TIAN HUA 天华制药

常州市天華制藥有限公司

CHANGZHOU TIANHUA PHARMACEUTICAL CO.,LTD.

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SAFETY DATA SHEET

1. Identification

Product identifier Methimazole

Other means of identification

CAS number 60-56-0 Synonyms Thiamazole

Chemical name 1-Methylimidazole-2-thiol

Recommended use For Manufacturing, processing or repacking.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name Changzhou Tianhua Pharmaceutical Co., Ltd.

Address 3# Houyang Chemical Zone,

Jintan, Changzhou,

China

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2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Serious eye damage/eye irritation Category 2A

Sensitization, skin Category 1B Reproductive toxicity Category 2

Specific target organ toxicity, repeated

exposure

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement Causes serious eye irritation. Suspected of damaging fertility or the unborn child. May cause an

allergic skin reaction. May cause damage to organs (thyroid gland) through prolonged or repeated

Category 2 (thyroid gland)

exposure.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Do not breathe dust. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye

protection/face protection.

Response If on skin: Wash with plenty of water/. If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention. Get

medical advice/attention if you feel unwell.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Methimazole	Thiamazole	60-56-0	100

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Remove contaminated clothing immediately and wash skin with soap and water. In case of

eczema or other skin disorders: Seek medical attention and take along these instructions.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if

present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

Most important

symptoms/effects, acute and

delayed

May cause allergic skin reaction. Pharmacologically active material. Occupational exposure may

cause physiological effects.

Indication of immediate medical attention and special treatment needed

Treat symptomatically. Overdose treatment may include the following: Administer activated charcoal as a slurry. For myelosuppression, administer colony stimulating factor for severe neutropenia. For severe thrombocytopenia or bleeding, transfuse platelets and/or packed red blood cells. Monitor CBC with differential and platelet count, liver enzymes, thyroid function, and fluid and electrolyte status. Hemodialysis, peritoneal dialysis, forced diuresis, or charcoal hemoperfusion have not been shown to be beneficial.

General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire fighting

Specific methods

equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing.

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the

material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Store in tight container. This material should be handled and stored per label instructions to Conditions for safe storage, ensure product integrity. including any incompatibilities

8. Exposure controls/personal protection

Occupational exposure limits No exposure limits noted for ingredient(s).

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering

controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary.

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

considerations

Hand protection Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved

or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of

skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection Respirators are generally not required for laboratory operations. Use a tight-fitting full-face

respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task

and the level of existing engineering controls.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene Handling practices in this SDS are recommendations for laboratory use of reference standards.

Procedures for any other uses or quantities should be determined after an appropriate

assessment.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid. **Form** Powder. White. Color

Odor Characteristic. Odor threshold Not available. pН Not available. Melting point/freezing point 293 °F (145 °C) Initial boiling point and boiling 536 °F (280 °C)

range

Flash point Not available. **Evaporation rate** Not available. Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

(%)

Not available.

Explosive limit - lower (%) Not available. Explosive limit - upper (%) Not available.

0.00004 kPa at 25 °C Vapor pressure

Vapor density Not available. Relative density Not available.

Solubility(ies)

Solubility (water) Freely soluble.

Solubility (other) Chloroform: Freely soluble.

Alcohol: Freely soluble.

Partition coefficient (n-octanol/water)

-0.34

Auto-ignition temperature Not available. **Decomposition temperature** Not available. Not available. **Viscosity**

Other information

Chemical family Thioamide derivative.

C4H6N2S Molecular formula Molecular weight 114.17

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Strong acids. Strong oxidizing agents. Strong bases.

Hazardous decomposition

products

SOx. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation Knowledge about health hazard is incomplete.

Skin contact May cause an allergic skin reaction.

Eye contact Causes serious eye irritation.

Symptoms related to the

physical, chemical, and

toxicological characteristics

Ingestion

Based on information from therapeutic use, this material may cause: Hypothyroidism. Gastrointestinal disturbances. Swelling. Central nervous system effects. Jaundice. Blood

disorders.

Information on toxicological effects

Acute toxicity

Product Species Test Results

Methimazole (CAS 60-56-0)

Oral

LD50 Rat 2250 mg/kg

Skin corrosion/irritation

Serious eye damage/eye irritation

Based on available data, the classification criteria are not met.

Local effects

Eye irritation

Causes serious eye irritation.

Result: Irritant. Species: Rabbit Severity: Strong. Skin irritation

Result: Non-irritant. Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization May cause an allergic skin reaction.

> Skin sensitization Result: Sensitizing. Species: Mouse

Germ cell mutagenicity Knowledge about mutagenicity is incomplete. Carcinogenicity Knowledge about carcinogenicity is incomplete.

0.5 - 18 mg/kg/day Carcinogenicity

Result: Positive results but clinical significance of the findings

are unclear. Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Methimazole (CAS 60-56-0) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Suspected of damaging fertility or the unborn child. Therapeutic use of methimazole can cause Reproductive toxicity

> adverse effects (hypothyroidism, goiter, and scalp defects) in the fetus, although the actual risk of fetal death or abnormal development appears to be low, especially if maternal doses are low. Fetal hypothyroidism and goiter usually occur when the antithyroid agents are used at the end of the

pregnancy.

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

May cause damage to organs () through prolonged or repeated exposure.

Aspiration hazard

Based on available data, the classification criteria are not met.

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

No data is available on the degradability of this substance.

12. Ecological information

Ecotoxicity

Mobility in soil

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

Bioaccumulative potential

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Dispose of in accordance with local regulations. Dispose in accordance with all applicable Local disposal regulations

regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and

Not applicable.

the IBC Code

General information It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

dous Yes

chemical

Classified hazard categories

Serious eye damage or eye irritation Respiratory or skin sensitization

Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

US state regulations

California Proposition 65



WARNING: This product can expose you to Methimazole, which is known to the State of California to cause

birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Developmental toxin

Methimazole (CAS 60-56-0) Listed: July 1, 1990

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes

Country(s) or region Inventory name On inventory (yes/no)*

Philippines Philippine Inventory of Chemicals and Chemical Substances No

(PICCS)

TaiwanTaiwan Chemical Substance Inventory (TCSI)YesUnited States & Puerto RicoToxic Substances Control Act (TSCA) InventoryYes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

 Issue date
 10-31-2019

 Revision date
 01-01-2021

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