



**SQUARE PHARMACEUTICALS PLC.
DHAKA UNIT**

MATERIAL SAFETY DATA SHEET

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Methimazole Tablets USP, 5 mg and 10 mg.

Generic Name: Methimazole Tablets, USP

Chemical Name API (IUPAC): 1-methylimidazole-2-thiol

Chemical Formula of API: C₄H₆N₂S

Legal Category: Prescription Only Medicine (POM)

Therapeutic Class: Thionamide antithyroid agent

Therapeutic Indication: Methimazole tablets are indicated:

- In patients with Graves' disease with hyperthyroidism or toxic multinodular goiter for whom surgery or radioactive iodine therapy is not an appropriate treatment option
- To ameliorate symptoms of hyperthyroidism in preparation for thyroidectomy or radioactive iodine therapy

How Supplied: 72578-212-00
72578-213-00

COMPANY INFORMATION:

SQUARE PHARMACEUTICALS PLC.

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SECTION 2: COMPOSITION AND INFORMATION ON INGREDIENTS

Composition:

Active Ingredient	Methimazole USP
Content	5 mg: Each Tablet contains Methimazole USP 5 mg.
	10 mg: Each Tablet contains Methimazole USP 10 mg.
Inactive ingredients	lactose monohydrate NF, pregelatinized starch NF, colloidal silicon dioxide NF, talc USP, and magnesium stearate NF.



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SECTION 3: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A

Label Elements

Signal Word: Danger

Hazard Statements: H360D - May damage the unborn child

Precautionary Statements: P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required

P308 + P313 - IF exposed or concerned: Get medical attention/advice

P405 - Store locked up

SECTION 4: FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

SECTION 5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.



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SECTION 6: ACCIDENTAL RELEASE MEASURE

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product used for Hyperthyroidism.



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SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Ingredients with workplace control parameters

Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use.

Body Protection

protective clothing

Respiratory protection

Required when dusts are generated. Recommended Filter type: Filter type P3

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Control of environmental exposure

Do not let product enter drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Parameters	Methimazole Tablets USP, 5 mg	Methimazole Tablets USP, 10 mg
Appearance	White to off-white, round, flat face beveled edge tablets, debossed "C" above bisect "1" below bisect on one side and plain on the other side.	White to off-white, round, flat face beveled edge tablets, debossed "C" above bisect "11" below bisect on one side and plain on the other side.
Color	White to off-white	

SECTION 10: STABILITY AND REACTIVITY DATA

Reactivity

No data available

Chemical stability Stable under normal conditions of use..

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available



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SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute toxicity Based on available data; the classification criteria are not met.

Acute toxicity

LD50 Oral - Mouse - 860 mg/kg

Remarks: Peripheral Nerve and Sensation:Spastic paralysis with or without sensory change.

Behavioral:Somnolence (general depressed activity).

Behavioral:Tremor.

Acute toxicity estimate Oral - 860 mg/kg

(ATE value derived from LD50/LC50 value)

Inhalation: No data available

Dermal: No data available

Skin corrosion/irritation

Skin - Rabbit

Result: No irritation

(OECD Test Guideline 404)

Remarks: (External MSDS)

Serious eye damage/eye irritation

Eyes - Rabbit

Result: Causes serious eye irritation.

(OECD Test Guideline 405)

Remarks: (External MSDS)

Respiratory or skin sensitization

- Mouse

Result: positive

Remarks: (External MSDS)

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

Suspected of damaging the unborn child.

Suspected of damaging fertility.

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

SECTION 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Mobility in Soil: No data available



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SECTION 13: DISPOSAL CONSIDERATION

Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

SECTION 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15: OTHER INFORMATION

MSDS Preparation Date: 05 March, 2025

MSDS Version Number: Original

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