

Material Safety Data Sheet

Revision date: 26 September 2012

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1. Identification of the substance/preparation and the company**Canesten Clotrimazole Topical Solution** (AUST R 18700)

Bayer Australia Limited (ABN 22 000 138 714)
Consumer Care Business Group
875 Pacific Highway (PO Box 903), Pymble NSW 2073
Telephone: 1800 023 884; Fax: 02 9391 6640
In case of emergency: 1800 033 111 (24 hours, toll free, Australia wide)

2. Composition / information on ingredients

Product is a drug mixture in a solution.

Active ingredient: Clotrimazole (1% w/v)
Excipients: Isopropanol (> 30% w/v)
Propylene glycol, polyethylene glycol

3. Hazard identification

Classified as hazardous according to criteria of the National Occupational Health and Safety Commission (NOSHC).

4. First aid measures

General information: In case of accident or if you feel unwell, see medical advice immediately (show the product &/or label where possible). Take off immediately all contaminated clothing.

Following eye contact:
Contamination of the eyes must be treated by thorough irrigation with water, with the eyelids held open. A doctor or ophthalmologist should be consulted immediately.

Following skin contact:
After contact with skin, wash immediately with plenty of soap and water.

Upon swallowing:
If swallowed, seek medical advice immediately and show the product and this safety data sheet where possible. Patient should be induced to vomit only under medical supervision.

5. Fire fighting measures

Suitable extinguishing media: water jet.

In case of fire, care must be taken to collect the quenching water.

Keep away from naked flame. Cool undamaged containers with water.

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6. Accidental release measures

Do not allow product to enter into sewage systems, biological sewage treatment plants, surface waters and/or groundwater.

Dam up with absorbing material (eg. sand or chemical binders based on hydrated calcium silicate). Do not breathe vapour/spray.

Remove residual product with water and detergent. To clean floors and all objects contaminated with this material, use plenty of water.

7. Handling and Storage

Do not empty into drains. Keep container tightly closed and protect from moisture. Handle and open container with care and only handle product with local exhaust ventilation.

Avoid heat above +40°C.

8. Exposure controls / Personal protection

For use in the pharmaceutical industry, goggles and one-wear gloves are recommended. Usual garments and cleanliness guidelines in accordance with GMP for drugs must be observed.

9. Physical and chemical properties

Form:	Solution
Colour:	Colourless
Odour:	Aromatic odour
Density:	0.95 g/cm ³ at 20°C
Solubility in water:	partly soluble / partly miscible
Flash point:	+27°C
Ignition temperature:	400°C

10. Stability and reactivity

Thermal decomposition:
No decomposition when used properly.

Hazardous decomposition products:
None when stored and handled correctly.

Hazardous reactions:
No hazardous reaction when used as directed.

Further information:
Combustible. Sensitive to moisture. Protect from heat.

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11. Toxicological information

Based on industrial experience and normal hygiene conditions, no adverse effects on health are known. Only medicines administered at the recommended doses are non-toxic. Breathing of fumes may lead to narcotic symptoms.

Chemical-pharmacological effect: Antimycotic.

12. Ecological information

Correct handling will produce no environmental problems. According to the present state of knowledge, no disturbance is caused in biological sewage treatment plants if the product is used properly.

13. Disposal considerations

Transport in closed, combustible containers to suitable incinerators.

14. Transport information

Classified as Dangerous Goods according to ADG6.

Shipping name: Flammable liquid, N.O.S. (Contains Isopropanol)

Main class: 3

UN Number: 1993

Packing Group: III

Hazchem: 3[Y]E

Emergency Guide: Guide 14 (SAA/SNZ HB76:1997)

ADG6 = 6th Edition of the Australian Dangerous Goods Code (ADG Code).

15. Regulatory Information

STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS (SUSDP):

This product contains Clotrimazole which is a Schedule 2 poison in its delivered form.

Mandatory signal heading: PHARMACY MEDICINE

Mandatory caution statement: KEEP OUT OF REACH OF CHILDREN

CONTROL OF WORKPLACE HAZARDOUS SUBSTANCES (COWHS):

Classified as hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) / Worksafe Australia.

Classification: Xi Irritant

Risk phrases: R36 Irritating to eyes

R67 Vapours may cause drowsiness and dizziness

Safety phrases: S24/25 Avoid contact with eyes and skin.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

EXPOSURE STANDARDS FOR ATMOSPHERIC CONTAMINANTS IN THE OCCUPATIONAL ENVIRONMENT [NOHSC:1003(1995)]:

Isopropyl alcohol: 400 ppm or 983 mg/m³ TWA; 500 ppm or 1230 mg/m³ STEL

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16. Other information

Statement of Use: Drug in solution
Methods of application: Topical Application
Change from previous issue: General update

The data given here is based on current knowledge and experience. The purpose of this Safety Data Sheet is to describe the products in terms of their safety requirements. The data does not signify any warranty with regard to the products' properties.