1. IDENTIFICATION

Product identifier: Riodine Concentrated Gargle 15 mL

Synonyms: RIO02811F, RIO01149S

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: +61 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: Treatment of sore throat
Restrictions on use: None
HSNO Number: Not applicable

2. HAZARD(S) IDENTIFICATION

Classification:

<table>
<thead>
<tr>
<th>Physical</th>
<th>Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammable Liquid Category 3 (H226)</td>
<td>Eye Irritation Category 2A (H319)</td>
</tr>
</tbody>
</table>

Label Elements

Warning!
Hazard statement(s)

Flammable liquid and vapour
Causes serious eye irritation.

Precautionary statement(s)

Keep away from heat, sparks, open flames and hot surfaces. No smoking.
Keep container tightly closed.
Wear eye protection.

IF in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.
IF on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
In case of fire: Use water fog or spray, carbon dioxide, dry chemical or alcohol-resistant foam to extinguish.
Store in a well-ventilated place. Keep cool.
Dispose of container and contents in compliance with all national and local regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS No.</th>
<th>Concentration</th>
<th>Substance Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>30%</td>
<td>Flammable Liquid Category 2 (H225) Eye Irritation Category 2A (H319)</td>
</tr>
<tr>
<td>Povidone Iodine (contains 10% iodine – hazard classification is based on iodine content)</td>
<td>25655-41-8</td>
<td>7.5% (0.75% iodine)</td>
<td>Skin Irritant 2 (H315) Eye Irritant 2A (H319) Specific Target Organ Toxicity – Single Exposure Category 3 (H335) Aquatic Acute Toxicity Category 1 (H400)</td>
</tr>
<tr>
<td>Non-hazardous ingredients</td>
<td>various</td>
<td>62.5%</td>
<td>Not hazardous</td>
</tr>
</tbody>
</table>

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.
Skin contact: If irritation develops and persists get medical attention. Remove any contaminated clothing and launder it before reuse.
Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for at least 15 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: Causes eye irritation. Inhalation may cause headache and drowsiness. Prolonged skin contact may dry the skin. 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 not generally required.
5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water fog or spray, carbon dioxide, dry chemical or alcohol-resistant foam.

Specific hazards arising from the chemical: Flammable liquid and vapour. Vapours are heavier than air and can collect in low areas presenting a fire hazard.

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.

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. Avoid breathing vapours. Use only with adequate ventilation. Wash thoroughly after handling. Remove contaminated clothing and launder before re-use. Keep product away from heat, sparks and all other sources of ignition. 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. Keep containers closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Exposure Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>1000 ppm STEL ACGIH TLV</td>
</tr>
<tr>
<td></td>
<td>1000 ppm TWA AU OEL</td>
</tr>
<tr>
<td></td>
<td>1000 ppm TWA NZ OEL</td>
</tr>
<tr>
<td>Povidone Iodine (as iodine)</td>
<td>0.01 ppm TWA (inhalable fraction and vapour), 0.1 ppm STEL (vapour and aerosol) ACGIH TLV</td>
</tr>
<tr>
<td></td>
<td>0.1 ppm TWA AU OEL</td>
</tr>
<tr>
<td></td>
<td>0.1 ppm STEL NZ OEL</td>
</tr>
</tbody>
</table>

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels. Use explosion-proof equipment where required.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure levels are exceeded or irritation is experienced, an approved organic vapour 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 in occupational setting. 
Eye protection: Chemical safety goggles recommended if needed to avoid eye contact. 
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Odour threshold</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>&gt;2-6.5</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not determined</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not determined</td>
</tr>
<tr>
<td>Flash point</td>
<td>30.5°C (closed cup)</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not determined</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>59.3 mmHg @ 25°C (ethanol)</td>
</tr>
<tr>
<td>Vapour density</td>
<td>1.59 (ethanol)</td>
</tr>
<tr>
<td>Relative density</td>
<td>0.97-1.00</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not determined</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not determined</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not determined</td>
</tr>
</tbody>
</table>

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 heat, sparks, flames, and all other sources of ignition. 
Incompatible materials: Avoid oxidizing agents, acids and bases. 
Hazardous decomposition products: Thermal decomposition may yield carbon oxides and iodine vapours.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure: 
Inhalation: Inhalation of vapours 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: No adverse effects are expected. Prolonged skin contact may dry skin. 
Eye contact: Contact may cause irritation with redness, pain and tearing. 
Chronic Effects: Iodine 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. The ability of povidone iodine to induce chromosome aberrations in D284 cells was evaluated in three different experiments. Povidone iodine did not increase the frequency of micronuclei in V79 cells. 
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.
Concentrated Sore Throat Gargle

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

12. ECOLOGICAL INFORMATION

**Ecotoxicity values:** 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

<table>
<thead>
<tr>
<th>UN Number</th>
<th>Proper shipping name</th>
<th>Hazard Class</th>
<th>Packing Group</th>
<th>Environmental Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMDG</td>
<td>UN1170 Ethanol Solution</td>
<td>3</td>
<td>III</td>
<td>No</td>
</tr>
<tr>
<td>IATA</td>
<td>UN1170 Ethanol Solution</td>
<td>3</td>
<td>III</td>
<td>No</td>
</tr>
<tr>
<td>ADG</td>
<td>UN1170 Ethanol Solution</td>
<td>3</td>
<td>III</td>
<td>No</td>
</tr>
</tbody>
</table>

**Hazchem Code:** ●2YE

**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.
16. OTHER INFORMATION

**NFPA Rating:** Health = 1  Flammability = 3  Instability = 0
**HMIS Rating:** Health = 2  Flammability = 3  Physical Hazard = 0

**SDS Revision History:** Change flashpoint and classification (Sections 2, 5, 9, 14)
**Date of preparation:** 18 December 2016
**Date of last revision:** 22 August 2016

**Full Text of GHS Classification and H Phrases from Section 3:**
H225 Highly flammable liquid and vapour.
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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