

1. IDENTIFICATION

Product identifier: Riodine Antiseptic Solution (15 mL, 100 mL, 500 mL)
Synonyms: 5000023709, 5000023710, 5000023707

Contact: Evaris Pharma
Address: 25-29 Delawney Street
 Balcatta, Western Australia, 6021

Telephone number: +61 8 9441 7800
Australia Emergency telephone: Poisons Information Centre: 13 11 26
New Zealand Emergency telephone: National Poisons Center: 0800764766

Recommended use: Antiseptic solution for treatment of skin wounds and infections.
Restrictions on use: None known.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not Hazardous	Not Hazardous

Label Elements

Not hazardous in accordance with the GHS, the WHS Regulations and HSNO Regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration	Substance Classification
Povidone Iodine (contains 11.3% iodine – hazard classification is based on iodine content)	25655-41-8	<10% (<1% iodine)	Skin Irritant 2 (H315) Eye Irritant 2A (H319) Specific Target Organ Toxicity – Single Exposure Category 3 (H335) Aquatic Acute Toxicity Category 1 (H400)

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin contact: This product is intended for use on the skin. If irritation develops and persists, discontinue use and get medical attention. Remove and contaminated clothing and launder it before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for several minutes. Remove contact lenses, if present and easy to do after 5 minutes of flushing, then continue flushing. Get medical attention if irritation persists.

Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Inhalation of mists may cause irritation of nose and throat.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not generally required.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any extinguishing media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Not flammable or combustible. Decomposition at high temperatures may release iodine vapours.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Stop spill at the source if it is safe to do so. Absorb with an inert material. Collect into a suitable container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid eye contact. Wash thoroughly after handling. Remove contaminated clothing and launder before re-use.

Conditions for safe storage, including any incompatibilities: Protect containers from physical damage. Store below 25°C.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Riodine Antiseptic Solution

Povidone Iodine (as iodine)	0.015mg/m ³ TWA (inhalable fraction and vapour) ACGIH TLV 0.1 ppm Peak AU OEL 0.1 ppm Ceiling NZ OEL
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Appropriate engineering controls: Use with adequate general or local exhaust ventilation to maintain exposure levels below occupational exposure limits.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, an approved supplied air respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with applicable regulations and good Industrial Hygiene practice.

Skin protection: Impervious gloves recommended for handling other than use.

Eye protection: Chemical safety goggles recommended if needed to avoid eye contact.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, colour, etc.): A dark brown liquid.

Odour: Characteristic odour (of iodine).

Odour threshold: 9 mg/m ³ (iodine)	pH: 3.0-5.5
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: None	Evaporation rate: Same as water
Flammability (solid, gas): Not applicable	VOC: Not determined
Flammable limits: LEL: None	UEL: None
Vapour pressure: Same as water	Vapour density: Same as water
Relative density: 1.03-1.05	Solubility(is): Miscible in water
Partition coefficient: n-octanol/water: Not determined	Auto-ignition temperature: Not determined
Decomposition temperature: Not determined	Viscosity: Not determined
Particle Characteristics: Not applicable	

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: Avoid heat.

Incompatible materials: None known.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides and iodine vapours.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract.

Ingestion: Swallowing may cause gastrointestinal irritation.

Skin contact: No adverse effects are expected. May cause mild irritation in some individuals.

Eye contact: Contact may cause mild irritation with redness and tearing.

Chronic Effects: Iodine may cause damage to the thyroid through prolonged or repeated exposure.

Acute Toxicity Values:

Povidone-Iodine: LD50 oral rat 8000 mg/kg

Skin Corrosion/Irritation: Not classified.

Serious Eye Damage/Irritation: Not classified.

Respiratory Sensitization: Not classified.

Skin Sensitization: Not classified as a sensitizer, however, some individuals may be allergic to iodine.

Germ Cell Mutagenicity: Not a germ cell mutagen. Iodine: The ability of povidone iodine to induce chromosome aberrations in D284 cells was evaluated in three different experiments. Povidone iodine did not induce chromosome aberrations with and without metabolic activation in D824 cells under testing conditions.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or ACGIH.

Reproductive Toxicity: Not a reproductive toxin. Iodine: A combined 28-day repeated dose toxicity study with the reproduction/developmental toxicity screening test was conducted with Iodine in rats by oral gavage. No reproduction/developmental toxicity was observed at any dose level. Based on these results, a reproduction and developmental No Observed Adverse Effect Level. (NOAEL) of 10 mg/kg was derived.

Specific Target Organ Toxicity (STOT) – single exposure: Not classified.

Specific Target Organ Toxicity (STOT) – repeated exposure: Not classified.

Aspiration Hazard: Not classified

12. ECOLOGICAL INFORMATION

Ecotoxicity values:

Iodine: Oncorhynchus mykiss LC50: 1.67 mg/L/96 hr, Daphnia magna LC50: 0.55 mg/L/48 hr, Desmodesmus subspicatus EC50: 0.13 mg/L/72 hr

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
IMDG		Not regulated			No
IATA		Not regulated			No
ADG		Not regulated			No

Hazchem Code: Not applicable

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP): Not scheduled

Australia Inventory: Drugs are not subject to the AICS.

New Zealand Inventory: Drugs are not subject to HSNO Act.

HSNO Number: Not Applicable

Agricultural Compounds and Veterinary Medicines Act 1997: Not applicable.

Montreal Protocol: Not applicable

Stockholm Convention: Not applicable

Rotterdam Convention: Not applicable

Basel Convention: Not applicable

International Convention on the Prevention of Pollution from Ships (MARPOL): Not applicable

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 0 Instability = 0
HMIS Rating: Health = 1 Flammability = 0 Physical Hazard = 0

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Full Text of GHS Classification and H Phrases from Section 3:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

List of Abbreviations or Acronyms:

ACGIH American Conference of Industrial Hygienists

ADG Australian Dangerous Goods

AICS Australian Inventory of Chemical Substances

AU Australia

EC Effective Concentration

EU European Union

GHS Globally Harmonized System of Classification and Labelling of Chemicals

HSNO Hazardous Substances and New Organisms

IARC International Agency of Research on Cancer

IATA International Air Transport Association

IMDG International Maritime Dangerous Goods

LC Lethal Concentration

LD Lethal Dosage

LEL Lower Explosive Limit

NTP National Toxicology Program

NZ New Zealand

OEL Occupational Exposure Limits

US OSHA United States Occupational Safety and Health Administration

PEL Permissible Exposure Limit

SDS Safety Data Sheet

STEL Short Term Exposure Limit

TWA Time-Weighted Average
UEL Upper Explosive Limit
VOC Volatile Organic Compounds
WES Workplace Exposure Standards
WHS Work Health and Safety

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