

Amprolium Solid Formulation

Version 2.1 Revision Date: 30.09.2023 SDS Number: 10858221-00003 Date of last issue: 04.04.2023
Date of first issue: 30.09.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : Amprolium Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Skin corrosion, Category 1	H314: Causes severe skin burns and eye damage.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Reproductive toxicity, Category 2	H361: Suspected of damaging fertility or the unborn child.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Danger

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Hazard statements : H314 Causes severe skin burns and eye damage.
 H361 Suspected of damaging fertility or the unborn child.
 H372 Causes damage to organs through prolonged or repeated exposure.
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
 P201 Obtain special instructions before use.
 P260 Do not breathe dust.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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

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.

Hazardous components which must be listed on the label:

Amprolium

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Amprolium	121-25-5 204-458-4	Repr. 2; H361 STOT RE 1; H372 (Central nervous system) Aquatic Chronic 3; H412	>= 50 - < 70

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of 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.
- 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).
- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Causes serious eye damage.
Suspected of damaging fertility or the unborn child.
Causes damage to organs through prolonged or repeated exposure.
Causes severe burns.

Causes digestive tract burns.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.
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SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
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Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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

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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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- | | | |
|-------------------------|---|--|
| Technical measures | : | <p>Static electricity may accumulate and ignite suspended dust causing an explosion.</p> <p>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</p> |
| Local/Total ventilation | : | <p>If sufficient ventilation is unavailable, use with local exhaust ventilation.</p> |
| Advice on safe handling | : | <p>Do not get on skin or clothing.</p> <p>Do not breathe dust.</p> <p>Do not swallow.</p> <p>Do not get in eyes.</p> <p>Wash skin thoroughly after handling.</p> <p>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment</p> <p>Keep container tightly closed.</p> <p>Minimize dust generation and accumulation.</p> <p>Keep container closed when not in use.</p> <p>Keep away from heat and sources of ignition.</p> <p>Take precautionary measures against static discharges.</p> <p>Do not eat, drink or smoke when using this product.</p> <p>Take care to prevent spills, waste and minimize release to the environment.</p> |
| Hygiene measures | : | <p>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.</p> <p>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.</p> |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|--|
| Requirements for storage areas and containers | : | <p>Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.</p> |
| Advice on common storage | : | <p>Do not store with the following product types:</p> <ul style="list-style-type: none"> Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases |

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7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Amprolium	121-25-5	TWA	40ug/m3 (OEB 3)	Internal
Further information: DSEN				
		Wipe limit	400ug/100cm2	Internal

8.2 Exposure controls

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

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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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.

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

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.

9.2 Other information

Flammability (liquids) : Not applicable

Molecular weight : No data available

Particle size : No data available

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SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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:

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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

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- As- : Weight of evidence does not support classification as a germ

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assessment 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.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

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

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NOAEL	:	20 mg/kg
Application Route	:	Oral
Exposure time	:	2 yr
Symptoms	:	Reduced body weight
Species	:	Dog
NOAEL	:	100 mg/kg
Application Route	:	Oral
Exposure time	:	2 yr
Target Organs	:	Central nervous system
Symptoms	:	Dilatation of the pupil, paralysis
Species	:	Dog
NOAEL	:	100 mg/kg
Application Route	:	Oral
Exposure time	:	59 Weeks
Target Organs	:	Central nervous system
Symptoms	:	ataxia, Convulsions, Coma, Loss of reflexes, Tremors

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Amprolium:**

Inhalation	:	Target Organs: Skin Symptoms: Allergic reactions
Eye contact	:	Target Organs: Lungs Symptoms: Allergic reactions, Asthma
Ingestion	:	Target Organs: Central nervous system Symptoms: Neurological disorders

SECTION 12: Ecological information**12.1 Toxicity****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

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12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

Amprolium:

Partition coefficient: n-
octanol/water : log Pow: -1,12
pH: 7

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
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

14.1 UN number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good

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IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information**15.1 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

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15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H361 : Suspected of damaging fertility or the unborn child.
 H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.
 H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard
 Repr. : Reproductive toxicity
 STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

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Sources 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/>

Classification of the mixture:

Skin Corr. 1	H314
Eye Dam. 1	H318
Repr. 2	H361
STOT RE 1	H372
Aquatic Chronic 3	H412

Classification procedure:

Based on product data or assessment
Based on product data or assessment
Calculation method
Calculation method
Calculation method

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.

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