Methenamine Tablets

Effective Date: 08-Feb-2003

Eli Lilly and Company
Material Safety Data Sheet

Section 1 - Chemical Product and Company

Manufacturer:
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Manufacturer's Emergency Phone:
1-317-276-2000
CHEMTREC:
1-800-424-9300 (North America)
1-703-527-3887 (International)

Common Name: Methenamine Tablets

CAS Number(s): 100-97-0
EC Number: 2029-05-8
Chemical Name: 1,3,5,7-Tetraazatricyclo[3.3.1.13,7]decane
Chemical Family: Tricyclic amine
Chemical Formula: C6 H12 N4
Molecular Weight: 140.200000
Synonym(s): Methenamine for Timed Burning; Hexamethylenetetramine; Methenamine; 004737 Formulation; HMTA Tablets
Lilly Serial Number(s): 004737
Lilly Item Code(s): TA0771; TA0772; TA1588

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

Ingredient	CAS
Methenamine	100-97-0

Exposure Guidelines: LEG <100 micrograms/m3 TWA for 8 or 12 hours.

Section 3 - Hazards Identification

Appearance: White to off-white powder finished as tablets
Physical State: Solid
Odor: Slight fishy

Emergency Overview

Emergency Overview Effective Date: 08-Feb-2003

Lilly Laboratory Labeling Codes:
Health 2 **Fire** 3 **Reactivity** 1

Primary Physical and Health Hazards: Flammable. Irritant. Suspect Allergen.

Caution Statement: Methenamine Tablets contain methenamine which is a flammable solid, may be irritating to the eyes, skin, and respiratory tract, and may cause allergic reactions.

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: Working with these uncoated tablets may result in exposure to methenamine dust. Occupational allergic reactions to methenamine have been reported in the literature. Irritation to skin, eyes, and mucous membranes have been reported.

Medical Conditions Aggravated by Exposure: Hypersensitivity to methenamine.

Carcinogenicity: Methenamine - Not listed by IARC, NTP, ACGIH, or OSHA. Two-year drinking water studies demonstrated no evidence of carcinogenicity in mice and rats. Two-year dietary studies demonstrated evidence of carcinogenicity in mice.

Section 4 - First Aid Measures

Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Section 5 - Fire Fighting Measures

Flash Point: 250 C (482 F)
Flash Method: Closed Cup
UEL: No applicable information found

LEL: No applicable information found

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: Is considered a flammable solid and will support combustion when exposed to an ignition source. As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

Hazardous Combustion Products: May emit toxic ammonia and formaldehyde fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

Spills: Scoop or scrape up for disposal. Do not vacuum. Avoid any source of ignition. Use non-sparking equipment. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

Section 7 - Handling and Storage

Storage Conditions: Warehouse: 10 to 40 C (50 to 104 F). Keep away from heat, sparks, and open flame.

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information. Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting:

Respiratory Protection: Use an approved respirator.

Eye Protection: Chemical goggles and/or face shield.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Section 9 - Physical and Chemical Properties

Appearance: White to off-white powder finished as tablets
Odor: Slight fishy
Boiling Point: Not applicable
Melting Point: Sublimes at about 263 C (505 F)
Specific Gravity: No applicable information found
pH: 8.4 @ 0.2 M
Evaporation Rate: No applicable information found

Water Solubility: Soluble
Vapor Density: 4.9 (Air = 1)
Vapor Pressure: No applicable information found

Section 10 - Stability and Reactivity

Stability: This material should not be exposed to temperatures above 85 C (185 F). This temperature is based on a laboratory test (Differential Scanning Calorimetry) and assumes near atmospheric pressures and quantities of less than 500 kg (1100 lb). For additional information refer to the CHL data base on ELVIS or contact the Lilly Chemical Hazards Laboratory.

Incompatibility: May react violently with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.) and strong acids.

Hazardous Decomposition: May emit toxic ammonia and formaldehyde fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Acute Exposure

Data for the active ingredient, methenamine, are reported.

Oral: Methenamine - Rat, median lethal dose greater than 2 g/kg.

Skin: Methenamine - No applicable information found.

Inhalation: Methenamine - No applicable information found.

Intravenous: Methenamine - Rat, median lethal dose 9200 mg/kg.

Subcutaneous: Methenamine - Mouse, median lethal dose 215 mg/kg, tremors.

Skin Contact: 0.2% Methenamine solution - Rabbit, nonirritant (repeated exposure)

Eye Contact: 0.2% Methenamine solution - Rabbit, nonirritant (repeated exposure)

Chronic Exposure

Data for the active ingredient, methenamine, are reported.

Target Organ Effects: Methenamine - No effects identified in animal studies.

Reproduction: Methenamine - No effects identified in animal studies.

Sensitization: 0.2% Methenamine solution - Guinea pig, not a contact sensitizer.

Mutagenicity: Methenamine - Both positive and negative results have been reported in bacterial tests. Not mutagenic in mammalian cells.

Section 12 - Ecological Information

Ecotoxicity Data: Methenamine
Fathead minnow 96-hour median lethal concentration: 50 g/L
Bleak fish 96-hour median lethal concentration: >10 g/L
Sheepshead minnow 96-hour median lethal concentration: 49 g/L
Daphnia magna 48-hour median effective concentration: 36 g/L
Harpacticoid copepod 96-hour median lethal concentration: 92.5 g/L
Green algae 14-day population growth effective concentration: 1.5 g/L

Environmental Fate: Methenamine
Bioconcentration factor: 0.40
Log Koc: 1.74
Henry's Law constant: 1.6 x 10(-9)
Hydrolysis half-life (days): 1

Environmental Summary: Methenamine - Practically non-toxic to aquatic organisms. Material is expected to be degraded by microorganisms. Material is mobile in the soil and expected to leach to the groundwater. Material is not expected to bioconcentrate in microorganisms. Material is expected to hydrolyze in aquatic environments. Material is not expected to volatilize from soil or aquatic environments.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

Regulatory Organizations:

DOT:
Proper Shipping Name: Hexamethylenetetramine
UN/NA: UN1328
Hazard Class: 4.1
Packing Group: III

ICAO/IATA:
Proper Shipping Name: Hexamethylenetetramine
UN/NA: UN1328
Hazard Class: 4.1
Packing Group: III

IMO:

Proper Shipping Name: Hexamethylenetetramine
UN/NA: UN1328
Hazard Class: 4.1
Packing Group: III

This material in final packaged form may be shipped under the Consumer Commodity exception by Highway within the United States under limited circumstances. Please contact your local Hazardous Material/Dangerous Goods representative for the proper use of this exception.

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Eli Lilly and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

TSCA - Yes
CERCLA - Not on this list
SARA 302 - Not on this list
SARA 313 - Not on this list
OSHA Substance Specific - No

EU Regulations

EC Classification
F (Highly Flammable)
Xn (Harmful)

Risk Phrases
R 11 - Highly flammable.
R 42/43 - May cause sensitization by inhalation and skin contact.

Safety Phrases
S 16 - Keep away from sources of ignition - No smoking.
S 22 - Do not breathe dust.
S 24 - Avoid contact with skin.
S 37 - Wear suitable gloves.

Section 16 - Other Information

MSDS Sections Revised: MSDS Status.

Emergency Overview Sections Revised: Emergency Overview Status.

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE

ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Eli Lilly and Company
Hazard Communication
317-277-6029

For additional copies contact:
Eli Lilly and Company
1-800-LILLY-Rx (1-800-545-5979)

GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association
BEI = Biological Exposure Index
CAS Number = Chemical Abstract Service Registry Number
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN = Chemical Hazard Alert Notice
CHEMTREC = Chemical Transportation Emergency Center
DOT = Department of Transportation
EC = European Community
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
EPA = Environmental Protection Agency
HEPA = High Efficiency Particulate Air (Filter)
IARC = International Agency for Research on Cancer
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association
IEG = Lilly Interim Exposure Guideline
IMO = International Maritime Organization
Kow = Octanol/Water Partition Coefficient
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
MSHA = Mine Safety and Health Administration
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances

SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline
STEL = Short Term Exposure Limit
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations
WEEL = Workplace Environmental Exposure Level (AIHA)