

Amprolium Formulation

Version 1.3 Revision Date: 01.10.2022 SDS Number: 8633866-00004 Date of last issue: 09.04.2022
Date of first issue: 21.05.2021

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Amprolium 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

Restrictions on use :
Not applicable

2. HAZARDS 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.

Amprolium Formulation

Version 1.3 Revision Date: 01.10.2022 SDS Number: 8633866-00004 Date of last issue: 09.04.2022
 Date of first issue: 21.05.2021

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 protection/ face protection.

Response:

P301 + P330 + P331 + 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/ 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------|----------|-----------------------|
| Amprolium | 121-25-5 | >= 20 -< 30 |

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.
 If not breathing, give artificial respiration.
 If breathing is difficult, give oxygen.

Amprolium Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 09.04.2022 |
| 1.3 | 01.10.2022 | 8633866-00004 | Date of first issue: 21.05.2021 |

- | | | |
|---|---|---|
| In case of skin contact | : | <p>Get medical attention immediately.</p> <p>In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.</p> <p>Get medical attention immediately.</p> <p>Wash clothing before reuse.</p> <p>Thoroughly clean shoes before reuse.</p> |
| In case of eye contact | : | <p>In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.</p> <p>If easy to do, remove contact lens, if worn.</p> <p>Get medical attention immediately.</p> |
| If swallowed | : | <p>If swallowed, DO NOT induce vomiting.</p> <p>If vomiting occurs have person lean forward.</p> <p>Call a physician or poison control centre immediately.</p> <p>Rinse mouth thoroughly with water.</p> <p>Never give anything by mouth to an unconscious person.</p> |
| Most important symptoms and effects, both acute and delayed | : | <p>Causes serious eye damage.</p> <p>Suspected of damaging fertility or the unborn child.</p> <p>Causes damage to organs through prolonged or repeated exposure if swallowed.</p> <p>Causes severe burns.</p> <p>Causes digestive tract burns.</p> |
| Protection of first-aiders | : | <p>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).</p> |
| Notes to physician | : | <p>Treat symptomatically and supportively.</p> |
-

5. FIREFIGHTING MEASURES

- | | | |
|---|---|--|
| Suitable extinguishing media | : | <p>Water spray</p> <p>Alcohol-resistant foam</p> <p>Carbon dioxide (CO₂)</p> <p>Dry chemical</p> |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire-fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides |
| Specific extinguishing methods | : | <p>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</p> <p>Use water spray to cool unopened containers.</p> <p>Remove undamaged containers from fire area if it is safe to do so.</p> <p>Evacuate area.</p> |
| Special protective equipment for firefighters | : | <p>In the event of fire, wear self-contained breathing apparatus.</p> <p>Use personal protective equipment.</p> |
-

6. ACCIDENTAL RELEASE MEASURES

- | | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | <p>Use personal protective equipment.</p> <p>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</p> |
|---|---|---|

Amprolium Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 09.04.2022 |
| 1.3 | 01.10.2022 | 8633866-00004 | Date of first issue: 21.05.2021 |

- 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 : 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.
- 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type | Control parame- | Basis |
|------------|---------|------------|-----------------|-------|
|------------|---------|------------|-----------------|-------|

Amprolium Formulation

Version 1.3 Revision Date: 01.10.2022 SDS Number: 8633866-00004 Date of last issue: 09.04.2022
 Date of first issue: 21.05.2021

| | | (Form of exposure) | ters / Permissible concentration | |
|---------------------------|----------|--------------------|----------------------------------|----------|
| Amprolium | 121-25-5 | TWA | 40ug/m3 (OEB 3) | Internal |
| Further information: DSEN | | | | |
| | | Wipe limit | 400ug/100cm2 | Internal |

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.
 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

Material : 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.

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 : liquid

Amprolium Formulation

Version 1.3 Revision Date: 01.10.2022 SDS Number: 8633866-00004 Date of last issue: 09.04.2022
Date of first issue: 21.05.2021

| | | |
|--|---|--|
| Colour | : | light yellow |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| pH | : | 2.0 - 3.0 |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | Not applicable |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | 0.900 - 1.100 g/cm ³ |
| Solubility(ies) Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |

10. STABILITY AND REACTIVITY

Amprolium Formulation

Version 1.3 Revision Date: 01.10.2022 SDS Number: 8633866-00004 Date of last issue: 09.04.2022
Date of first issue: 21.05.2021

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:**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

Version 1.3 Revision Date: 01.10.2022 SDS Number: 8633866-00004 Date of last issue: 09.04.2022
Date of first issue: 21.05.2021

Components:**Amprolium:**

Test Type : Local lymph node assay (LLNA)
Exposure routes : Dermal
Species : Mouse
Result : Sensitiser

Germ cell mutagenicity

Not classified based on available information.

Components:**Amprolium:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: positive

Test Type: in vitro micronucleus test
Result: positive

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.

Components:**Amprolium:**

Species : Rat
Exposure time : 2 Years
Result : negative

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Components:**Amprolium:**

Effects on fertility : Test Type: Multi-generation study

Amprolium Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 09.04.2022 |
| 1.3 | 01.10.2022 | 8633866-00004 | Date of first issue: 21.05.2021 |

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

Amprolium Formulation

Version 1.3 Revision Date: 01.10.2022 SDS Number: 8633866-00004 Date of last issue: 09.04.2022
Date of first issue: 21.05.2021

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

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

Amprolium Formulation

Version Revision Date: SDS Number: Date of last issue: 09.04.2022
1.3 01.10.2022 8633866-00004 Date of first issue: 21.05.2021

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**

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.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

Amprolium Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 09.04.2022 |
| 1.3 | 01.10.2022 | 8633866-00004 | Date of first issue: 21.05.2021 |

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

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 01.10.2022

Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD
compile the Safety Data eChem Portal search results and European Chemicals Agen-
Sheet cy, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

Full text of other abbreviations

AIC - 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 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 substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances

Amprolium Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 09.04.2022 |
| 1.3 | 01.10.2022 | 8633866-00004 | Date of first issue: 21.05.2021 |

es; (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.

SG / EN