

Page 1 / 10 Revision Date 31-Mar-2025 Version 4

Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THECOMPANY/UNDERTAKING

Product Identifier

Perihalan Produk: <u>Miconazole nitrate, 10 mg/ml in ethanol</u>
Product Description: <u>Miconazole nitrate, 10 mg/ml in ethanol</u>

Cat No.: J67244

Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Laboratory chemicals.
Uses advised against No Information available

Company Thermo Fisher Scientific Fisher Scientific (M) Sdn Bhd

Hap Seng Business Park, Lot 01-03, 01-04 Aras 1 Unity Square, No 12, Persiaran Perusahaan, Seksyen 23, 40300 Shah Alam,

Selangor Darul Ehsan, Malaysia. Main line: +60 3-5525 7888

Supplier

E-mail address Enquiry.my@thermofisher.com

Emergency Telephone Number Tel: +03-5525 7888

CHEMTREC Malaysia 1-800-815-308 (Malay)

CHEMTREC Malaysia (Kuala Lumpur) +(60)-327884561 (Malay)

SECTION 2: HAZARDS IDENTIFICATION

Classification of the substance or mixture

Flammable liquids	Category 2 (H225)
Skin Sensitization	Category 1 (H317)
Specific target organ toxicity - (single exposure)	Category 2 (H371)

Label Elements



Signal Word Danger

Hazard Statements

H225 - Highly flammable liquid and vapor

ALFAAJ67244

Miconazole nitrate, 10 mg/ml in ethanol

H371 - May cause damage to organs

H317 - May cause an allergic skin reaction

Precautionary Statements

Prevention

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

P233 - Keep container tightly closed

P240 - Ground and bond container and receiving equipment

P242 - Use non-sparking tools

P243 - Take action to prevent static discharges

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P271 - Use only outdoors or in a well-ventilated area

P272 - Contaminated work clothing should not be allowed out of the workplace

P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response

P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P370 + P378 - In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish

P362 + P364 - Take off contaminated clothing and wash it before reuse

P308 + P311 - IF exposed or concerned: Call a POISON CENTER or doctor

Storage

P403 + P235 - Store in a well-ventilated place. Keep cool

Disposal

P501 - Dispose of contents/ container to an approved waste disposal plant

Other Hazards

This product does not contain any known or suspected endocrine disruptors

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight %
Ethyl alcohol	64-17-5	88.857
Methyl alcohol	67-56-1	4.9365
Isopropyl alcohol	67-63-0	4.9365
Miconazole nitrate	22832-87-7	1.27

SECTION 4: FIRST AID MEASURES

Description of first aid measures

General Advice If symptoms persist, call a physician.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists,

call a physician.

Ingestion Clean mouth with water and drink afterwards plenty of water.

Inhalation Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if

symptoms occur.

ALFAAJ67244

Revision Date 31-Mar-2025

Miconazole nitrate, 10 mg/ml in ethanol

Revision Date 31-Mar-2025

Self-Protection of the First Aider

Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

Most important symptoms and effects, both acute and delayed

Difficulty in breathing. May cause allergic skin reaction. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting. Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing.

Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing media

Suitable Extinguishing Media

Carbon dioxide (CO₂). Powder. Water spray. In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion. Water mist may be used to cool closed containers.

Extinguishing media which must not be used for safety reasons

No information available.

Special hazards arising from the substance or mixture

Flammable. Containers may explode when heated. Vapors may form explosive mixtures with air. Vapors may travel to source of ignition and flash back.

Hazardous Combustion Products

Carbon monoxide (CO), Carbon dioxide (CO2), Nitrogen oxides (NOx), Hydrogen chloride.

Advice for fire-fighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Ensure adequate ventilation. Use personal protective equipment as required. Remove all sources of ignition. Take precautionary measures against static discharges.

Environmental precautions

Do not flush into surface water or sanitary sewer system.

Methods and Material for Containment and Cleaning Up

Soak up with inert absorbent material. Keep in suitable, closed containers for disposal. Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment.

Reference to Other Sections

Refer to protective measures listed in Sections 8 and 13.

Revision Date 31-Mar-2025

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Keep away from open flames, hot surfaces and sources of ignition. Use only non-sparking tools. To avoid ignition of vapors by static electricity discharge, all metal parts of the equipment must be grounded. Take precautionary measures against static discharges.

Conditions for Safe Storage, Including any Incompatibilities

Store in freezer. Keep container tightly closed in a dry and well-ventilated place. Keep away from heat, sparks and flame.

Specific End Uses

Use in laboratories.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Component	Malaysia	ACGIH TLV	OSHA PEL
Ethyl alcohol		STEL: 1000 ppm	(Vacated) TWA: 1000 ppm
			(Vacated) TWA: 1900 mg/m ³
			TWA: 1000 ppm
			TWA: 1900 mg/m ³
Methyl alcohol		TWA: 200 ppm	(Vacated) TWA: 200 ppm
		STEL: 250 ppm	(Vacated) TWA: 260 mg/m ³
		Skin	(Vacated) STEL: 250 ppm
			(Vacated) STEL: 325 mg/m ³
			Skin
			TWA: 200 ppm
			TWA: 260 mg/m ³
Isopropyl alcohol		TWA: 200 ppm	(Vacated) TWA: 400 ppm
		STEL: 400 ppm	(Vacated) TWA: 980 mg/m ³
			(Vacated) STEL: 500 ppm
			(Vacated) STEL: 1225 mg/m ³
			TWA: 400 ppm
			TWA: 980 mg/m ³

Component	European Union	The United Kingdom	Germany	
Ethyl alcohol		TWA: 1000 ppm TWA; 1920 mg/m ³	200 ppm TWA MAK; 380 mg/m ³	
		TWA	TWA MAK	
		WEL - STEL: 3000 ppm STEL;		
		5760 mg/m ³ STEL		
Methyl alcohol	TWA: 200 ppm 8 hr	WEL - TWA: 200 ppm TWA; 266	100 ppm TWA MAK; 130 mg/m ³	
	TWA: 260 mg/m ³ 8 hr	mg/m³ TWA	TWA MAKSkin absorber	
	Skin	WEL - STEL: 250 ppm STEL; 333		
		mg/m³ STEL		
Isopropyl alcohol		STEL: 500 ppm 15 min	TWA: 200 ppm (8 Stunden). AGW -	
		STEL: 1250 mg/m ³ 15 min	exposure factor 2	
		TWA: 400 ppm 8 hr	TWA: 500 mg/m³ (8 Stunden). AGW	
		TWA: 999 mg/m ³ 8 hr	- exposure factor 2	
			TWA: 200 ppm (8 Stunden). MAK	
			TWA: 500 mg/m³ (8 Stunden). MAK	
			Höhepunkt: 400 ppm	
			Höhepunkt: 1000 mg/m ³	

Exposure Controls

Engineering Measures

Ensure adequate ventilation, especially in confined areas. Use explosion-proof electrical/ventilating/lighting equipment. Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to

Miconazole nitrate, 10 mg/ml in ethanol

control hazardous materials at source

Personal protective equipment

Eve Protection Wear safety glasses with side shields (or goggles)

Hand Protection Protective gloves Long sleeved clothing Skin and body protection

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Respiratory Protection When workers are facing concentrations above the exposure limit they must use

appropriate certified respirators

Recommended Filter type: **SCBA**

To protect the wearer, respiratory protective equipment must be the correct fit and be used

and maintained properly

When RPE is used a face piece Fit Test should be conducted

Handle in accordance with good industrial hygiene and safety practice Hygiene Measures

Environmental exposure controls Prevent product from entering drains Do not allow material to contaminate ground water

system

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance

Physical State

Odor No information available **Odor Threshold** No data available Hq No information available

Melting Point/Range No data available No data available **Softening Point Boiling Point/Range** 78 °C / 172.4 °F Flash Point 17 °C / 62.6 °F

Method - No information available

No data available **Evaporation Rate**

Flammability (solid, gas) Not applicable Liquid

Explosion Limits No data available

23 hPa @ 20 °C **Vapor Pressure** No data available

Vapor Density (Air = 1.0)Specific Gravity / Density No data available

Bulk Density Not applicable

Liquid

Water Solubility Miscible

No information available Solubility in other solvents

ALFAAJ67244

Revision Date 31-Mar-2025

Miconazole nitrate, 10 mg/ml in ethanol

Partition Coefficient (n-octanol/water)

Componentlog PowEthyl alcohol-0.32Methyl alcohol-0.74Isopropyl alcohol0.05

Autoignition Temperature
Decomposition Temperature
Viscosity

No data available
No data available
No data available

Explosive Properties

Oxidizing Properties No information available

Vapors may form explosive mixtures with air

Revision Date 31-Mar-2025

SECTION 10: STABILITY AND REACTIVITY

Reactivity

None known, based on information available.

Chemical Stability

Stable under normal conditions.

Possibility of Hazardous Reactions

Hazardous Polymerization No information available.
Hazardous Reactions None under normal processing.

Conditions to Avoid

Keep away from open flames, hot surfaces and sources of ignition.

Incompatible Materials

Oxidizing agent.

Hazardous Decomposition Products

Carbon monoxide (CO). Carbon dioxide (CO₂). Nitrogen oxides (NOx). Hydrogen chloride.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Product Information

(a) acute toxicity;

OralBased on available data, the classification criteria are not metDermalBased on available data, the classification criteria are not metInhalationBased on available data, the classification criteria are not met

ALFAAJ67244

Miconazole nitrate, 10 mg/ml in ethanol

Toxicology data for the components

Component	mponent LD50 Oral LD50 Dermal		LC50 Inhalation		
Ethyl alcohol	LD50 = 7060 mg/kg (Rat)	-	20000 ppm/10H (Rat)		
Methyl alcohol	LD50 = 1187 - 2769 mg/kg (Rat)	LD50 = 17100 mg/kg (Rabbit)	LC50 = 128.2 mg/L (Rat) 4 h		
Isopropyl alcohol	5045 mg/kg (Rat) 3600 mg/kg (Mouse)	12800 mg/kg (Rat)	72.6 mg/L (Rat)4 h		
Miconazole nitrate	LD50 = 920 mg/kg (Rat)	-	-		

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

Respiratory No data available Skin Category 1

Component	Test method	Test species	Study result
Methyl alcohol	OECD Test Guideline 406	guinea pig	non-sensitising
67-56-1 (4.9365)	Guinea Pig Maximisation Test		
	(GPMT)		

No information available

No data available (e) germ cell mutagenicity;

(f) carcinogenicity; No data available

The table below indicates whether each agency has listed any ingredient as a carcinogen

(a) reproductive toxicity: No data available

(3)				
Component	Test method	Test species / Duration	Study result	
Methyl alcohol	OECD Test Guideline 416	Rat / Inhalation	NOAEC =	
67-56-1 (4.9365)		2 Generation	1.3 mg/l (air)	

(h) STOT-single exposure; Category 2

Results / Target organs Central nervous system (CNS), Optic nerve.

No data available (i) STOT-repeated exposure;

Target Organs No information available.

No data available (j) aspiration hazard;

delayed

Symptoms / effects,both acute and Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting. Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest

pain, muscle pain or flushing.

Endocrine Disrupting Properties Assess endocrine disrupting properties for human health. This product does not contain any

known or suspected endocrine disruptors.

SECTION 12: ECOLOGICAL INFORMATION

ALFAAJ67244

Revision Date 31-Mar-2025

Revision Date 31-Mar-2025

Ecotoxicity effects

Contains a substance which is:. Toxic to aquatic organisms. The product contains following substances which are hazardous for the environment.

Component	Freshwater Fish	Water Flea	Freshwater Algae	Microtox
Ethyl alcohol	Fathead minnow (Pimephales promelas) LC50 = 14200 mg/l/96h	EC50 = 9268 mg/L/48h EC50 = 10800 mg/L/24h	EC50 (72h) = 275 mg/l (Chlorella vulgaris)	Photobacterium phosphoreum:EC50 = 34634 mg/L/30 min Photobacterium phosphoreum:EC50 = 35470 mg/L/5 min
Methyl alcohol	Pimephales promelas: LC50 > 10000 mg/L 96h	EC50 > 10000 mg/L 24h		EC50 = 39000 mg/L 25 min EC50 = 40000 mg/L 15 min EC50 = 43000 mg/L 5 min
Isopropyl alcohol	flow-through	13299 mg/L EC50 = 48 h 9714 mg/L EC50 = 24 h	(Desmodesmus	Photobacterium phosphoreum 5 min

Persistence and degradability

Persistence Persistence is unlikely, based on information available.

 , c. c. c. c. c. c. c. j, c. c. c. c.	
Component	Degradability
Methyl alcohol	DT50 ~ 17.2d
67-56-1 (4 9365)	>94% after 20d

Degradation in sewage treatment plant

Contains substances known to be hazardous to the environment or not degradable in waste water treatment plants.

Bioaccumulative potential Bioaccumulation is unlikely

Component	log Pow	Bioconcentration factor (BCF)
Ethyl alcohol	-0.32	No data available
Methyl alcohol	-0.74	<10 dimensionless
Isopropyl alcohol	0.05	No data available

Mobility in soil

The product contains volatile organic compounds (VOC) which will evaporate easily from all

surfaces. Will likely be mobile in the environment due to its volatility. Disperses rapidly in

air.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors

Other adverse effects No information available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from Residues/Unused

Products

Waste is classified as hazardous Dispose of in accordance with the European Directives on waste and hazardous waste Dispose of in accordance with local regulations

Miconazole nitrate, 10 mg/ml in ethanol

-

Contaminated Packaging Dispose of this container to hazardous or special waste collection point. Empty containers

retain product residue, (liquid and/or vapor), and can be dangerous Keep product and

Revision Date 31-Mar-2025

empty container away from heat and sources of ignition

Other Information Do not flush to sewer Waste codes should be assigned by the user based on the

application for which the product was used Can be landfilled or incinerated, when in

compliance with local regulations

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO

UN-No UN1987 Hazard Class 3 Packing Group III

Proper Shipping Name ALCOHOLS, N.O.S. (ETHANOL (ETHYL ALCOHOL), METHANOL)

Road and Rail Transport

UN-No UN1987 Hazard Class 3 Packing Group III

Proper Shipping Name ALCOHOLS, N.O.S. (ETHANOL (ETHYL ALCOHOL), METHANOL)

<u>IATA</u>

UN-No UN1987
Hazard Class 3
Packing Group III

Proper Shipping Name ALCOHOLS, N.O.S. (ETHANOL (ETHYL ALCOHOL), METHANOL)

Special Precautions for User No special precautions required

SECTION 15: REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories X = listed

Component	EINECS	TSCA	DSL	PICCS	ENCS	ISHL	IECSC	AICS	KECL
Ethyl alcohol	200-578-6	X	Х	Х	Х	X	Х	Х	KE-13217
Methyl alcohol	200-659-6	Х	Х	Х	Х	X	Х	Х	KE-23193
Isopropyl alcohol	200-661-7	Х	Х	Х	Х	X	Х	Х	KE-29363
Miconazole nitrate	245-256-6	-	Х	-	-		-	-	-

	Component	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
ſ	Ethyl alcohol				Annex I - Y42
ſ	Methyl alcohol	500 tonne	5000 tonne		
Γ	Isopropyl alcohol				Annex I - Y42

National Regulations

ALFAAJ67244

Miconazole nitrate, 10 mg/ml in ethanol

Persistent Organic Pollutant Ozone Depletion Potential

This product does not contain any known or suspected substance This product does not contain any known or suspected substance

SECTION 16: OTHER INFORMATION

Legend

CAS - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances **IECSC** - Chinese Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50% POW - Partition coefficient Octanol:Water

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

Revision Date 31-Mar-2025

Substances List

ENCS - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances NZIoC - New Zealand Inventory of Chemicals

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

ICAO/IATA - International Civil Aviation Organization/International Air **Transport Association**

MARPOL - International Convention for the Prevention of Pollution from

ATE - Acute Toxicity Estimate VOC - (Volatile Organic Compound)

Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

Prepared By Health, Safety and Environmental Department

Revision Date 31-Mar-2025 **Revision Summary** Not applicable.

In accordance with local and national regulations: Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet