

1 Identification of the substances/ mixture and of the company/ undertaking**1.1 Product Identifiers**

Product Number M1209
Product Name *Fluconazole Testing Medium (Twin Pack)
REACH Registration Number This product is a mixture. Reach registration number is not available for this mixture.

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

1.2.1 Relevant identified uses Laboratory Chemicals, Analytical Purpose, Biochemical Analysis
For InVitro Diagnostic Use

1.3 Details of the supplier of the safety data sheet

Produced by HiMedia Laboratories Private Limited
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1.4 Emergency Tel. No.

Emergency Tel. No. Please contact the regional HiMedia representation in your country

2 Hazards Identification**2.1 Classification of the substance or mixture**

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

Not a hazardous substance or mixture according to Regulation (EC) No.1272/2008.

2.2 Label elements

Labeling according to Regulation (EC) No.1272/2008

The product does not need to be labelled in accordance with EC directives or respective national laws.

2.3 Other Hazards

None

3 Composition/Information On Ingredients**3.2 Mixture**

Component		Classification	Concentration
Calcium chloride, anhydrous			
CAS No. :	10043-52-4	As Per EC Regulation 1272/2008 Eye Irrit. 2A H319	>=0.1 - <=1.0%
EC No. :	233-140-8		

Component	Classification	Concentration
Nicotinic acid		
CAS No. : 59-67-6 EC No. : 200-441-0	As Per EC Regulation 1272/2008 Eye Irrit. 2A H319	>=0.001 - <=0.01%

Component	Classification	Concentration
Boric acid		
CAS No. : 10043-35-3 EC No. : 233-139-2 Index-No : 005-007-00-2	As Per EC Regulation 1272/2008 Repr.Tox. 1A, 1B H360	>=0.001 - <=0.01%

Component	Classification	Concentration
Zinc sulphate		
CAS No. : 7446-19-7 EC No. : 231-793-3	As Per EC Regulation 1272/2008 Eye Dam. 1; Aquatic Chronic 1 H318; H410	>=0.001 - <=0.01%

Component	Classification	Concentration
p-Amino benzoic acid (PABA)		
CAS No. : 150-13-0 EC No. : 205-753-0	As Per EC Regulation 1272/2008 Skin Irrit. 2; Skin Sens. 1; Eye Irrit. 2A H315; H317; H319	>=0.001 - <=0.01%

Component	Classification	Concentration
Ferric chloride		
CAS No. : 7705-08-0 EC No. : 231-729-4	As Per EC Regulation 1272/2008 Met. Corr. 1; Acute Tox.oral 4; Skin Irrit. 2; Eye Dam. 1 H290; H302; H315; H318	>=0.001 - <=0.01%

Component	Classification	Concentration
Cupric sulphate		
CAS No. : 7758-98-7 EC No. : 231-847-6	As Per EC Regulation 1272/2008 Acute Tox.oral 4; Skin Irrit. 2; Eye Irrit. 2A H302; H315; H319	>=0.001 - <=0.01%

Component	Classification	Concentration
Potassium iodide		
CAS No. : 7681-11-0 EC No. : 231-659-4	As Per EC Regulation 1272/2008 Acute Tox.oral 4; Skin Irrit. 2; Eye Irrit. 2A H302; H315; H319	>=0.0001 - <=0.001%

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Refer Section 16 for complete statement of H codes and its classification

4 First Aid Measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse immediately with plenty of water for at least 15 minutes. Consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of immediate medical attention and special treatment needed

No data available

5 Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media

No data available.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, Oxides of phosphorus, Potassium oxides, Magnesium oxides, Sulphur oxides

5.3 Precautions for fire-fighters

Wear self contained breathing apparatus for fire fighting if necessary

5.4 Further information

No data available

6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Soak up with inert adsorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see Section 13.

7 Handling and Storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist. Normal measures for preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Recommended Storage Temperature : On receipt store between 2-8°C

7.3 Specific end uses

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8 Exposure Controls/Personal Protection

8.1 Control parameters

Components with workplace control parameters

8.2 Exposure controls

Appropriate engineering controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the products.

Personal protective equipment

Hygiene measure

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with the product.

Eye/face protection

Tightly fitting safety goggles; Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 2016/425/EEC and the standard EN ISO 374-1/2016 derived from it.

Body protection

Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Environment exposure controls

Do not empty into drains.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	Part A : Cream to light yellow homogeneous coarse powder. Part B : White to light yellow homogeneous free flowing powder.
Odour	No data available
Odour Threshold	No data available
pH	Not Applicable
Melting/freezing point	No data available
Initial boiling point and boiling range	No data available
Flash point	No data available
Flammability (Solid, gas)	No data available
Vapour pressure	No data available
Relative density	No data available
Water Solubility	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available
Vapour density	No data available
Thermal decomposition	No data available

9.2 Other safety information

No data available

10 Stability and Reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

No data available

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

Refer Section 5.2

11 Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available

Specific target organ toxicity- single exposure

No data available

Aspiration hazard

No data available

Potential Health Effects

Inhalation

REFER SECTION 2

Skin

REFER SECTION 2

Eyes

REFER SECTION 2

Ingestion

REFER SECTION 2

Additional Information

RTECS : No data available

11.2 Components

Calcium chloride

Acute oral toxicity

Rat LD50 : 1,000 mg/kg

(As per IUCLID)

Acute dermal toxicity

Rat LD50 : 2,630 mg/kg

(As per IUCLID)

Skin irritation

Rabbit

Result : No irritation

(As per OECD Test Guideline 404)

Eye irritation

Rabbit

Result: Eye irritation

(As per OECD Test Guideline 405)

Causes serious eye irritation.

Additional Information

RTECS: EV9800000

Niacin (Nicotinic acid)*Acute oral toxicity*

Rat LD50: >5000 mg/kg;24h(ECHA)

Acute dermal toxicity

Rat LD50: >2000 mg/kg;24h(ECHA)

Acute inhalation toxicity

Rat LD50: >3.8 mg/L; 4h(ECHA)

Skin irritation

Rabbit: Does not cause irritation to skin(ECHA)

Eye irritation

Rabbit:May cause slight to mild irritation to eyes(ECHA)

Sensitisation

Nonsensitizer(ECHA)

Repeated Exposures

No significant effect seen on rats(ECHA)

Germ cell mutagenicity

Genotoxicity invitro

Chinese hamster Ovary (CHO)

Result: Negative(ECHA)

Genotoxicity invivo

Mammalian Bone Marrow Chromosome Aberration Test

Result: Negative(ECHA)

Mutagenicity (mammal cell test): micronucleus

No data available

Carcinogenicity

No data available

Reproductive toxicity

No data available

Teratogenicity

Rats, 20 d

Result: Negative(ECHA)

Additional information

RTECS QT0525000

Boric Acid*Acute Toxicity*

Rat oral LD50 : 2660 mg/kg

Rabbit dermal LD50 : 2000 mg/kg

Mouse Oral: LD50 = 3450 mg/kg.

Additional information

RTECS : ED4550000

Specific concentration limits (SCL): >5.5%

Boric acid is included in the Candidate List of Substances of Very High Concern (SVHC) according to Regulation (EC) No. 1907/2006 (REACH)

Zinc Sulphate, Heptahydrate

Acute Oral Toxicity

Rat LD50: 1,260 mg/kg (As Per RTECS)

Additional information

RTECS: ZH5300000

PABA (Para aminobenzoic acid)(4-aminobenzoic acid)

Acute oral toxicity

Rat LD50 : 6gm/kg(RTECS)

Mouse LD50 : 2850mg/kg

Rabbit LD50 : 1830 mg/kg

Dog LD50 : 1000 mg/kg

Acute inhalation toxicity

No data available

Acute dermal toxicity

No data available

Skin irritation

No data available

Eye irritation

No data available

Sensitisation

STOT :May cause respiratory irritation

Genetic toxicity(in-vitro)

Ames Test

Negative (National Toxicological Program)

Germ cell mutagenicity

Mouse

Causes DNA damage

Carcinogenicity

IARC Group 3 (It is not established as carcinogen to humans)

Toxicity to Reproduction

No data available

Teratogenicity

No data available

Additional information:

RTECS: No data available

Ferric chloride

Acute oral toxicity

Rat LD50: 3,200mg/kg (As per OECD Guideline 401)

Acute inhalation toxicity

No data available

Acute dermal toxicity

Rabbit LD50: > 559mg/kg (As per EPA OPP 81-2)

Skin irritation
Rabbit Result: Non Irritant(As per OECD Guideline 404)
Eye irritation
Rabbit Result: Irreversible effects on the eye (ECHA)
Sensitisation
Guinea pig Result: Not sensitising
Genetic toxicity(in-vitro)
Mammalian cell gene mutation assay
Mouse lymphoma cells Result :Negative
Genetic toxicity(in-vivo)
Mouse Result: Positive (ECHA)
Carcinogenicity
No data available
Toxicity to Reproduction
No data available
Teratogenicity
No data available

Additional information:

RTECS: LJ9100000

Potassium iodide

Acute oral toxicity
Rat LD50:3118mg/kg; (As Per OECD Test Guideline 401)
Acute intravenous toxicity
Rat LD50 : 285mg/kg
Skin irritation
No data available
Eye irritation
No data available
Sensitisation
No data available
Genetic toxicity(in-vitro)
Mammalian cell micronucleus test
Result:Negative
Genetic toxicity(in-vivo)
Rat Chromosome aberration assay
Result:Negative
Carcinogenicity
Rat
Not carcinogenic(As per OECD guideline 453)
Teratogenicity
Rat
No developmental toxicity/teratogenicity (ECHA)

Additional information:

RTECS: TT2975000

12 Ecological Information

12.1 Toxicity

No data available

Components

Calcium chloride

Toxicity to fish

Lepomis macrochirus (Bluegill sunfish) LC50 : 10,650 mg/l; 96 h
(As per IUCLID)

Toxicity to daphnia and other aquatic invertebrates

Daphnia magna (Water flea) EC50 : 144 mg/l; 48 h
(As per IUCLID)

Toxicity to algae

Algae LC50 : 3,130 mg/l; 120 h
(As per IUCLID)

Components

Niacin(Nicotinic acid)

Toxicity to fish

Brown trout (Salmo Trutta Fario) LC50: 520 mg/l; 96 h(ECHA)

Toxicity to daphnia and other aquatic invertebrates

Daphnia magna EC50: 77 mg /L; 48 h(ECHA)

Toxicity to algae

Desmodesmus subspicatus Scenedesmus subspicatus)
EC50: 89.93 mg/L 72 h(ECHA)

Toxicity to microorganisms

Pseudomonas putida EC50: 120 mg /L; 16 h(ECHA)

Pseudomonas putida EC10: 88 mg /L; 16 h(ECHA)

Component

Boric Acid

Toxicity to fish

Gambusia affinis LC50 :5600 mg/l

Rainbow trout LC50:150mg B/L;24d

Goldfish LC50:46mg; 7d

Toxicity to daphnia and other aquatic invertebrates

Daphnia EC50 :115 mg/l

Components

Zinc Sulphate, Heptahydrate

Toxicity to fish

Oncorhynchus mykiss (rainbow trout) LC50: 0.1 mg/l; 96 h
(As Per ECOTOX Database)

Toxicity to algae
Scenedesmus quadricuada (green algae) IC50: 0.52 mg/l; 5 d
(As Per IUCLID)

Components

PABA (Para aminobenzoic acid) (4-aminobenzoic acid)

Toxicity to daphnia and other aquatic invertebrates

Daphnia magna (Water flea) EC50 : 546 mg/l; 24 h.

Toxicity to Bacteria

Microtox test

Phytobacterium phosphoreum EC50: 27.4 mg/l; 30 mins.

Components:

Ferric chloride

Toxicity to microorganisms

Activated sludge IC50: ca. 170 mg/L (ECHA)

Components:

Potassium iodide

Toxicity to fish

Oncorhynchus mykiss (Rainbow trout) Static test : LC50: 3780 mg/L; 96h (As per OECD Guideline 203)

Toxicity to aquatic invertebrates

Daphnia magna (Water flea) Static test: EC50: 10.6 mg/L; 24h (As per OECD Guideline 202)

Toxicity to aquatic algae and cyanobacteria

Scenedesmus quadricauda (green algae) Static test: Toxicity threshold: 2370 mg/L; 7d

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 PBT and vPvB assessment

This substance or mixture contains no components considered to be persistent, bioaccumulating nor toxic (PBT) at levels of 0.1% or higher.

12.6 Other adverse effects

No data available

13 Disposal Considerations

13.1 Waste treatments methods

Product

Offer surplus and non-recyclable solutions to a licenced company. Contact a licenced professional waste disposal service to dispose of this material.

13.2 Contaminated packaging

Dispose of as unused product.

14 Transport Information

14.1 UN-No

ADNR : ADR : IATA_C : IATA_P : IMDG : RID :

14.2 UN proper shipping name

ADNR : Not dangerous goods
ADR : Not dangerous goods
IATA_C : Not dangerous goods
IATA_P : Not dangerous goods
IMDG : Not dangerous goods
RID : Not dangerous goods

14.3 Transport hazard class(es)

ADNR : - ADR : - IATA_C : - IATA_P : - IMDG : - RID : -

14.4 Packaging group

ADNR : ADR : IATA_C : IATA_P : IMDG : RID :

14.5 Environmental hazards

ADNR : No ADR : No IMDG : Marine Pollutant No IATA_C : No IATA_P : No RID : No

14.6 Special precautions for use

No data available

15 Regulatory Information

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

15.1 Safety health and environment regulations/legislation specific for the substance or mixture

No data available

15.2 Chemical Safety Assessment

No data available

16 Other information

H290	May be corrosive to metals
H302	Harmful if swallowed
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H360	May damage fertility or the unborn child
H410	Very toxic to aquatic life with long lasting effects
Acute Tox.oral 4	Acute toxicity, oral, Category 4
Aquatic Chronic 1	Hazardous to the aquatic environment, long term hazard, Category 1
Eye Dam. 1	Serious eye damage or eye irritation, Category 1
Eye Irrit. 2A	Serious eye damage or eye irritation, Category 2A
Met. Corr. 1	Corrosive to metals, Category 1
Repr.Tox. 1A, 1B	Reproductive toxicity, Category 1A, 1B
Skin Irrit. 2	Skin corrosion or irritation, Category 2
Skin Sens. 1	Sensitisation, Skin, Category 1

Further Information

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