



VIF 188

Date: 03/04/2001

Revision of: 03/04/2001

Name: Surolan

1 COMPANY

Janssen Pharmaceutica N.V.
Turnhoutseweg 30
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2 PRODUCT INFORMATION

Composition:

MICONAZOLE NITRATE (R 14889) : ~ 2.3 %

Hazard symbols : Xn

R-phrases : R 22

Polymixin B sulphate : ~ 0.07 %

Hazard symbols : -

R-phrases : -

Prednisolone acetate : ~ 0.5 %

Hazard symbols : Xn

R-phrases : R 20/21/22

Colloidal anhydrous silica : ~ 0.75 %

Hazard symbols : -

R-phrases : -

Liquid paraffin : not known

Hazard symbols : -

R-phrases : -

3 POSSIBLE HAZARDS

Prednisolone acetate is a corticosteroid. Polymixine B sulphate is a antibiotic.

4 FIRST AID MEASURES**4.1 ORAL ROUTE**

Rinse mouth with water. Notify the company medical services or a doctor.

4.2 EYES

Rinse the eyes with plenty of running water for at least 20 minutes. Keep eyelids open and let the eyes rotate in all directions.

4.3 SKIN

Remove contaminated clothing immediately and wash skin generously with soap and water.



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Inapplicable at room temperature. If a spray is used or at higher temperatures: Remove victim immediately from danger zone and take it to fresh air. In case of respiratory problems or respiratory arrest, administer artificial respiration. Keep victim warm and still. Contact medical service or doctor.

4.5 MEDICATION (to be applied exclusively by a physician)

Symptomatic treatment.

5 FIRE-FIGHTING MEASURES

- atomized water
- powder
- sand
- CO₂
- foam

Do not extinguish with:

- not applicable

Personal protective equipment:

- gloves
- protective clothing
- breathing equipment as for fire brigade

Combustion products:

- nitrogen oxides
- chlorine
- hydrogen chloride
- carbon monoxide
- carbon dioxide
- water
- sulfur oxides

6 ACCIDENTAL RELEASE AND CLEANING UP**6.1 Personal protective equipment:**

- long suitable gloves (e.g. Neoprene)
- closed working clothes with chemical suit
- full face mask with multi-purpose charcoal filter (e.g. ABEK-P3)

6.2 Environmental precautions:

Prevent all spread of the dust into the environment.



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Absorb substance in an inert absorbing material (e.g. Fedri, Dresser Dri, sand) and remove in a closed reseptacle for purposes of destruction as chemical waste. Upon dust dispersion, first demarcate the surroundings before starting to clean up.

7 HANDLING AND STORAGE**7.1 Precautions on handling :**

- ventilation

7.2 Storage:

Package:

- plastic packaging
- glass
- dark glass

Conditions:

- dry in closed packaging and in a well ventilated area

8 EXPOSURE LIMITS AND PERSONAL PROTECTION**8.1 Technical installation:**

- local ventilation and/or general ventilation

8.2 Limit values:

OEL-STEL: not known
OEL: not known

Ref.:
Ref.:



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Name: Surolan**8.3 Personal protection:****EYES:**

- safety glasses
- in manufacturing units: see respiration

SKIN:

- suitable gloves (plastic)
- lab: closed working clothes
- production: closed working clothes with plastic apron

INHALATION:

- lab: in the hot or local ventilation
- in manufacturing units: full face mask with a multi-purpose charcoal filter (e.g. ABEK-P3)

PbOEL-class: 3

9 PHYSICAL AND CHEMICAL PROPERTIES**9.1 GENERAL**

- Physical state: white suspension.
- Odour: none
- Melting point: not known
- Boiling point: inapplicable
- Vapour pressure (20 °C): not known
- Vapour density: not known
- Viscosity: not known
- Relative density (*d*): not known
- Solubility in water: not known
- pH: not known at concentration: not known
- Solubility in solvents:

- Distribution coefficient n-octanol/water - log P: not known
- Solubility in fats: not known
- Specific conductance: not known



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- Flash point: not known
- Auto-ignition temperature: not known
- Explosion range vol. % in air: - LEL: not known - UEL: not known
- Oxidizing properties: not known

- Shock sensitivity: not known
- Friction sensitivity: not known
- Thermal sensitivity (Koenen test): not known

DIN:

DIN:

10 STABILITY AND REACTIVITY**10.1 Stability**

- Exothermicity - lowest temperature: not known
- Gas evolving (>10 liter gas/kg below 220 °C): not known
- Light stability: not known
- Thermal decomposition: not known

10.2 Reactivity

- Avoid contact with:
 - oxidation agents

- Decomposition products:
 - not known

- Water:
 - not known

- Polymerisation risk:
 - not known



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11 TOXICOLOGICAL DATA**11.1 Acute toxicity and symptoms**

Acute toxicity:

R 14889: or. rat LD50 : 640 mg/kg

polymixin B sulphate: oral mice LD50 :
790 mg/kg

Symtoms by overdose:

Oral:

- miconazole nitrate: vomiting, diarrhoe, rarely heart rhythm disorders, convulsions (fits, muscle spasms)

Eyes:

- not known

Skin:

- not known

Inhalation:

- inapplicable

Sensitizing:

- not known

11.2 Subacute toxicity

Miconazole nitrate: Vaginal administration to monkeys and rabbits for three months was without any toxic effect; topical administration to rabbits for 1 month was also without any toxic effect. Oral administration to rats and dogs did not bring about any toxic effects either.

11.3 Mutagenesis tests

Miconazole nitrate is not mutagenic in the Ames test with Salmonella typhimurium, Echerichia coli and Klebsiella pneumonia

11.4 Carcinogenic activity

Miconazole nitrate: No studies available.

11.5 Reproductive effects

Miconazole nitrate: No effect on fertility was evidenced in rats. Only at maternally toxic doses, miconazole was embryotoxic in rats and rabbits. Miconazole was not teratogenic in rats or rabbits.

Prednisolone acetate: reproductive disorders in experimental animals.

11.6 Pharmacological activity

Miconazole nitrate is a potent antifungal.



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12 ECOLOGICAL PROPERTIES**12.1 Elimination data**

Abiotic (COD): not known

Aerobiotic: not known

12.2 Distribution over environmental compartments**12.3 Ecotoxicological data**

13 DISPOSAL CONSIDERATIONS

Not allowed via dust-bin or sewerage:

- Comply with the following directives: handle waste according to current procedures drawn up by the Environment Department or according to local bye-laws.

14 TRANSPORT DATA

ADR/RID	Class: free Letter:	UN-no.:	pckgr.:	label:
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IMDG	Class: free Marine pollutant: not applicable	UN-no.:	pckgr.:	label:
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ICAO/IATA	Class: free Proper technical name:	UN-no.:	pckgr.:	label:
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Additional information:



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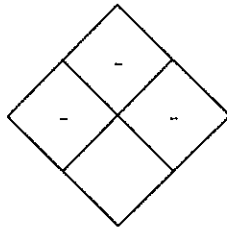
Name: Surolan

15 REGULATORY DATA (LABELLING)

EEC-no:

Symbols:R-phrases: • Not subject to EC directive 67/548.S-phrases:

Hazard rating:



Local legislation/regulations:



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16 OTHER INFORMATION

Please note that, despite the greatest possible care with which this information sheet has been drawn up, we accept no responsibility for the comprehensiveness or accuracy of the information herein.

Vertical lines to the left indicate changes to the previous version

References:

- EC direction 67/548
- Toxicology department Janssen Pharmaceutica
- ARAB art. 723-bis
- Medical service department
- ADR 1999
- Veterinary medicine department.