

SAFETY DATA SHEET



Amprolium Solid Formulation

Version 4.0 Revision Date: 14.04.2025 SDS Number: 10858466-00006 Date of last issue: 06.07.2024 Date of first issue: 30.09.2022

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Amprolium Solid Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Dermal) : Category 5
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 : H313 May be harmful in contact with skin.
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 dust.
P264 Wash skin thoroughly after handling.

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P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P330 + P310 IF SWALLOWED: Rinse mouth.
Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/ physician.

P303 + P361 + P353 + P310 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower. Immediately call a POISON CENTER or doctor/ physician.

P304 + P340 + P310 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/ physician.

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 or doctor/ physician.

P312 Call a POISON CENTER or doctor/ physician if you feel unwell.

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

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------|----------|-----------------------|
| Amprolium | 121-25-5 | >= 50 -< 70 |

SECTION 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.
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.

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|---|---|
| In case of eye contact | Get medical attention immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse. : 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. |
| If swallowed | Get medical attention immediately. : If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control center immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. |
| Most important symptoms and effects, both acute and delayed | Causes digestive tract burns. May be harmful in contact with skin. Causes serious eye damage. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure if swallowed. Causes severe burns. |
| 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. |

SECTION 5. FIRE-FIGHTING MEASURES

| | |
|--|---|
| Suitable extinguishing media | : Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : None known. |
| Specific hazards during fire fighting | : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. 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 fire-fighters | : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

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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. 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 : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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 : Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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 dust. 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. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. 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.

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| | 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 labeled 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: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
|------------|---------------------------|-------------------------------------|--|----------|
| Amprolium | 121-25-5 | TWA | 40 ug/m3 (OEB 3) | Internal |
| | Further information: DSEN | | | |
| | | Wipe limit | 140 ug/100cm ² | Internal |

| | |
|-----------------------------|---|
| Engineering measures | : 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 |

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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 | : | powder |
| Color | : | light yellow |
| Odor | : | No data available |
| Odor 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 | : | Not applicable |
| Evaporation rate | : | Not applicable |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : | Not applicable |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapor pressure | : | Not applicable |
| Relative vapor density | : | Not applicable |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Autoignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |

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|--------------------------|---|--|
| Viscosity, kinematic | : | Not applicable |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle characteristics | | |
| Particle size | : | No data available |

SECTION 10. STABILITY AND REACTIVITY

| | | |
|------------------------------------|---|--|
| Reactivity | : | Not classified as a reactivity hazard. |
| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents. |
| Conditions to avoid | : | Heat, flames and sparks. Avoid dust formation. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

May be harmful in contact with skin.

Product:

| | | |
|-----------------------|---|--|
| Acute oral toxicity | : | Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method |
| Acute dermal toxicity | : | Acute toxicity estimate: 4,167 mg/kg Method: Calculation method |

Components:

Amprolium:

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

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Amprolium:

||| Test Type : Local lymph node assay (LLNA)
||| Routes of exposure : Dermal
||| Species : Mouse
||| Result : Sensitizer

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

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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
Species: Mouse
Application Route: Oral
Fertility: NOAEL: 200 mg/kg body weight
Result: Effects on reproduction parameters.
Remarks: Maternal toxicity observed.

Effects on fetal 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.

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Components:

Amprolium:

| | | |
|--------------------|---|---|
| Routes of exposure | : | 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 y |
| Symptoms | : | Reduced body weight |
| Species | : | Dog |
| NOAEL | : | 100 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 2 y |
| 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:

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| 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 | : Do not dispose of waste into sewer. 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

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.

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Domestic regulation

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, : Not applicable
essential chemical products and machinery for
producing capsules, tablets and pills.

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025
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 Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - 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 Substanc-

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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

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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