1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ethamsylate Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 50 Tuas West Drive
          Singapore - Singapore 638408
Telephone: +1-908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification
Serious eye damage/eye irritation: Category 2

GHS label elements
Hazard pictograms: !
Signal word: Warning
Hazard statements: H319 Causes serious eye irritation.
Precautionary statements: Prevention:
P264 Wash skin thoroughly after handling.
P280 Wear eye protection/face protection.
Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/attention.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS
4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. Get medical attention if symptoms occur.

In case of skin contact: Wash with water and soap as a precaution. Get medical attention if symptoms occur.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: Causes serious eye irritation.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Sulphur oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Avoid inhalation of vapour or mist. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labelled containers.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

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<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameters / Permissible</th>
<th>Basis</th>
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Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type

Hand protection: Chemical-resistant gloves

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: Aqueous solution

**Colour**: Colourless

**Odour**: No data available

**Odour Threshold**: No data available

**pH**: 6.0 - 7.0

**Melting point/freezing point**: No data available

**Initial boiling point and boiling range**: No data available
SAFETY DATA SHEET

Ethamsylate Formulation

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.
11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

**Acute toxicity**
Not classified based on available information.

**Components:**

**Ethamsylate:**
- **Acute oral toxicity:**
  - LD50 (Rat): 7,500 mg/kg
  - LD50 (Mouse): 8,300 mg/kg
  - LD50 (Guinea pig): 3,500 mg/kg
- **Acute toxicity (other routes of administration):**
  - LD50 (Mouse): > 4,000 mg/kg
    - Application Route: Intramuscular
  - LD50 (Mouse): 29,750 mg/kg
    - Application Route: Intraperitoneal
  - LD50 (Mouse): 760 mg/kg
    - Application Route: Intravenous
  - LD50 (Mouse): 6,040 mg/kg
    - Application Route: Subcutaneous
  - LD50 (Rat): > 4,000 mg/kg
    - Application Route: Intramuscular
  - LD50 (Rat): 1,350 mg/kg
    - Application Route: Intravenous
  - LD50 (Rat): 5,250 mg/kg
    - Application Route: Subcutaneous

**Skin corrosion/irritation**
Not classified based on available information.

**Serious eye damage/eye irritation**
Causes serious eye irritation.

**Components:**

**Ethamsylate:**
- **Species:** Rabbit
- **Result:** Moderate eye irritation
- **Method:** Draize Test
- **Remarks:** Moderate eye irritation
Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:

Ethamsylate:
Genotoxicity in vitro : Test Type: Mutagenicity (Salmonella typhimurium - reverse mutation assay)  
Result: negative

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

Components:

Ethamsylate:
Effects on foetal development : Test Type: Reproduction/Developmental toxicity screening test  
Species: Rat, female  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 300 mg/kg body weight  
Teratogenicity: NOAEL: 300 mg/kg body weight  
Result: No adverse effects

Test Type: Reproduction/Developmental toxicity screening test  
Species: Mouse, female  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 300 mg/kg body weight  
Teratogenicity: NOAEL: 300 mg/kg body weight  
Result: No adverse effects

Test Type: Reproduction/Developmental toxicity screening test  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 300 mg/kg body weight  
Teratogenicity: NOAEL: 300 mg/kg body weight  
Result: No adverse effects

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.
8. ASPIRATION TOXICITY
Not classified based on available information.

9. EXPERIENCE WITH HUMAN EXPOSURE

10. COMPONENTS:

Ethamsylate:
Ingestion: Symptoms: Headache, hypotension, Nausea
Remarks: The most common side effects are: Symptoms: bleeding, pruritis

11. FURTHER INFORMATION

Components:

Ethamsylate:
Remarks: The toxicological properties of this material have not been fully investigated

12. ECOLOGICAL INFORMATION

Ecotoxicity
No data available

Persistence and degradability
No data available

Bioaccumulative potential
No data available

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations
UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations : Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations : Not applicable

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information


Date format : dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International
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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.