SAFETY DATA SHEET

Amprolium Formulation

Section 1: Identification

Product name : Amprolium Formulation

Manufacturer or supplier’s details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Section 2: Hazard identification

GHS Classification

Skin corrosion/irritation : Category 1
Serious eye damage/eye irritation : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Central nervous system)

GHS label elements

Hazard pictograms : 

Signal word : Danger
Hazard statements : H314 Causes severe skin burns and eye damage.
                    H361 Suspected of damaging fertility or the unborn child.
                    H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Precautionary statements : Prevention:
                          P201 Obtain special instructions before use.
                          P202 Do not handle until all safety precautions have been read and understood.
                          P260 Do not breathe mist or vapours.
                          P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protec-
tion/ face protection.

Response:
P301 + P330 + P310 IF SWALLOWED: Rinse mouth.
Do NOT induce vomiting. Immediately call a POISON
CENTER/ doctor.
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off
immediately all contaminated clothing. Rinse skin with water or
shower. Immediately call a POISON CENTER/ doctor.
P304 + P340 + P310 IF INHALED: Remove person to fresh air
and keep comfortable for breathing. Immediately call a
POISON CENTER/ doctor.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with
water for several minutes. Remove contact lenses, if present
and easy to do. Continue rinsing. Immediately call a POISON
CENTER/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/
attention.
P363 Wash contaminated clothing before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste
disposal plant.

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients
Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amprolium</td>
<td>121-25-5</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
</tbody>
</table>

Section 4: First-aid measures
General advice : In the case of accident or if you feel unwell, seek medical ad-
vice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention immediately.

In case of skin contact : In case of contact, immediately flush skin with plenty of water
for at least 15 minutes while removing contaminated clothing
and shoes.
### Section 5: Fire-fighting 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

**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.

### Section 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).
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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.

Section 7: Handling and storage

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

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe mist or vapours.
- Do not swallow.
- Do not get in eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

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.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Oxidizing agents
  - Explosives
Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amprolium</td>
<td>121-25-5</td>
<td>TWA</td>
<td>40ug/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400ug/100cm²</td>
</tr>
</tbody>
</table>

Engineering measures:
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

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

Remarks: Consider double gloving.

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. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Section 9: Physical and chemical properties

Appearance: liquid

Colour: light yellow

Odour: No data available
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<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>2.0 - 3.0</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>0.900 - 1.100 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

## Section 10: Stability and reactivity

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reac-: Can react with strong oxidizing agents.
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Section 7: Handling and Storage

Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Components:
Amprolium:
Acute oral toxicity:
- LD50 (Mouse): 3,980 mg/kg
- LD50 (Rat): 4,000 - 4,890 mg/kg
- LD50 (Dog): > 500 mg/kg

Acute dermal toxicity:
- LD50 (Rat): > 2,000 mg/kg

Skin corrosion/irritation:
Causes severe burns.

Components:
Amprolium:
Species: Rabbit
Result: No skin irritation

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

Components:
Amprolium:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation:
Not classified based on available information.

Respiratory sensitisation:
Not classified based on available information.
**Amprolium Formulation**

<table>
<thead>
<tr>
<th>Components:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amprolium:</strong></td>
</tr>
<tr>
<td>Test Type: Local lymph node assay (LLNA)</td>
</tr>
<tr>
<td>Exposure routes: Dermal</td>
</tr>
<tr>
<td>Species: Mouse</td>
</tr>
<tr>
<td>Result: Sensitiser</td>
</tr>
</tbody>
</table>

**Chronic toxicity**

**Germ cell mutagenicity**
Not classified based on available information.

<table>
<thead>
<tr>
<th>Components:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amprolium:</strong></td>
</tr>
<tr>
<td>Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Result: negative</td>
</tr>
<tr>
<td>Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive</td>
</tr>
<tr>
<td>Test Type: in vitro micronucleus test Result: positive</td>
</tr>
</tbody>
</table>

Genotoxicity in vivo: Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Result: negative

Test Type: unscheduled DNA synthesis assay Species: Rat Cell type: Liver cells Result: negative

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

**Carcinogenicity**
Not classified based on available information.

<table>
<thead>
<tr>
<th>Components:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amprolium:</strong></td>
</tr>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Exposure time: 2 Years</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Reproductive toxicity**
Suspected of damaging fertility or the unborn child.

<table>
<thead>
<tr>
<th>Components:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amprolium:</strong></td>
</tr>
</tbody>
</table>
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Effects on fertility: Test Type: Multi-generation study
Species: Mouse
Application Route: Oral
Fertility: NOAEL: 200 mg/kg body weight
Result: Effects on reproduction parameters
Remarks: Maternal toxicity observed.

Effects on foetal development: Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 200 mg/kg body weight
Result: No significant adverse effects were reported

Reproductive toxicity - Assessment: Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Components:
Amprolium:
Exposure routes: Oral
Target Organs: Central nervous system
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity
Components:
Amprolium:
Species: Rat
NOAEL: 20 mg/kg
Application Route: Oral
Exposure time: 2 yr
Symptoms: Reduced body weight

Species: Dog
NOAEL: 100 mg/kg
Application Route: Oral
Exposure time: 2 yr
Target Organs: Central nervous system
Symptoms: Dilatation of the pupil, paralysis

Species: Dog
NOAEL: 100 mg/kg
Application Route: Oral
Exposure time: 59 Weeks
Target Organs: Central nervous system
Symptoms: ataxia, Convulsions, Coma, Loss of reflexes, Tremors
Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Amprolium:
Inhalation: Target Organs: Skin
Symptoms: Allergic reactions

Eye contact: Target Organs: Lungs
Symptoms: Allergic reactions, Asthma

Ingestion: Target Organs: Central nervous system
Symptoms: Neurological disorders

Section 12: Ecological information

Ecotoxicity

Components:

Amprolium:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 110 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Persistence and degradability
No data available

Bioaccumulative potential

Components:

Amprolium:
Partition coefficient: n-octanol/water: log Pow: -1.12
pH: 7

Mobility in soil
No data available

Other adverse effects
No data available
Section 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.

Section 14: Transport information

International Regulations

UNRTDG
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable

IATA-DGR
- UN/ID No.: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable
- Packing instruction (cargo aircraft): Not applicable
- Packing instruction (passenger aircraft): Not applicable

IMDG-Code
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable
- EmS Code: Not applicable
- Marine pollutant: Not applicable

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

National Regulations

NZS 5433
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable
- Hazchem Code: Not applicable
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Version: 1.1  Revision Date: 27.08.2021
SDS Number: 8633867-00002  Date of last issue: 21.05.2021
Date of first issue: 21.05.2021

Special precautions for user
Not applicable

Section 15: Regulatory information

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

HSNO Approval Number
HSR100758 Veterinary Medicines Non dispersive Closed System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

Section 16: Other information

Further information

Date format : dd.mm.yyyy

Full text of other abbreviations

AIIIC - 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 Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median
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Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substances; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

NZ / EN