

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

### SECTION 1. IDENTIFICATION

Product name : Amprolium Solid Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
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@merck.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 in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

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

#### Other hazards

None known.

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
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.

Supplemental Hazard State- : Corrosive to the respiratory tract.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version 5.0      Revision Date: 06/17/2025      SDS Number: 10858452-00007      Date of last issue: 04/14/2025  
Date of first issue: 09/30/2022

ments

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

### Response:

P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER.  
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Immediately call a POISON CENTER.  
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER.  
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.  
P308 + P313 IF exposed or concerned: Get medical attention.  
P363 Wash contaminated clothing before reuse.

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Amprolium	121-25-5*	>= 45 - <= 70	TSC

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

		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. Get medical attention immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.
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 immediately.
If swallowed	:	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. 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. Corrosive to the respiratory tract.
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 (CO2) 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

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

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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version 5.0      Revision Date: 06/17/2025      SDS Number: 10858452-00007      Date of last issue: 04/14/2025  
Date of first issue: 09/30/2022

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.

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

inert or nuisance dust      50 Million particles per cubic foot  
Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3

15 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3

5 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

15 Million particles per cubic foot  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

Dust, nuisance dust and particulates      10 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (Total dust)  
Basis: CAL PEL

5 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (respirable dust fraction)  
Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Amprolium	121-25-5	TWA	40 ug/m3 (OEB 3)	Internal
Further information: DSEN				
		Wipe limit	140 ug/100cm2	Internal

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

**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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

### 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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : powder

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

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

Not classified based on available information.

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

#### **Skin corrosion/irritation**

Causes severe burns.



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

### 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 Species: Mouse Cell type: Bone marrow Result: negative
	Test Type: unscheduled DNA synthesis assay

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

	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

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### 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

Corrosive to the respiratory tract.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

### STOT-repeated exposure

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

#### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

### 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
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#### 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. Do not dispose of waste into sewer.
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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

### IATA-DGR

Not regulated as a dangerous good

### IMDG-Code

Not regulated as a dangerous good

### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### Domestic regulation

### 49 CFR

Not regulated as a dangerous good

### Special precautions for user

Not applicable

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Combustible dust  
Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)  
Skin corrosion or irritation  
Serious eye damage or eye irritation

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

Amprolium	121-25-5
Lactose	63-42-3

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

AICS	: not determined
DSL	: not determined
IECSC	: not determined

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



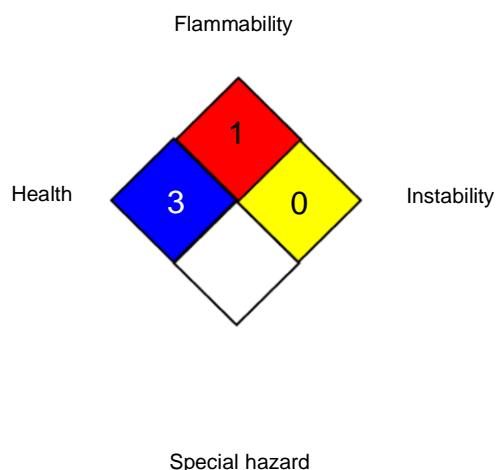
## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

CAL PEL	:	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
CAL PEL / PEL	:	Permissible exposure limit
OSHA Z-3 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
5.0	06/17/2025	10858452-00007	Date of first issue: 09/30/2022

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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; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - 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

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/>

Revision Date : 06/17/2025

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

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.

US / Z8