

Amprolium Solid Formulation

Version 2.0 Revision Date: 04.04.2023 SDS Number: 10858464-00003 Date of last issue: 03.11.2022
Date of first issue: 30.09.2022

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Amprolium Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

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

Restrictions on use :
Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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)


Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic hazard : Category 3

GHS label elements

Amprolium Solid Formulation

Version 2.0 Revision Date: 04.04.2023 SDS Number: 10858464-00003 Date of last issue: 03.11.2022
 Date of first issue: 30.09.2022

- 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.
 H412 Harmful to aquatic life with long lasting effects.
- Precautionary statements : **Prevention:**
 P203 Obtain, read and follow all safety instructions before use.
 P260 Do not breathe dust.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:**
 P301 + P330 + P331 + P316 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Get emergency medical help immediately.
 P302 + P361 + P354 + P316 IF ON SKIN: Take off immediately all contaminated clothing. Immediately rinse with water for several minutes. Get emergency medical help immediately.
 P304 + P340 + P316 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get emergency medical help immediately.
 P305 + P354 + P338 + P316 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get emergency medical help immediately.
 P318 IF exposed or concerned, get medical advice.
 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

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Amprolium Solid Formulation

Version 2.0 Revision Date: 04.04.2023 SDS Number: 10858464-00003 Date of last issue: 03.11.2022
 Date of first issue: 30.09.2022

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

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.
 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 centre 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.

5. FIREFIGHTING 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.

Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.11.2022
2.0	04.04.2023	10858464-00003	Date of first issue: 30.09.2022

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.

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.

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

Amprolium Solid Formulation

Version 2.0 Revision Date: 04.04.2023 SDS Number: 10858464-00003 Date of last issue: 03.11.2022
 Date of first issue: 30.09.2022

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

Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.11.2022
2.0	04.04.2023	10858464-00003	Date of first issue: 30.09.2022

- 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 : powder
- 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 : 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
- Vapour pressure : Not applicable
- Relative vapour density : Not applicable
- Relative density : No data available

Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.11.2022
2.0	04.04.2023	10858464-00003	Date of first issue: 30.09.2022

Density	:	No data available
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	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

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.

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

Amprolium Solid Formulation

Version 2.0 Revision Date: 04.04.2023 SDS Number: 10858464-00003 Date of last issue: 03.11.2022
Date of first issue: 30.09.2022

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.

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

Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.11.2022
2.0	04.04.2023	10858464-00003	Date of first issue: 30.09.2022

		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 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.

Amprolium Solid Formulation

Version 2.0 Revision Date: 04.04.2023 SDS Number: 10858464-00003 Date of last issue: 03.11.2022
 Date of first issue: 30.09.2022

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

Amprolium Solid Formulation

Version 2.0 Revision Date: 04.04.2023 SDS Number: 10858464-00003 Date of last issue: 03.11.2022
 Date of first issue: 30.09.2022

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

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.11.2022
2.0	04.04.2023	10858464-00003	Date of first issue: 30.09.2022

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.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture****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 : 04.04.2023

Further informationSources of key data used to compile the 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.

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 Or-

Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.11.2022
2.0	04.04.2023	10858464-00003	Date of first issue: 30.09.2022

ganisation 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; (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.

IN / EN