

SECTION 1 IDENTIFICATION OF THE MATERIAL AND SUPPLIER

GHS Product identifier:	Proud-Aid Wound Care Treatment for Horses
Other means of identification:	Proud-Aid
Recommended use of the product and restrictions on use:	To aid in the treatment of cuts, wounds and abrasions and aid in the treatment and prevention of excessive granulation tissue (Proud Flesh)
Supplier's Details:	Pharmachem Australia Pty Ltd Unit 6, 70 Fison Ave West Eagle Farm QLD 4009 Telephone: (07) 3868 0333
Emergency phone number:	13 11 26 (Poisons Information Hotline)

SECTION 2 HAZARDS IDENTIFICATION

Classification of Product:

This product is classified as a health hazard and an aquatic hazard in accordance with the following classification criteria of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Eighth Revised Edition.

However, it should be noted that the product is packaged in 100 g individual containers and because of this, the actual level of hazard is expected to be minimal.

Skin irritant

Category 2

GHS label elements, including precautionary statements:

Pictogram:



Signal word:

Warning

Hazard statements:

Causes skin irritation

Precautionary statements:

Prevention:	Keep out of reach of children Wear suitable protective clothing and gloves Do not eat drink or smoke when using this product Wash hands thoroughly after handling
Response:	If on skin wash with plenty of soap and water If skin irritation occurs get medical advice/attention

Serious eye damage/eye irritation Category 1

GHS label elements, including precautionary statements:

Pictogram:



Signal word: Danger
 Hazard statement: Causes serious eye damage
 Precautionary statements:
 Prevention: Avoid contact with eyes. Wear safety glasses / goggles
 Wash hands thoroughly after handling
 Response: Call the Poisons Information Centre or a doctor
 If in eyes rinse cautiously with water for several minutes. Remove
 contact lenses, if present and easy to do. Continue rinsing.

Acute aquatic toxicity Category 1
 GHS label elements, including precautionary statements:
 Pictogram:



Signal word: Warning
 Hazard statement: Very toxic to aquatic life
 Precautionary statements:
 Prevention: Read label before use.
 Avoid release to the environment.
 Response: Collect spillage

Chronic aquatic toxicity Category 1
 GHS label elements, including precautionary statements:
 Pictogram:



Signal word: Warning
 Hazard statement: Very toxic to aquatic life with long lasting effects.
 Precautionary statement
 Prevention: Read label before use.
 Avoid release to the environment.
 Response: Collect spillage

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No	Concentration (g/kg)
Calcium hydroxide	1305-62-0	344 g/kg
Copper sulfate	7758-98-7	29 g/kg
Proprietary non-hazardous ingredients		to 1000 g/kg

SECTION 4 FIRST AID MEASURES

The following First Aid directions have been set by the Office of Chemical Safety (OCS) of the Commonwealth Department of Health:

If poisoning occurs, contact a doctor or Poisons Information Centre. Telephone 131126.
 If skin contact occurs, remove contaminated clothing and wash skin thoroughly. If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

However, the following additional information is provided for assistance in emergent circumstances:

- Inhalation: No first aid measures normally required. However, if inhalation has occurred, and irritation has developed, remove to fresh air and observe until recovered. If irritation becomes painful or persists more than about 30 minutes, seek medical advice.
- Skin Contact: Flush with lukewarm, gently flowing water for 5 minutes or until chemical is removed.
- Eye Contact: Immediately flush the contaminated eye(s) with lukewarm, gently flowing water for 20 minutes or until the product is removed, while holding the eyelid(s) open. Take care not to rinse contaminated water into the unaffected eye or onto the face. Obtain medical attention immediately. Take special care if exposed person is wearing contact lenses.
- Ingestion: If swallowed, do NOT induce vomiting. Wash mouth with water.

SECTION 5 FIRE FIGHTING MEASURES

Product is considered to be non – combustible and not a significant fire risk.

- Suitable extinguishing media: Use extinguishing media suitable for the surrounding fire.
- Hazards from combustion products: None known
- Special protective precautions and equipment for fire fighters: Use precautions appropriate for the surrounding fire.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Emergency procedures:

Contain spillage by mixing with absorbent material. Do not allow product to enter sewers, waterways or drains.

Methods and materials for containment and clean up:

Spills should be absorbed with inert material such as clay or proprietary clean up materials and placed in drums or other receptacles for transport to an approved local authority disposal facility. Workers cleaning up spilled product should wear eye protection and clothing to protect the skin.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling:

The following Safety Directions have been set by the Australian Pesticides and Veterinary Medicines Authority (APVMA):

Harmful if swallowed. Will damage the eyes. Avoid contact with eyes and skin. When using the product wear rubber gloves. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. Wash hands after use. After each day's use wash gloves and contaminated clothing.

Conditions for safe storage, including any incompatibilities:

The following storage directions have been approved for this product by the APVMA:

Store below 30°C (Room Temperature). Keep container tightly closed.

In addition, store locked up in a cool, dry place. Protect containers against physical damage.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits have not been set for Proud-Aid. The only ingredient in the product for which a limit has been set is calcium hydroxide. However, it should be noted that calcium hydroxide in this product is present in a gel formulation and therefore calcium hydroxide dust or particles are not present.

Calcium hydroxide (Slaked lime)
Time Weighted Average (TWA): 5 mg/m³

Short Term Exposure Limit (STEL): Not set

Biological limit values: None set
 Engineering controls:
 Ventilation: Not considered necessary during normal usage
 Personal protective equipment: Avoid contact with eyes. Wear safety glasses / goggles.
 Wear suitable protective clothing and gloves

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Physical Description & colour: Thick, dark green gel-like paste.
 Odour: No data.
 Boiling Point: Approximately 100°C at 100kPa.
 Freezing/Melting Point: No specific data. Pasty solid at normal temperatures.
 Volatiles: Water component.
 Vapour Pressure: 2.37 kPa at 20°C (water vapour pressure).
 Vapour Density: No data.
 Specific Gravity: No data.
 Water Solubility: Not available.
 pH: 12-13 (as supplied)
 Volatility: No data.
 Odour Threshold: No data.
 Evaporation Rate: Not applicable.
 Coeff Oil/water Distribution: No data
 Viscosity: Not applicable.
 Autoignition temp: Does not burn.

SECTION 10 STABILITY AND REACTIVITY

Chemical stability: Stable
 Conditions to avoid: Protect from light.
 Incompatible materials: None known
 Hazardous decomposition products: None known
 Hazardous reactions: None known

SECTION 11 TOXICOLOGICAL INFORMATION

Routes of Exposure:

Exposure to Proud-Aid can occur through ingestion and eye or skin contact. The major routes of exposure are expected to be eye and skin contact. There are no toxicology data available for Proud - Aid. Information has been provided for individual ingredients.

Signs and Symptoms of acute overexposure:

Eye: Corrosive to the eye
 Skin: Corrosive to the skin
 Ingestion: Unknown
 Inhalation: Unknown

Summary of toxicology:

Calcium hydroxide

The substance irritates the respiratory tract and is corrosive to the eyes and the skin. Calcium hydroxide in various forms is one of the commonest causes of severe chemical burns of eyes.

Reference Sources:

Calcium Hydroxide ICSC: 0408 April 1997, [INCHEM]

Grant WM, Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986. [HSDB]

Copper sulphate

Prolonged or repeated exposure to copper salts can cause irritation, producing itching and redness of the skin. Some may become sensitized to copper sulphate and develop allergic contact dermatitis. Contact of eye will result in conjunctivitis, oedema of eyelids and ulceration and turbidity of cornea.

Reference Sources:

Patty, F. (ed.). Industrial Hygiene and Toxicology: Volume II: Toxicology. 2nd ed. New York: Interscience Publishers, 1963. [HSDB]

International Programme on Chemical Safety Poisons Information Monograph (Group Monograph) G002 Chemical - Copper and Copper Salts. [INCHEM]

Acute toxicity:

LD50 (Rabbit): 125 mg/kg bw

Reference Source: [WHO; Environ Health Criteria 200: Copper p.101 (1998)] ** PEER REVIEWED ** [HSDB]

Chronic toxicity

Primary Organ: Renal toxicity (Kidney)

For rats in the 13-week study, the no-observed-adverse-effect level (NOAEL) for evidence of histologic injury to the kidney was 1000 ppm for males and 500 ppm for females, while the NOAEL for liver inflammation was 1000 ppm for males and 2000 ppm for females. Hyperplasia with hyperkeratosis of the epithelium on the limiting ridge separating the forestomach from the glandular stomach was also seen in rats of each sex, and the NOAEL for this change was 1000 ppm cupric sulfate in the feed. Additionally, clinical pathology alterations noted in the 13-week study, along with histologic changes in bone marrow noted in the 2-week feed study, were indicative of a microcytic anaemia with a compensatory bone marrow response. Mice appeared to be much more resistant to the toxic effects of cupric sulfate than rats. The primary target tissue in mice was the epithelium of the limiting ridge of the forestomach. The NOAEL for the hyperplasia and hyperkeratosis seen at this site in mice was 2000 ppm cupric sulfate in the feed.

(NTP working group Source: TA:National Toxicology Program Toxicity Report Series PG:94 p YR:1993 IP: VI:29) [NTP] [TOXLINE]

SECTION 12 ECOLOGICAL INFORMATION

This product is considered to be very toxic to the aquatic environment with short term and long-lasting effects because of the presence of copper sulfate. Other ingredients do not contribute significantly to the environmental toxicity of the product and information has therefore been provided for copper sulfate only. However, it should be noted that the product is supplied in 100 g containers only and it is therefore not expected to pose a credible threat to the environment.

Copper sulfate

Fish (Acute)

LC50 [96 hr, Fathead minnow (*Pimephales promelas*)]: 2.8 µg/L = 0.0028 mg/l

Reference Source: Ref no: 8034. Welsh, P.G., J.F. Skidmore, D.J. Spry, D.G. Dixon, P.V. Hodson, N.J. Hutchinson, and B.E. Hickie (1993) Effect of pH and Dissolved Organic Carbon on the Toxicity of Copper to Larval Fathead Minnow (*Pimephales promelas*) in Natural Lake Waters of Low. Can.J.Fish.Aquat.Sci.50(7):1356-1362; In: Proc.35th Conf.Int.Assoc.Great Lakes Res., May 31-June 4, 1992, Univ.of Waterloo, ONT, Canada:176 (1992) (ABS) [ECOTOX]

Fish (Chronic)

NOEC [15 day, Rainbow trout, (Donaldson trout) (*Oncorhynchus mykiss*)]: < 12 µg/L (< 0.012 mg/l)

Reference Source: Ref no: 17849. Neville, C.M. (1995) Short-Term Early Life Stage Growth Test Using Sacfry and Early Swim-Up Stages of Rainbow Trout (*Oncorhynchus mykiss*): Method Development – Ontario Ministry of the Environment & Energy, Toronto, Ontario:63 p.; 27 p.(U.S.NTIS MIC-95-08185) [ECOTOX]

Crustacean (Acute)

EC50 (Mortality) [48 hr, Water flea (*Bosmina longirostris*)]: 1.4 µg/L (= 0.0014 mg/l)

Reference Source: Ref no: 16629. Koivisto, S., M. Ketola, and M. Walls (1992) Comparison of Five Cladoceran Species in Short- and Long-Term Copper Exposure. *Hydrobiologia* 248(2):125-136. [ECOTOX]

Algae (Acute)

EC50 [72 hr, alga, saltwater (*Thalassiosira pseudonana*)]: 5 µg/L (= 0.005 mg/l)

Reference Source: [USEPA; Ambient Water Quality Criteria Doc: Copper p.60 (1985) EPA 440/5-84-031]**Peer Reviewed** [HSDB]

Bioaccumulative: Not determined

Rapidly Degradable: No
[IUCLID 2000]

Ecotoxic to terrestrial vertebrates

LD50 (Rabbit): 125 mg/kg body weight

Reference Source: [WHO; Environ Health Criteria 200: Copper p.101 (1998)] ** PEER REVIEWED** [HSDB]

Environmental precautions:

Do not contaminate dams, rivers or streams with pesticide or used container.

SECTION 13 DISPOSAL CONSIDERATIONS

Disposal methods and containers:

APVMA approved container disposal directions indicate that containers may be wrapped in paper and placed in household garbage. Unused product should be disposed of in accordance with local authority instructions

Special precautions for landfill or incineration: Do not burn product or empty containers

SECTION 14 TRANSPORT INFORMATION

Not defined as Dangerous Goods by the Australian Code for the Transport of Dangerous Goods by Road and Rail

SECTION 15 REGULATORY INFORMATION

This product has been registered by the APVMA (Proud-Aid Wound Care Treatment for Horses / 62714). In granting registration to any product, the APVMA has exercised its legislative responsibility to ensure that the product is suitably formulated and properly labelled and, when used according to instructions is:

- safe to the host, the user, consumers and the environment;
- efficacious (that is, the product does the job it claims it shall do); and
- not unduly prejudicial to trade.

The APVMA uses the services of a number of Australian and State government agencies as advisers to help with some of these evaluations of applications for registration of agricultural and veterinary chemical products. These include:

- the Office of Chemical Safety (OCS) of the Commonwealth Department of Health which:
 - evaluates and reports on toxicology and metabolism studies; proposes first aid and safety directions; determines poison schedule classifications; and establishes acceptable daily intakes (ADIs) and acute reference doses (ARfD); and
 - evaluates the occupational health and safety aspects of an application and recommends safety directions and occupational controls on use and advises on a Safety Data Sheet (SDS);
- the Commonwealth Department of Agriculture, Water and the Environment (DAWE) which evaluates environmental data and recommends appropriate use controls and instructions for the product that will protect the environment; and
- State and Territory departments responsible for agricultural and primary industries which evaluate and reports on efficacy and target crop or animal safety data for new agricultural chemicals and new uses of registered products. In some cases, the APVMA contracts this work out to other agencies such as universities, the CSIRO or to other experts.

All ingredients appear in the Australian Inventory of Industrial Chemicals (AIIC) maintained under the Australian Industrial Chemicals Introduction Scheme (AICIS).

Copper sulfate has been subjected to an IMAP (Inventory Multi-tiered Assessment and Prioritisation) tier I assessment under the former National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and it is considered that it poses no unreasonable risk to human health based on this assessment.

Calcium hydroxide has been subjected to an IMAP human health tier II assessment under NICNAS and it is considered that this assessment of the chemical is sufficient, provided that the recommended amendment to the classification is adopted and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory. The amended classifications have been specified in Section 2 of this SDS.

Proud-Aid is a Schedule 6 poison (copper sulfate) under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

SECTION 16 OTHER INFORMATION

References:

1. FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals, (as updated), APVMA (Australian Pesticides and Veterinary Medicines Authority), <https://apvma.gov.au/node/26586>
2. Code of Practice – Preparation of safety data sheets for hazardous chemicals, Safe Work Australia, May 2018, <https://www.safeworkaustralia.gov.au/doc/model-code-practice-preparation-safety-data-sheets-hazardous-chemicals>
3. Australian Inventory of Industrial Chemicals (as updated), AICIS (Australian industrial Chemicals Introduction Scheme), Australian Government Department of Health, <https://www.industrialchemicals.gov.au/search-inventory>
4. APVMA Registrations and Permits, <https://apvma.gov.au/node/1060>
5. ADI [Acceptable Daily Intake] List (as updated), Commonwealth Department of Health, TGA (Therapeutic Goods Administration), <https://apvma.gov.au/sites/default/files/publication/74511-acceptable-daily-intakes-adi-for-agricultural-and-veterinary-chemicals-used-in-food-producing-crops-or-animals-edition-4-2020.pdf>
6. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code), Edition 7.7, 2020, <https://www.ntc.gov.au/sites/default/files/assets/files/ADG%20Code%207.7-0.pdf>
7. SUSMP (Standard for the Uniform Scheduling of Medicines and Poisons) (as updated), Chemicals and Medicines Scheduling Secretariat (MD122), Scheduling and Committee Governance, TGA, Commonwealth Department of Health, <https://www.tga.gov.au/publication/poisons-standard-susmp>
8. Hazardous Chemical Information System (HCIS), Safework Australia (as updated), <http://hcis.safeworkaustralia.gov.au/>
9. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Eighth Revised Edition, United Nations, New York and Geneva, 2019, <https://unece.org/ghs-rev8-2019>
10. NIOSH Pocket Guide to Chemical Hazards
11. Chemical Classification and Information Database (CCID) (as updated), New Zealand Environmental Protection Authority, <http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx>

All information contained in this Safety Data Sheet is as accurate and up to date as possible. Since Pharmachem cannot anticipate or control the conditions under which this information may be used, each user should review the information in the specific context of the intended application. Pharmachem will not be responsible for damages of any nature resulting from use of or reliance upon the information. No expressed or implied warranties are given other than those implied as mandatory by Commonwealth State or Territory legislation.