

1. IDENTIFICATION

Product identifier: Obstetric Care Lotion Chlorhexidine Gluconate 1% w/w
Synonyms: 5000023564(50g), 5000023563(200g)

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 Centre: 0800764766**

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not Hazardous	Eye Irritation Category 2A (H319)

Label Elements

DANGER!

Hazard statement(s)

Causes serious eye irritation.



Precautionary statement(s)

Wash hands thoroughly after handling.
 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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration	Substance Classification
Mineral Oil	8042-47-5	<10% w/w	Not Hazardous
Chlorhexidine Gluconate	18472-51-0	<2.5%	Eye Damage Category 1 (H318) Aquatic Acute Toxicity Category 1 (H400) Aquatic Chronic Toxicity Category 1 (H410)

4. FIRST-AID MEASURES

Inhalation: No first aid should be required. If irritation occurs or symptoms develop, get medical attention. **Skin contact:** If irritation develops and persists 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 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. Prolonged skin contact may dry the skin.

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 foam.

Specific hazards arising from the chemical: Not flammable or combustible. Thermal decomposition may generate oxides of carbon and chlorine compounds.

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.

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. Keep containers closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Mineral Oil (as mist)	5 mg/m ³ (inhalable) TWA ACGIH TLV 5 mg/m ³ TWA AU OEL 5 mg/m ³ TWA NZ OEL
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Chlorhexidine Gluconate	None Established
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Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure levels are exceeded or irritation is experienced, an approved particulate 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.

Eye protection: Chemical safety goggles recommended if needed to avoid eye contact. **Other:** None known.

9. PHYSICAL AND CHEMICAL PROPERTIES
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Appearance (physical state, colour, etc.): White lotion

Odour: Faint odour

Odour threshold: Not applicable	pH: 5.0-6.0
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 determined	Auto-ignition temperature: Not determined
Decomposition temperature: Not determined	Viscosity: Not determined

10. STABILITY AND REACTABILITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides and chlorine compounds.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes.

Ingestion: Swallowing may cause gastrointestinal irritation and diarrhoea.

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: None known.

Sensitization: Not a sensitizer.

Germ Cell Mutagenicity: Not a germ cell mutagen. Chlorhexidine gluconate was negative in the in-vitro mammalian gene cell mutation asses (OECD 476), the Ames test, and the mammalian chromosome aberration test (OECD 473). It was also negative in an in-vivo micronucleus test in mice.

Reproductive Toxicity: Not a reproductive toxin. Chlorhexidine gluconate did not cause malformations or variations of any kind when tested in rats.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or ACGIH. Chlorhexidine did not cause cancer in lifetime feeding studies in rats or mice.

Acute Toxicity Values:

Chlorhexidine Gluconate: LD50 oral rat >2000 mg/kg, LD50 dermal rabbit >5000 mg/kg
Mineral Oil: LD50 oral rat >2000 mg/kg, LD50 dermal rabbit >2000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: Chlorhexidine gluconate: LC50 danio rerio 2.08 mg/L/96 hr; EC50 daphnia magna 0.087 mg/L/48 hr, NOEC 0.02 mg/L/21 d. (mortality); ErC50 algae 0.081 mg/L/72 hr.

Persistence and degradability: Chlorhexidine gluconate is 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	N/A	Not Regulated			No
IATA	N/A	Not Regulated			No
ADG	N/A	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): Schedule 5.

Australia Inventory: This product is a drug and is exempt from AICS.

New Zealand Inventory: This product is a drug and is exempt from HSNO regulations.

16. OTHER INFORMATION

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

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

H318 Causes serious eye damage.

H400 Very toxic to aquatic life.

H410 Very 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

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

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.

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