

SECTION 1 IDENTIFICATION OF THE MATERIAL AND SUPPLIER

GHS Product identifier:	Pharmachem Antiseptic Dusting Powder
Other means of identification:	Antiseptic Dusting Powder
Recommended use of the product and restrictions on use:	An antiseptic powder for use following dehorning, speying or castrating cattle
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 environmental hazard in accordance with the following classification criteria of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Eighth Revised Edition.

Health hazards: Causes skin irritation, causes eye irritation, suspected reproductive toxicant

Environmental hazards: Acute aquatic toxicity, chronic aquatic toxicity

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

Eye irritant: Category 2
GHS label elements, including precautionary statements:
Pictogram:



Signal word: Warning
Hazard statements: Causes eye irritation
Precautionary statements:
Prevention: Avoid contact with eyes. Wear safety glasses / goggles
Wash hands thoroughly after handling
Response: If in eyes rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Reproductive toxicity: Category 2
GHS label elements, including precautionary statements:
Pictogram:



Signal word: Warning
Hazard statement: Suspected of damaging fertility when ingested
Precautionary statements:
Prevention: Wear face shield and dust mask
Response: If exposed or concerned get medical advice/attention.

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



Signal word: Warning
Hazard statements: 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 statements: 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.	Proportion
Boric Acid	10043-35-3	250 g/kg
Zinc Oxide	1314-13-2	100 g/kg
Salicylic Acid	69-72-7	50 g/kg
Inert filler	Not Applicable	QS 1kg

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.

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

Ingested: Contact a doctor or Poisons Information Centre
 Eyes: Immediately hold eyes open and wash continuously with water for 15 minutes. Ensure irrigation under the eyelids by occasionally lifting upper and lower lids. Seek medical attention promptly.
 Skin: Remove affected clothing. Wash affected areas with water, and soap if available. Seek medical attention in the event of persistent irritation.
 Inhaled: If dust is inhaled, remove to fresh air. Encourage patient to blow nose to ensure clear breathing passages. Rinse mouth with water. Lay down and rest patient and seek medical advice if necessary.

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:
 Clear area of personnel and move upwind. If inhalation risk of overexposure exists, wear an SAA approved dust respirator.

Methods and materials for containment and clean up:
 Use dry clean-up procedures and avoid generating dust. Vacuum up or sweep up and collect recoverable product into suitable containers for disposal.

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): Wash hands after use

Conditions for safe storage, including any incompatibilities:

The following storage directions have been approved for this product by the APVMA:
Store in the tightly closed original container below 30°C (Room Temperature)

In addition, it is advisable to keep containers and product dry. Store under cover. Protect containers against physical damage.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

National exposure standards:

TWA (Zinc Oxide Dust): 10 mg/m³

Biological limit values: None set

Engineering controls:

Ventilation: Not considered necessary during normal usage

Personal protective equipment

Not considered necessary during normal usage. PVC or neoprene gloves and chemical safety glasses can be worn if desired. Contact lenses pose a special hazard – soft lenses may absorb irritants and all lenses concentrate them.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Fine white powder

Odour: Odourless

pH: 6 (1% aqueous solution)

SECTION 10 STABILITY AND REACTIVITY

Chemical stability: Stable

Conditions to avoid: None known

Incompatible materials: Strong acids, water, strong bases, alkali metals

Hazardous decomposition products: None known

Hazardous reactions: Boric acid reacts violently with potassium and acid anhydrides

SECTION 11 TOXICOLOGICAL INFORMATION

Routes of Exposure:

Exposure to Antiseptic Dusting Powder 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 Antiseptic Dusting Powder. Information has been provided for individual ingredients.

Signs and Symptoms of acute overexposure:

Eye: Contact with eyes causes irritation.

Skin: Contact with skin causes irritation.

Ingestion: Unknown

Inhalation: Unknown.

Summary of toxicology:

Boric acid:

Skin irritation:

Species: Unknown

Result: Irritant to skin in dry form.

Reference source: Sax, N.I. and R.J. Lewis, Sr. (eds.). Hawleys Condensed Chemical Dictionary. 11th ed. New York: Van Nostrand Reinhold Co., 1987. 162. [HSDB]

Eye irritation:

Species: Rabbit

Result: Slightly irritating

Remark: 100mg boric acid was applied to one eye of each of six rabbits. The eyes were rinsed after 24 hours. Changes in coloration and texture of the eye and blistered appearance to conjunctiva. Classified in US Category III (40 CFR 156) "Corneal involvement or irritation clearing in 7 days or less."

Reference source: Borax Consolidated Ltd. Guilford. R.L. Doyle, " Primary eye irritation of boric acid" Ref.88-3444-21 of 7 February, Hill Top Biolabs Inc., Cincinnati Ohio 45242 USA. (Unpublished report No. TX-089-006 to US Borax and Chemical Corporation) [IUCLID 2000]

Reproductive toxicity

Chronic Effects on Humans:

Mutagenic effects: Mutagenic for bacteria and/or yeast.

Developmental toxicity: Classified Reproductive system/toxin/female, Reproductive system/toxin/male [Possible]. May cause damage to the following organs: kidneys, cardiovascular system, central nervous system (CNS).

Other Toxic Effects on Humans:

Hazardous in case of skin contact (irritant), of ingestion, of inhalation. Slightly hazardous in case of skin contact (permeator).

Special Remarks on Chronic Effects on Humans:

May cause adverse reproductive effects (fertility, fetotoxicity) based on animal studies. May affect genetic material. May cause teratogenic effects based on animal studies.

Acute toxicity:

LD₅₀ – Oral (Rat): 2660 mg/kg

LDLO – Oral (Man): 429 mg/kg

LDLO – Oral (Woman): 200 mg/kg

LD₅₀ – Oral (Mouse): 3450 mg/kg

LD₅₀ – Subcutaneous (Mouse): 1740 mg/kg

LD₅₀ – Intravenous (Mouse): 1240 mg/kg

LCLO – Inhalation (Rat): 28 mg/m³/4h

Salicylic acid:

Skin irritation:

Species: Human (f)

Result: Irritating

Reference source: Rhone-Poulenc Chimie Courbevoie Cedex (77) Berner, B. et al. (1989) J. Toxicol. Cutan. Ocul. Toxicol.8, 481-492 [IUCLID 2000]

Eye irritation:

Species: Rabbit

Result: Highly irritating.

Reference source: Rhone-Poulenc Chimie Courbevoie Cedex (61) BIO-FAX Study Nb. 21-3/71, Indust. Biotest Lab., Inc. Northbrook, Ill.(1971) (69) Sax NI, Lewis RJ, Dang. Prop. Indust. Mater., 7th Edit., Van Nostrand Reihold (1988) [IUCLID 2000]

Acute toxicity:
LD₅₀ – Oral (Rat): 891 mg/kg
LD₅₀ – Oral (Mouse): 480 mg/kg
LC₅₀ – Inhalation (Mammalian): 300 mg/m³

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 zinc oxide. Other ingredients do not contribute significantly to the environmental toxicity of the product and information has therefore been provided for zinc oxide only. Based on concentration cut-offs in the GHS, this product is considered to be very hazardous to algae and crustaceans, but not classifiable in relation to fish.

Ecotoxicity – Zinc oxide:

Aquatic toxicity – Fish

LC₅₀ - *Oncorhynchus mykiss* (rainbow trout) - 1.1 mg/L - 96.0 h

Aquatic toxicity – Crustaceans

Species: *Daphnia magna*

Type of exposure: Static

Duration: 48 h

Endpoint: LC₅₀

Value: 98 µg/L (= 0.098 mg/L)

Reference source: Ref No: 9180. Author(s): Gale, N.L., B.G. Wixson, and M. Erten Publication Year:

1992 Title: An Evaluation of the Acute Toxicity of Lead, Zinc, and Cadmium in Missouri Ozark

Groundwater, Trace Subst. Environ. Health 25:169-183 [IUCLID 2000]

Aquatic toxicity – algae

Algae (unicellular)

Selenastrum capricornutum

ErC50g: 0.17

EbC50g: 0.043

NOErCg: 0.010

NOEbCg: < 0.005

[g = growth (r: growth rate; b: biomass)]

Reference: LISEC '97 [2,7]

Persistence and degradability: Zinc oxide as an inorganic salt is non-biodegradable.

Bioaccumulative potential: Log Pow 1.53 (Estimated value)
Low potential for bioaccumulation (Log Kow < 4).

Mobility:

A major part of zinc present in surface waters ends up deposited in sediments of rivers, estuaries and coastal areas where it binds to organic and inorganic matter, which reduces its mobility and bioavailability. Log Koc – 2.2 (Literature study)

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 under the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code)

SECTION 15 REGULATORY INFORMATION

This product has been registered by the APVMA (Pharmaceutical Antiseptic Dusting Powder / 41230). 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 (AIIS)).

Boric acid has undergone a Human Health Tier II assessment under AICIS (Australian Industrial Chemicals Introduction Scheme) and it is considered that current risk management measures are adequate to protect public and workers' health and safety, provided that all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory. Should additional uses become available that may pose a risk to workers and/or the public, a Tier III assessment will be undertaken to characterise the exposure and potential risk from these use scenarios.

Boric acid has also undergone an AICIS Environment Tier II assessment, and it is considered that release of boron to surface waters from chemicals in this group will have limited long-term environmental effects due to the low chronic aquatic toxicity of boric acid. Release of boron to surface soil may result in localised toxic effects in terrestrial plants, depending on background boron concentrations, affected plant species, and soil characteristics. However, there are well developed regulatory guidelines and practices in place to manage the risks from over application of boron to soils in Australia.

Zinc oxide has been subject to an IMAP tier I assessment under AICIS and identified as low concern to human health by application of expert validated rules under the AICIS targeted tier I approach. It is considered to pose no unreasonable risk to human health based on this assessment.

Salicylic acid has undergone a Human Health Tier II assessment under AICIS and it is considered that further risk management is required. Sufficient information is available to recommend the chemical to be risk managed for public safety from the potential use in cosmetics products through scheduling, and occupational health and safety through classification and labelling. However, the chemical is sufficiently assessed subject to implementation of risk recommendations.

Boric acid at the concentration present in this product appears in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Zinc oxide and salicylic acid at the concentrations present in this product are not scheduled in the 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.