

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Vashe® Wound Solution

1.2. Intended Use of the Product

Use of the Substance/Mixture: Topical Applications/Cleansing, Irrigating, Moistening, Debridement

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

Company

Urgo Medical North America

3801 Hulen Street

Suite 251

Fort Worth, TX 76107

(817) 885-8273

www.urgomedical.us

1.4. Emergency Telephone Number

Emergency Number : (855) 888-8273

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable according to 29 CFR 1910.1200.

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	AQUA / Aqua	(CAS-No.) 7732-18-5	99.6	Not classified
Sodium chloride	Sea salt / Sodium chloride (NaCl) / SODIUM CHLORIDE / Sodium salt of hydrochloric acid / Salt / SEA SALT	(CAS-No.) 7647-14-5	0.4	Not classified
Hypochlorous acid	Hydroxychloride	(CAS-No.) 7790-92-3	<= 0.033	Not classified

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: First aid measures are not required for this product. The need for first aid is not anticipated under normal conditions of use.

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: Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/Injuries After Inhalation: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Symptoms/Injuries After Skin Contact: Not irritating to skin.

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

Symptoms/Injuries After Ingestion: Ingestion is not expected to be harmful.

Chronic Symptoms: None known.

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

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, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

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.

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

Hazardous Combustion Products: Sodium oxides, Chlorine gas .

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: No special precautions required.

6.1.1. For Non-Emergency Personnel

No additional information available

6.1.2. For Emergency Personnel

No additional information available

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Absorb and/or contain spill with inert material.

Methods for Cleaning Up: Transfer spilled material to a suitable container for disposal. Clean up spills immediately and dispose of waste safely.

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: Wash hands and other exposed areas with water before eating, drinking or smoking and when leaving work. Avoid breathing vapors.

Handling Temperature: 0 - 50 °C

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.

Incompatible Materials: Strong acids, strong bases, strong oxidizers. Heavy metals, reducing agents, ammonia, ether, hydrogen peroxide, chlorhexidine gluconate and silver nitrate.

Storage Temperature: Do not expose product to temperature below 0°C (32°F) or above 50°C (122°F). Do not freeze. Store at room temperature between 5°C (41°F) and 25°C (77°F) away from direct sunlight and heat.

7.3. Specific End Use(s)

Topical Applications/Cleansing, Irrigating, Moistening, Debridement

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).

8.2. Exposure Controls

Appropriate Engineering Controls : Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment : Not generally required. The use of personal protective equipment may be necessary as conditions warrant.

Eye and Face Protection : Not generally required. The use of personal protective equipment, goggles or safety glasses, may be necessary as conditions warrant.

Skin and Body Protection : Not generally required. The wear of suitable protective clothing may be necessary as conditions warrant.

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- Respiratory Protection** : Not generally required. 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 liquid
Odor	: Slight chlorine
Odor Threshold	: No data available
pH	: 3.5 - 6.75
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: 100 °C (212 °F) Decomposes
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
Specific Gravity	: 1.01 g/ml @20°C
Solubility	: Soluble
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. Do not expose product to temperature below 0°C (32°F) or above 50°C (122°F). Do not Freeze.
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers. Heavy metals, reducing agents, ammonia, ether, hydrogen peroxide, chlorhexidine gluconate and silver nitrate.
- 10.6. Hazardous Decomposition Products:** None expected under normal conditions of use.

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

Vashe® Wound Solution	
LD50 Oral Rat	5 g/kg Vashe® solution at a concentration of 530ppm AFC and a pH of 5.9 when tested in the Acute Oral toxicity (FHSA method) (Ref. ISO 10993-11) showed no oral toxicity at a dose of 5 g/kg by the oral route in a rat.
Sodium chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 g/m ³ (Exposure time: 1 h)

Skin Corrosion/Irritation: Not classified (pH: 3.5 - 6.75)

Serious Eye Damage/Irritation: Vashe® solution was evaluated for the potential to product ocular irritation in rabbits based on the requirements of ISO 10993-10. No irritation was observed. Vashe® solution was not considered an irritant. (pH: 3.5 - 6.75)

Respiratory or Skin Sensitization: No sensitizing reaction was observed for guinea pigs.

Germ Cell Mutagenicity: Results demonstrated that Vashe® solution at a concentration of 530ppm AFC and a pH of 5.9 when tested in the Bacterial Mutagenicity Assay (Ames method) (Ref. ISO 10993- 3) showed no mutagenic activity.

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Carcinogenicity: Not classified

Cytotoxicity: Results demonstrated that Vashe® solution at a concentration of 495ppm AFC and a pH of 4.4, and at a concentration of 332 ppm and pH of 3.0, when tested in the ISO- 10993-5 Cytotoxicity test (Agar Diffusion Assay) showed no cytotoxicity (a score of 0). The studies demonstrate that Vashe® is also non-cytotoxic at a concentration of 450ppm AFC and at a pH of 4.4, and at a concentration of 330 ppm and at a pH of 3.0.

Biocompatibility: Previous GLP studies performed to ISO 10993-5 standards have demonstrated that Vashe® is biocompatible at a concentration of greater than 330ppm AFC in the standard pH range (3.5- 6. 75).

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Symptoms/Injuries After Skin Contact: Not irritating to skin.

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

Symptoms/Injuries After Ingestion: Ingestion is not expected to be harmful.

Chronic Symptoms: None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General	Not classified.
Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (5560 - 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 Daphnia 1	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	340.7 (340.7 - 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)

12.2. Persistence and Degradability

Vashe® Wound Solution	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Vashe® Wound Solution	
Bioaccumulative Potential	Not established.
Sodium chloride (7647-14-5)	
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.

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

Sodium chloride (7647-14-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Hypochlorous acid (7790-92-3)

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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

15.2. US State Regulations Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed

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

Date of Preparation or Latest Revision : 10/05/2020

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

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)