



SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: **Riodine S Surgical Scrub 500 mL**
Synonyms: **RIO00804F, RIO00605S**

Global Contact: Perrigo Company
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: +1 269-673-8451
Emergency telephone: **+1 888-464-2986**

Australian Contact: Perrigo Australia
Address: 25-29 Delawney Street
Balcatta, Western Australia 6021 Australia

Telephone number: +618 9441 7800
Emergency telephone: +1 760-476-3962 Code 333304
Poisons Information Centre: 13 11 26

New Zealand Contact: Orion Laboratories (NZ) Ltd
Address: PO Box 781
Whangaparaoa, New Zealand

Telephone number: +618 9441 7800
Emergency telephone: +1 760-476-3962 Code 333304
National Poisons Centre: 0800 764 766

Recommended use: Pre and post-operative scrub.
Restrictions on use: None known.

HSNO Number: Not Applicable

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not Hazardous	Skin Irritation Category 2 (H315) Eye Damage Category 1 (H318)

Label Elements

DANGER!



Hazard statement(s)

Causes skin irritation.
Causes serious eye damage.

Precautionary statement(s)

Wash hands thoroughly after handling.
Wear eye protection.

Precautionary statement(s)

IF in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical attention.
IF on skin: Wash with plenty of water. If skin irritation occurs: Get medical attention. Take off contaminated clothing and wash it before reuse.
Dispose of container and contents in compliance with all national and local regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration	Substance Classification
Ethoxylated nonylphenol, sulphate, ammonium salt	68649-55-8	10-30%	Skin Irritant 2 (H315) Eye Damage 1 (H318) Aquatic Acute Category 2 (H401) Aquatic Chronic Category 2 (H411)
Povidone Iodine (contains 10% iodine – hazard classification is based on iodine content)	25655-41-8	5-15% (0.5-1.5% iodine)	Skin Irritant 2 (H315) Eye Irritant 2A (H319) Specific Target Organ Toxicity – Single Exposure Category 3 (H335) Aquatic Acute Toxicity Category 1 (H400)
Lauric acid diethanolamide	120-40-1	<15%	Skin Irritant 2 (H315) Eye Damage 1 (H318) Aquatic Acute Category 2 (H401) Aquatic Chronic Category 2 (H411)
Ethanol	64-17-5	<10%	Flammable Liquid Category 2 (H225) Eye Irritation Category 2A (H319)
Non-hazardous ingredients	various	30-60%	Not hazardous

4. FIRST-AID MEASURES

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

Skin contact: This product is intended for use on the skin. Skin irritation is not expected when used as directed. If irritation develops and persists, discontinue use and get medical attention. Remove contaminated clothing and launder it before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for at least 20 minutes. Remove contact lenses, if present and easy to do after 5 minutes of flushing, then continue flushing. Get immediate medical attention.

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: Causes severe eye irritation with possible damage. May cause skin irritation, particularly on prolonged contact. May cause damage to the thyroid through prolonged or repeated exposure.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is recommended for eye contact.

5. FIRE-FIGHTING MEASURES

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

Specific hazards arising from the chemical: Not flammable but may burn under fire conditions emitting toxic iodine vapours. Contains a small amount of ethanol. Flammable ethanol vapours may be emitted and collect in confined areas.

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. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. Eliminate all ignition sources and ventilate the area. Caution: spill area will be slippery.

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: Prevent eye contact. Avoid breathing vapors or mists. Use with adequate ventilation. Wash thoroughly after handling. Remove contaminated clothing and launder before re-use. Keep product away from excessive heat, direct sunlight and flames. Do not leave the container in direct sunlight.

Conditions for safe storage, including any incompatibilities: Protect containers from physical damage. Store in a cool area. Keep away from excessive heat and open flames. Store out of direct sunlight. Store away from oxidizers. Store below 25°C.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Ethoxylated nonylphenol, sulphate, ammonium salt	None Established
Povidone Iodine (as iodine)	0.01 ppm TWA (inhalable fraction and vapor), 0.1 ppm STEL (vapor and aerosol) ACGIH TLV 0.1 ppm TWA AU OEL 0.1 ppm STEL NZ OEL
Ethanol	1000 ppm STEL ACGIH TLV 1000 ppm TWA AU OEL 1000 ppm TWA NZ OEL
Lauric acid diethanolamide	None Established

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 organic vapor with a particulate prefilter or 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.): Brown viscous liquid.

Odour: Characteristic odor (of iodine).

Odour threshold: Not determined	pH: 4.0-6.0
Melting point/freezing point: Not determined	Boiling Point: Approx. 100°C
Flash point: Not determined	Evaporation rate: Not determined
Flammability (solid, gas): Not applicable	VOC: Not determined
Flammable limits: LEL: 3% (ethanol)	UEL: 19% (ethanol)
Vapour pressure: <58.1 mbar 20°C (ethanol)	Vapour density: 1.59 (ethanol)
Relative density: 1.04	Solubility(is): Miscible in water
Partition coefficient: n-octanol/water: Not determined	Auto-ignition temperature: Not determined
Decomposition temperature: Not determined	Viscosity: Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: Reaction with strong oxidizers will generate heat and cause fire.

Conditions to avoid: Avoid excessive heat, direct sunlight and flames.

Incompatible materials: Avoid oxidizing agents, acids and bases.

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

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of vapors may cause irritation of the mucous membranes and upper respiratory tract and central nervous system effects such as dizziness, drowsiness and headache.

Ingestion: Swallowing may cause gastrointestinal irritation and nervous system effects such as drowsiness and dizziness.

Skin contact: May cause irritation on prolonged contact.

Eye contact: Contact causes severe irritation with redness, pain and tearing. Corneal damage is possible.

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

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

Germ Cell Mutagenicity: Not a germ cell mutagen. Ethanol did not induce mutations in mouse lymphoma L5178Y TK+/- cells and did not induce micronuclei in Chinese hamster V79 cells in the absence of metabolic activation. No chromosomal aberrations or sister chromatid exchanges were observed in Chinese hamster ovary cells treated with ethanol. Ethanol did not increase the frequency of micronuclei in the bone marrow of mice. 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.

Reproductive Toxicity: Not a reproductive toxin. Alcoholic beverages are known to cause developmental toxicity when intentionally ingested during pregnancy. 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.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or ACGIH. Ingestion of alcoholic beverages is known to cause cancer in humans (IARC group 1).

Acute Toxicity Values:

Ethanol: LD50 oral rat 7060 mg/kg; LC50 inhalation rat 20000 ppm/10 hr.

Povidone Iodine: LD50 oral rat 8000 mg/kg

Ethoxylated nonylphenol, sulphate, ammonium salt: LD50 oral rat >2000 mg/kg.

Lauric acid diethanolamide: LD50 oral rat >2000 mg/kg.

12. ECOLOGICAL INFORMATION

Ecotoxicity values:

Ethoxylated nonylphenol, sulphate, ammonium salt: Rainbow Trout: LC50 41mg/L/96hr

Ethanol: Rainbow Trout: LC50 13000mg/L/96hr, Daphnia magna: LC50 9268-14221 mg/L/48hr, Chlorella pyrenoidosa (green algae; growth inhibition) 9310 mg/L/48hr

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: Ethanol is readily biodegradable.

Bioaccumulative potential: Ethanol BCF= 3, potential for bioaccumulation is low

Mobility in soil: Ethanol is expected to have high mobility in soil.

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	UN3082	Environmentally Hazardous Substance, liquid, n.o.s. (Ethoxylated nonylphenol, sulphate, ammonium salt)	9	III	Marine Pollutant
IATA	UN3082	Environmentally Hazardous Substance, liquid, n.o.s. (Ethoxylated nonylphenol, sulphate, ammonium salt)	9	III	Yes
ADG	UN3082	Environmentally Hazardous Substance, liquid, n.o.s. (Ethoxylated nonylphenol, sulphate, ammonium salt)	9	III	Yes

Note: Per AU01 this product is not regulated when transported via road and rail

Note 2: This product is classified as a Marine Pollutant (Environmentally Hazardous Substance) in accordance with the IMDG Code and the UN Model Regulations. However, it is packaged in either single packages or inner packagings in combination packages containing net quantities of less than 5 kg/5 L (IMDG Code 2.10.2.7; ICAO Special Instruction A197) so is shipped unregulated. Shipment may be regulated if contents are removed from inner packaging and combined into containers exceeding 5 L or 5 kg.

Hazchem Code: ●3Z

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 and medical devices are not subject to AICS.

New Zealand Inventory: Drugs and medical devices are not subject to HSNO.

16. OTHER INFORMATION

NFPA Rating: Health = 3 Flammability = 1 Instability = 0
HMIS Rating: Health = 3 Flammability = 1 Physical Hazard = 0

SDS Revision History: Convert to AU/NZ GHS format

Date of preparation: 20 December 2016

Date of last revision: 10 June 2013

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

H225 Highly flammable liquid and vapor
H315 Causes skin irritation
H318 Causes serious eye damage.
H319 Causes serious eye irritation
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H401 Toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

List of Abbreviations or Acronyms:

ACGIH American Conference of Industrial Hygienists
ADG Australian Dangerous Goods
AICS Australian Inventory of Chemical Substances
A L'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

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).