

Safety Data Sheet

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product Name Miconazole 1.0% alc

Article Number M-027

Applications Diagnosis of contact allergy.

Manufacturer Chemotechnique MB Diagnostics AB

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2. HAZARD IDENTIFICATION

Health hazards

The objective of applying a hapten on the patient's skin is the diagnosis of contact allergy. Localized dermal allergic reaction may occur at test site.

Signs and symptom of exposure

Dermal irritation.

Medical conditions aggravated by exposure

Dermatitis.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Classification according to (EC) No. 1272/2008 [EU-GHS/CLP]

Component CAS-No. Content Classification

Ethanol Absolute 99.5% 64-17-5 99.0% Flamm. liquids 2; H225

Miconazole 22916-47-8 1.0% Acute tox. Oral 4, Resp. sensit. 1;

H302, H334

Classification according to EU Directive 67/548/EEC and 1999/45/EC

Component CAS-No. Content Classification

Ethanol Absolute 99.5% 64-17-5 99.0% F; R11

Miconazole 22916-47-8 1.0% Xn; R22, R42

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4. FIRST AID MEASURES

Emergency and first aid procedures

Obtain medical attention.

5. FIRE-FIGHTING MEASURES*

Suitable extinguish media

Water spray, foam, dry powder or CO2 powder

Fire- and explosion risks

Very flammable. Vapors can form explosive mixtures with air. The vapors are heavier than air and can spread along the ground.

Fire extinguishing methods

Containers in the vicinity of the fire should be moved or cooled down with water. Wear self-contained respiratory protected device and fully protected suit at fire-fighting.

*Data is shown for Ethanol Absolute only

6. ACCIDENTAL RELEASES MEASURES

Steps to be taken if material is released or spilled

Contain and place in a closed container.

7. HANDLING AND STORAGE

Precautions to be taken in handling and storage

Store dark at 5-8°C. Avoid extended exposure to light. Store in a well-sealed container. FOR EXTERNAL USE ONLY.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory protection

Not required.

Ventilation

Local exhaust.

Protective gloves

Disposal gloves.

Eye protection

Not required with normal use.

Work/Hygienic practices

Wash hands after each use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance Transparent, Colorless Liquid

Odour Odourless

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Relative density* 0.79 g/cm³
Boiling point* 78.5°C
Flash point* >12°C

Explosion limit* 3.5-15 (vol-%)

Vapour pressure* 5.9 kPa

10. STABILITY AND REACTIVITY

Incompability

May react with strong oxidizing agents.

Stability

Stable at recommended storage conditions.

Hazardous byproducts

Combustion may generate CO, CO2 and other oxides.

Hazardous polymerization

Will not occur.

11. TOXICOLOGICAL INFORMATION

No data available.

12. ECOLOGICAL INFORMATION

No data available.

13. DISPOSAL CONSIDERATIONS

Waste disposal method

Comply with federal, state/provincial and local regulation.

14. TRANSPORT INFORMATION

Not dangerous goods.

15. REGULATORY INFORMATION

The classification is according to the latest editions of the EU lists, and extended by company and literature data.

16. OTHER INFORMATION

Text of H-statements and R-phrases mentioned in Section 3

Acute tox. Oral 4

Flamm. liquids 2

Resp. sensit. 1

H225

Acute toxicity, Oral (Category 4)

Flammable liquids (Category 2)

Respiratory sensitization (Category 1)

Highly flammable liquid and vapour

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^{*}Data is shown for Ethanol Absolute only

H302 Harmful if swallowed

H334 May cause allergy or asthma symptoms or

breathing difficulties if inhaled

 $\begin{array}{ccc} \mathsf{F} & & \mathsf{Flammable} \\ \mathsf{Xn} & & \mathsf{Harmful} \end{array}$

R11 Highly flammable
R22 Harmful if swallowed

R42 May cause sensitisation by inhalation

Pharmaceutical quality of tested hapten is confirmed by Chemotechnique Diagnostics according to validated analytical methods. Hapten passed test according to GMP standards.

Chemotechnique Diagnostics makes no representation as to the comprehensiveness or correctness of the information provided. It is intended only as a guide to a properly trained individual in the appropriate handling of the material.

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