SECTION 1: IDENTIFICATION

Product identifier

Trade name: PULSAR II™ Disposable Pulse Irrigation Kits

Recommended use and restriction on use

Recommended use:

The Disposable Pulse Irrigation Kit, is an instrument designed to irrigate wound and remove infectious microorganisms, foreign debris, and necrotic tissue from the wound. The irrigation bag is used to accompany with the Pulsar II™ Pulse Irrigator as a closed protective cover, and collect contaminated fluid for professional disposal.

Restrictions on use:

Gangrene	Wet gangrene or dry gangrene(toe or extremity)
Deep soft tissue infection (untreated)	Necrotizing fasciitis needs primary surgical debridement first, followed by use of disposable pulse irrigation kit as secondary to manage the open wound bed.
Exposed soft organ tissue	lung, heart, eye ,trachea, nerve, brain, bladder, liver, spleen, pancreas.
Exposed vascular structures or prosthetics	
Major arteries and major veins and vascular grafts	
Malignancy(untreated)	Biopsy proven malignancy

SECTION 2: HAZARDS IDENTIFICATION

Emergency Overview

The product contains alkaline battery size AA LR6 1.5V. The hazards come from that the batteries may explode or leak, and cause injury, if recharged, disposed of in fire, mixed with a different battery type, inserted backwards or disassembled. Replaces all used batteries at the time. Do not carry batteries loose in your pocket or purse. Do not remove te battery label.

Potential Health Effects

Eye Contact	Contact with battery contents may cause severe irritation and burns.
Skin Contact	Contact with battery contents may cause severe irritation and burns.
Inhalation	Inhalation of vapors of fumes released due to heated or a large number of leaking batteries may respiratory and eye irritation.
Ingestion	Swallowing is not anticipated due to battery size. Ingestion of battery contents(from a leaking battery) may cause mouth, throat and intestinal burns and damage.

SECTION 3: INFORMATION ON MATERIALS THAT MAY COME INTO CONTACT WITH THE HUMAN BODY

List of Components	REF Number	Ingredients	CAS#
PULSAR II Irrigator/ Kit	209-00/209-04/209-06	Polycarbonate Acrylonitrile Butadiene Styrene	25037-45-0 9003-56-9
Standard Tip	209-00-68	Polyamide 66 Styrene Methyl Methacrylate Copolymer	32131-17-2 N/A
Tunnel Tip	209-00-47	Polyvinyl Chloride NAS 30 ACRYLIC SMMA	9002-86-2 N/A
Hydra Adaptor	209-00-64	Silicon Rubber NBR	N/A N/A
Disposable Irrigation Bag	210-05 210-08	Low Density Polyethylene 3M™ Double Coated Medical Tape 9889	9002-88-4 N/A

SECTION 4: FIRST AID MEASURES

Eye Contact

If battery is leaking and material contacts the eyes, flush throughly with copious amount of running water for 30 minutes. Seek immediate medical advise.

Skin contact

If battery is leaking and material contacts the skin, remove any contaminated clothing and flush exposed skin with copious amounts of running water for at least 15 minutes. If irritation, injury or pain persists, seek medical advice.

Inhaled

If battery is leaking, contents may be irritating to respiratory passage. Move to fresh air. If irritation persists, seek medical advice.

Swallowed

If battery contents are swallowed, do not induce vomiting. If the victim is alert, have them rinse their mouth are the surrounding skin with water for at least 15 minutes. Seek immediate medical attention.

SECTION 5: FIRE FIGHTING MEASURES

Fire and Explosion Hazards

Battery may burst and release hazardous decomposition products when exposed to fire situation.

Extinguishing Media

Use any extinguishing media that is appropriate for the surrounding fire.

Special Fire Fighting Procedures

Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing. Fight fire from a distance or protected area. Cool fire exposed batteries to prevent rupture . Use caution when handling fire- exposed containers.

Hazardous Combustion Products

Thermal degradation may produce hazardous fumes of zinc and manganese; hydrogen gas, caustic vapors of potassium hydroxide and other toxic by-products.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Notify safety personnel of large spills. Caustic potassium hydroxide may be released from leaking or ruptured batteries. Clean-up personnel should wear appropriate protective clothing to avoid eye and skin contact and inhalation of vapors of fumes. Increase ventilation. Carefully collect batteries and place in an appropriate container for disposal.

SECTION 7: HANDLING AND STORAGE

Handling

The materials and components used in this device were selected to ensure that the device could be shipped by any standard commercial method without special handling conditions.

Storage

Environment temperature	-20℃-49℃
Environment humidity	0-90%

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

The product does not contain any relevant quantities of materials with critical values that have to be monitored at workplace. No exposure to the battery components should occur during normal consumer use.

Ventilation	No special ventilation is needed for normal use.
Respiratory Protection	None required for normal use.
Skin Protection	None required for normal use.
Eye Protection	None required for normal use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor	Solid object / no odor
Boiling point @ 760 mm Hg （℃）	Not applicable for an article
Water Solubility（mm Hg 25℃）	Insoluble
Vapor Pressure	Not applicable for an article
Vapor Density (Air=1)	Not applicable for an article
Percent Volatile by Volume (%)	Not applicable for an article
Evaporation Rate (Buty1 Acetate=1)	Not applicable for an article
PH	Not applicable for an article

SECTION 10: STABILITY AND REACTIVITY

Stability	The product is stable
Incompatibility/ Conditions to avoid	Contents are incompatible with strong oxidizing agents. Do not heat, crush, disassemble, short circuit or recharge
Hazardous decomposition products	Thermal decomposition may produce hazardous fumes of zinc and manganese; caustic vapors of potassium hydroxide and other toxic by-products.
Hazardous polymerization	Will not occur

SECTION 11: TOXICOLOGICAL INFORMATION

Eye Contact

If battery is leaking and material contacts the eyes, flush throughly with copious amount of running water for 30 minutes. Seek immediate medical advise.

Skin contact

If battery is leaking and material contacts the skin, remove any contaminated clothing and flush exposed skin with copious amounts of running water for at least 15 minutes. If irritation, injury or pain persists, seek medical advice.

Inhaled

If battery is leaking, contents may be irritating to respiratory passage. Move to fresh air. If irritation persists, seek medical advice.

Swallowed

If battery contents are swallowed, do not induce vomiting. If the victim is alert, have them rinse their mouth are the surrounding skin with water for at least 15 minutes. Seek immediate medical attention.

Acute Toxicity Data

Manganese Dioxide	LD 50 oral rat ＞3478 mg/kg
Potassium Hydroxide	LD 50 oral rat 273 mg/kg

Chronic Effects

The chemicals in the battery are contained in a sealed can and exposure dose not occur during normal handling and use. No chronic effects would be expected from handling a leaking battery.

Target Organs

Skin, eyes, and respiratory system.

Carcinogenicity

None of the components of this product are listed as carcinogens by ACGIH, IARC, NTP or OSHA.

SECTION 12: ECOLOGICAL INFORMATION

No ecotoxicity data is available. This product is not expected to present an environment hazard.

SECTION 13: DISPOSAL INFORMATION

Disposal should be in accordance with Federal, sate/provincal and local laws and regulations regarding treatment, storage and disposal for hazardous and nonhazardous wastes.

SECTION 14: TRANSPORT INFORMATION

Ground Transport (ADR/RID/US DOT)	49 CFR172.102 Special Provision 130
Air Transport (IATA)	Special Provision A123 (IATA DGR Edotion 2019-60th Edition
Marine/ Water Transport (IMDG/ICAO)	None

Note: Special provision apply and shippers should consult the most current versions of the transportation regulations.

SECTION 15: REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture.

United States (USA)

SARA

Section 302 (extremely hazardous substances)	None of the ingredients are listed
Section 355 (extremely hazardous substances)	None of the ingredients are listed
Section 313 (specific toxic chemical substances)	None of the ingredients are listed
TSCA (toxic substances control act)	All components of this product are listed

Proposition 65 (California)

This product has been evaluated and dose not require warning labeling under California proposition 65.

Carcinogenic categories

Environment protection agency	None of the ingredients are listed
International agency for research on cancer	None of the ingredients are listed
Nation institute for occupational safety and health	None of the ingredients are listed
Canadian Domestic Substances List (DSL)	All components of this product are listed

SECTION 16: OTHER INFORMATION

Reference: IATA DGR Edition 2019 (60th Edition)

Disclaimer:

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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