

1. IDENTIFICATION

Product identifier : BIPP Gauze

Synonyms: 5000023543

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: Packing cavities following ear, nose or throat procedures.

Restrictions on use: None known.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not Hazardous	Acute Toxicity Category 4 (H302) Skin Irritant 2 (H315) Eye Irritant 2A (H319) Specific Target Organ Toxicity – Single Exposure Category 3 (H335) Specific Target Organ Toxicity – Repeated Exposure Category 1 (H372)

Label Elements:

DANGER:



Hazard statement(s)

Harmful if swallowed.

Causes serious eye irritation.

Causes skin irritation.

May cause respiratory irritation.

Causes damage to the thyroid through prolonged or repeated exposure if swallowed.

Precautionary statement(s)

Do not breathe dust.

Wash hands thoroughly after handling.

Do not eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Precautionary statement(s)

IF Swallowed: Call a poison center or doctor if you feel unwell. Rinse mouth.

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 INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell.

IF on skin: Wash with plenty of soap and water. If skin irritation occurs: Get medical attention. Take off contaminated clothing and wash it before reuse.

Get medical attention if you feel unwell.

Wear eye protection and protective gloves.

Store locked up

Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration	Substance Classification
Iodoform	7553-56-2	40-60%	Acute Toxicity Category 4 (H302, H312, H332) Skin Irritant 2 (H315) Eye Irritant 2A (H319) Specific Target Organ Toxicity – Single Exposure Category 3 (H335) Specific Target Organ Toxicity – Repeated Exposure Category 1 (H372) Aquatic Acute Toxicity Category 1 (H400)
Bismuth Subnitrate	1304-85-4	10-30%	Not Hazardous
Liquid Paraffin	8042-47-5	10-30%	Aspiration Hazard Category 1 (H304)

4. FIRST-AID MEASURES

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

Skin contact: Wash exposed skin thoroughly with soap and water. If irritation develops 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 for 15 minutes. 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: Harmful if swallowed. Causes eye and skin irritation. Inhalation of dusts from product may cause irritation of nose and throat. 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 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: Collect in a manner that does not generate dust. Place in a suitable container for disposal. Clean the area thoroughly.

7. HANDLING AND STORAGE

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

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Iodine	0.015mg/m ³ TWA (inhalable fraction and vapour) ACGIH TLV 0.1 ppm Peak AU OEL 0.1 ppm Ceiling NZ OEL
Bismuth Subnitrate	None Established
Liquid Paraffin	5 mg/m ³ (inhalable) TWA ACGIH TLV 5 mg/m ³ TWA AU OEL 5 mg/m ³ (inhalable) TWA, 10 mg/m ³ STEL NZ OEL

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.): Bright yellow paste.

Odour: Characteristic odour (of iodine).

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

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 dusts may cause irritation of the mucous membranes and upper respiratory tract.

Ingestion: Harmful if swallowed. Swallowing may cause gastrointestinal irritation with nausea and vomiting.

Skin contact: Causes skin irritation.

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

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

Acute Toxicity Values: Acute Toxicity Estimates: Oral 1667 mg/kg. Dermal 2857 mg/kg. Inhalation >9.2 mg/L

Iodoform (Iodine): LD50 oral rat 315 mg/kg, LD50 dermal rabbit 1425 mg/kg. LC50 inhalation rat >4.588 mg/L/4 h

Bismuth Subnitrate: LD50 oral rat >2000 mg/kg. LC50 inhalation rat >5.07 mg/L/4 h

Liquid Paraffin: LD50 oral rat <5000 mg/kg, LD50 dermal rabbit >2000 mg/kg. LC50 inhalation rat >5 mg/L/4 h

Skin Corrosion/Irritation: Causes skin irritation.

Serious Eye Damage/Irritation: Causes serious eye irritation.

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, ACGIH or EU CLP.

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: May cause respiratory irritation.

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

Bismuth Subnitrate: No toxicity to the limit of solubility 137 mg/L.

Liquid Petroleum: LC50 fish >1000 mg/L/96h; LC50 *daphnia magna* >100 mg/L/48h; EC50 algae >100 mg/L/72h

Persistence and degradability: Ingredients are not readily biodegradable.

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	UN3077	Environmentally hazardous substance, solid, n.o.s. (iodine)	9	III	Marine Pollutant
IATA	UN3077	Environmentally hazardous substance, solid, n.o.s. (iodine)	9	III	Yes
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): Iodine is Schedule 2 and 6.

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

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

H302 Harmful if swallowed.
H304 May be fatal if swallowed and enters airways.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H372 Causes damage to organs through prolonged or repeated exposure.
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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