

Amprolium Formulation

Version Revision Date: SDS Number: Date of last issue: 30.04.2024 3.0 06.07.2024 8633870-00010 Date of first issue: 21.05.2021

SECTION 1: IDENTIFICATION

Product name : Amprolium Formulation

Manufacturer or supplier's details

Company : Intervet Australia Pty Limited (trading as MSD Animal Health)

Address : 91-105 Harpin Street

Bendigo 3550, Victoria Austrailia

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

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

Skin corrosion/irritation : Category 1

Serious eye damage/eye irri-

tation

Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - :

repeated exposure (Oral)

Category 1 (Central nervous system)

GHS label elements

Hazard pictograms





Signal word : Danger

Hazard statements : H314 Causes severe skin burns and eye damage.

H361 Suspected of damaging fertility or the unborn child. H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Precautionary statements : Prevention:





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P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe mist or vapours.

P264 Wash skin thoroughly after handling.

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

Response:

P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor.

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

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

P308 + P313 IF exposed or concerned: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------|----------|-----------------------|
| Amprolium | 121-25-5 | >= 10 -< 30 |

SECTION 4. FIRST AID MEASURES

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.



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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 contact, immediately flush eyes with plenty of water In case of eye contact

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 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.

Causes digestive tract burns.

First Aid responders should pay attention to self-protection, Protection of first-aiders

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

SECTION 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

Hazardous combustion prod: :

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

Exposure to combustion products may be a hazard to health.

cumstances and the surrounding environment.

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Evacuate area.

Special protective equipment:

for firefighters

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, protec: :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

See Engineering measures under EXPOSURE Technical measures

CONTROLS/PERSONAL PROTECTION section.

If sufficient ventilation is unavailable, use with local exhaust Local/Total ventilation

ventilation.

Advice on safe handling Do not get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

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,



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industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

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

SECTION 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 | 40 ug/m3 (OEB 3) | Internal | |
| | Further information: DSEN | | | | |
| | | Wipe limit | 140 ug/100cm2 | Internal | |

Engineering measures: Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-

less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face con-

tainment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type
Hand protection

Particulates type

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.



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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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : light yellow

Odour : No data available

Odour Threshold : No data available

pH : 2.0 - 3.0

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : Not applicable

Relative vapour density : No data available

Relative density : No data available

Density : 0.900 - 1.100 g/cm³

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature

: No data available



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Decomposition temperature No data available

Viscosity

Viscosity, kinematic No data available

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Inhalation Exposure routes

> Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Amprolium:

Acute oral toxicity : LD50 (Mouse): 3,980 mg/kg

LD50 (Rat): 4,000 - 4,890 mg/kg

LD50 (Dog): > 500 mg/kg

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

Skin corrosion/irritation

Causes severe burns.

Components:

Amprolium:

Species Rabbit

Result No skin irritation



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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 : Sensitiser

Chronic toxicity

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



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Germ cell mutagenicity -

: Weight of evidence does not support classification as a germ

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 develop-

Test Type: Development

ment

Species: Rabbit

Application Route: Oral

Developmental Toxicity: NOAEL: 200 mg/kg body weight Result: No significant adverse effects were reported

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and

fertility, and/or on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

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

Components:

Amprolium:

Exposure routes : Oral

Target Organs : Central nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.



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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: DogNOAEL: 100 mg/kgApplication Route: OralExposure 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, AsthmaTarget Organs: Central nervous systemSymptoms: Neurological disorders

DMATION

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Ingestion

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 : EC50 (Daphnia magna (Water flea)): 110 mg/l



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aquatic invertebrates Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): 100

plants mg/l

Exposure time: 72 h Method: OECD Test Guideline 201

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Amprolium:

Partition coefficient: n- : log Pow: -1.12

octanol/water 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable Proper shipping name : Not applicable Class : Not applicable



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Subsidiary risk Not applicable Packing group Not applicable Labels Not applicable Packing instruction (cargo Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

IMDG-Code

UN number Not applicable Not applicable Proper shipping name Class Not applicable Subsidiary risk Not applicable Packing group Not applicable Labels Not applicable EmS Code Not applicable Not applicable Marine pollutant

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

ADG

UN number Not applicable Not applicable Proper shipping name Class Not applicable Not applicable Subsidiary risk Not applicable Packing group Labels Not applicable Not applicable Hazchem Code

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Therapeutic Goods (Poisons: Standard) Instrument

No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or

threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements There is no applicable prohibition,

authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regula-

tions.

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

AICS not determined

DSL not determined



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IECSC : not determined

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

Revision Date : 06.07.2024

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD compile the Safety Data : eChem Portal search results and European Chemicals Agen-

Sheet cy, http://echa.europa.eu/

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

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; 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



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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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