93-9)		
USA ACGIH	ACGIH TWA (mg/m ³)	0.2 mg/m ³ (thoracic particulate matter)
USA ACGIH	ACGIH chemical category	Suspected Human Carcinogen contained in strong inorganic acid mists
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	1 mg/m ³
USA IDLH	US IDLH (mg/m ³)	15 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	1 mg/m ³

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.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Face shield. Insufficient ventilation: wear respiratory protection.



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

Physical State

: Liquid

Appearance

: Clear, colorless to slightly blue solution essentially free from visible particulates

Odor

: No data available

Odor Threshold

: No data available

pH

: 1.5 - 3.5

Evaporation Rate

: No data available

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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)	: Not applicable
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:** 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.
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers. Metals. Strong reducing agents. Alkalis.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition generates : Corrosive vapors.

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.

Sulfuric acid (7664-93-9)	
LC50 Fish 1	500 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])
LC50 Fish 2	42 mg/l (Exposure time: 96 h - Species: Gambusia affinis [static])
Sulfuric acid, copper(2+) salt (1:1), pentahydrate (7758-99-8)	
LC50 Fish 1	0.66 (0.66 - 1.15) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [semi-static])
EC50 Daphnia 1	0.147 (0.147 - 0.227) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 Fish 2	0.09 (0.09 - 0.19) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
Zinc sulfate heptahydrate (7446-20-0)	
LC50 Fish 1	0.169 mg/l Oncorhynchus Mykiss at neutral/high pH and low hardness
EC50 Daphnia 1	0.068 ml/l (Exposure time: 48 h - Species: Daphnia magna)
NOEC Chronic Fish	<= 0.0749 mg/l (Zinc)

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.
Sulfuric acid (7664-93-9)	
BCF Fish 1	(no bioaccumulation)

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

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

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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.

Chemical Name (CAS No.)	Carcinogenicity	Developmental Toxicity	Female Reproductive Toxicity	Male Reproductive Toxicity
Sulfuric acid (7664-93-9)	X			

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

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H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H331	Toxic if inhaled
H335	May cause respiratory irritation
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

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)